

2025 MVP Health Care[®] Medical Policies

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Acute Inpatient Rehabilitation

Type of Policy: Medical

Prior Approval Date: 05/01/2023

Approval Date: 10/02/2023

Effective Date: 12/01/2023

Related Polices: N/A

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

Inpatient level of care requires prior authorization.

Codes Requiring Retrospective Review

N/A

Experimental/Investigational

N/A

Common Diagnosis Codes

ICD-10- CM Diagnosis Codes: G10, G11.0, G11.1, G11.2, G11.3, G11.4, G11.8, G11.9, G12.1, G12.2, G12.20, G12.21, G12.22, G12.29, G12.8, G12.9, G13.0, G13.1, G13.2, G13.8, G14, G35, G37.9, G58.0, G58.7, G58.8, G58.9, G61, G61.0, G61.1, G61.8, G61.81, G61.89, G61.9, G83.0, G83.1, G83.10, G83.11, G83.12, G83.13, G83.14, G83.2, G83.20, G83.21, G83.22, G83.23, G83.24, G83.3, G83.30, G83.31, G83.32, G83.33, G83.34, G83.4, G83.5, G83.8, G83.81, G83.82, G83.83, G83.84, G83.89, G83.9, M05.0, M05.01, M05.011, M05.012, M05.019, M05.02, M05.021, M05.022, M05.029, M05.03, M05.031, M05.032, M05.039, M05.04, M05.041, M05.042, M05.049, M05.05, M05.051, M05.052, M05.059, M05.06, M05.061, M05.062, M05.069, M05.07, M05.071, M05.072, M05.079, M05.211, M05.212, M05.212, M05.221, M05.222, M05.229, M05.5

Common Diagnosis Codes associated with this policy have been provided for informational purposes only. The list of codes may not be all-inclusive and may be updated to reflect any applicable revisions to the ICD-10 code sets and/or medical necessity guidelines applied in this policy.

Common Procedure Codes

N/A

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

Acute rehabilitation is a comprehensive, intensive unit or hospital-based rehabilitative program that employs a coordinated, interdisciplinary team-care delivery system of multiple services. The inpatient rehabilitative program involves at least two rehabilitative disciplines with a minimum of three hours of acute rehabilitation each day and continuing 24-hour medical availability by a rehabilitative physician and rehabilitative nursing to ensure safe and effective treatment for complex medical conditions.

Indications/Criteria

Documentation Requirements

- 1. Medical necessity must be documented in the medical record and be available upon request.
- 2. Specifics of PT/OT/ST evaluation must be submitted at the time of the request including, but not limited to:
 - the customer's current functional limitation including goals to be obtained;
 - the customer's neurological deficits and functional status prior to event;
 - o the customer's current functional deficits, mental status and ability to learn;
 - o the customer's motivation to participate in rehabilitation;
 - the customer's functional communication, physical activity and endurance (including clinical and respiratory presentation, standardized tests and measures);
 - o the customer's social/caregiver support, discharge environmental factors; and
 - o the customer's/caregiver's expectations of rehabilitation.

Indications for acute inpatient rehabilitation include, but are not limited to, the following:

- brain injury; or
- cerebral vascular accident; or

- spinal cord injury; or
- Guillian Barre; or
- CNS hemorrhage; or
- amputation; or
- bilateral joint replacement; or
- transplant recipient.

Customers of all ages (Pediatric [child] and Adult) will be considered for acute inpatient rehabilitation when all of the following criteria are met:

- a patient requires 24-hour a day access to a registered nurse with specialized training in rehabilitation; and
- a patient requires the 24-hour availability of a physician with specialized training or experience in rehabilitation, including face-to-face visits, at least three (3) days per week to assess the patient both medically and functionally, as well as to modify the course of treatment as needed to maximize the patient's capacity to benefit from the rehabilitation process; and
- Beginning with the second week of admission, a non-physician practitioner with specialized training and experience in inpatient rehabilitation may conduct 1 of the 3 required face-to-face visits with the customer per week.
- the customer requires an intensive rehabilitation therapy program that consists of at least three (3) hours of therapy per day, five (5) days per week or 15 hours per week (appropriate for customer age, development, and cognition); and
- the rehabilitation program includes at least two therapies (e.g, physical therapy, occupational therapy, speech therapy); and
- The standard of care for an intensive rehabilitation therapy patients is individualized (i.e., one-on-one) therapy. Group therapies serve as an adjunct to individual therapies.
- the customer has one or more persistent disabilities that require at least minimal assistance in mobility, basic activities of daily living, bowel or bladder control, cognition, emotional functioning, pain management, swallowing or communication; and
- the customer is medically stable, is able to fully participate in the rehabilitation program, and has the potential for significant measurable improvement in functional status. Measurable, practical improvement in the patient's functional condition is expected to be accomplished within a predetermined and reasonable period of time; and

- the customer has a discharge residence other than a Residential Health Care Facility, sufficient family/caregiver support to ensure personal and medical safety, and consensus among the patient, family/caregivers and health care team of discharge setting; and
- treatment is precluded in a lower level of care due to clinical complexity and/or cognitive ability.

Note: In order to be classified as an inpatient rehabilitation facility, a facility must meet the requirements specified in Title 42 Code of Federal Regulations (CFR) 412.23(b) (2), as well as other regulatory requirements.

Exclusions

- Not meeting Indications/Criteria listed in this policy.
- The Inpatient Rehabilitation Facility (IRF) benefit is not to be used as an alternative to completion of the full course of treatment in the referring hospital. A patient who has not yet completed the full course of treatment in the referring hospital is expected to remain in the referring hospital, with appropriate rehabilitative treatment provided, until such time as the patient has completed the full course of treatment. IRF admissions for patients who are still completing their course of treatment in the referring hospital and who, therefore, are not able to participate in, and benefit from, the intensive rehabilitation therapy services provided in IRFs will be considered not medically necessary.
- The Inpatient Rehabilitation Facility (IRF) IRF benefit is not medically necessary for patients who have completed their full course of treatment in the referring hospital but do not require intensive rehabilitation. Benefits are available for such patients in a less-intensive setting.
- Services will be denied as not medically necessary when there is no reasonable expectation of improvement in quality of life or level of functioning.
- Customers will be discharged from the acute rehabilitation program for any of the following conditions:
 - the customer has achieved the established goals, or the goals can be attained at a lower level of care; or
 - o the customer's needs have been met or services can be provided at a lower level of care; or
 - the customer no longer demonstrates functional improvement; or
 - o the customer appears to no longer benefit from acute rehabilitation; or
 - the customer refuses to participate in the program or has been non-compliant with the rehabilitation program; or

o the customer is unable to tolerate or regularly attend the prescribed rehabilitation program.

Medicaid Managed Care Variation

For Managed Medicaid medically fragile children with physical health/behavioral health needs, MVP considers the customer's specific service levels along within the larger context of the child's overall needs in accordance with the requirements set forth by the Office of Health Insurance Programs Principles for Medically Fragile Children.

References (Updated 2023)

- 1. Bozic KJ, Wagie A, Naessens JM, Berry DJ, Rubash HE. Predictors of discharge to an inpatient extended care facility after total hip or knee arthroplasty. J Arthroplasty. 2006 Sep;21(6 Suppl 2):151-6
- 2. Centers for Medicare & Medicaid Services (2010). Inpatient Rehabilitation Facilities Classification Criteria. Available: www.cms.hhs.gov/InpatientRehabFacPPS/03 Criteria.asp#TopOfPage
- 3. Centers for Medicare and Medicaid. Medicare Benefit Policy Manual. Chapter1-Inpatient Hospital Services Covered Under Part A. Available:

 <a href="https://www.hhs.gov/guidance/document/medicare-benefit-policy-manual-chapter-linear-benefit-bene
- 4. Centers for Medicare & Medicaid Services. Medicare Learning Network. Inpatient Rehabilitation Facility Prospective Payment System. ICN 006847. September 2014. Available: https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/html/medicare-payment-systems.html#Inpatient2
- Centers for Medicare & Medicaid Services. Medicare Benefit Policy Manual, Chapter 1. Inpatient Hospital Services Covered Under part A. Rev.10892, 08-06-21. Available: https://www.cms.gov/Regulations-and-Guidance/Manuals/downloads/bp102c01.pdf
- 6. Deutsch A, Granger CV, Heinemann AW, Fiedler RC, DeJong G, Kane RL, et al. Poststroke rehabilitation: outcomes and reimbursement of inpatient rehabilitation facilities and subacute rehabilitation programs. Stroke. 2006 Jun;37(6):1477-82.
- 7. Flanagan SR, Hibbard MR, Riordan B, Gordon WA. Traumatic brain injury in the elderly: diagnostic and treatment challenges. Clin Geriatr Med. 2006 May;22(2):449-68, x
- 8. Khan F, Disler P. Multidisciplinary rehabilitation interventions for joint replacement at the knee and hip for arthropathies (Cochrane Review). In: The Cochrane Library, Issue 1, 2003. Amended November 2004.
- 9. Mahomed NN, Davis AM, Hawker G, Badley E, Davey JR, Syed KA, Coyte PC, Gandhi R, Wright JG. Inpatient compared with home-based rehabilitation following primary

- MVP Health Care Medical Policy unilateral total hip or knee replacement: a randomized controlled trial. J Bone Joint Surg Am. 2008 Aug;90(8):1673-80.
- 10. New York State Department of Health Children's Medicaid System Transformation September 29, 2017 Available: https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&cad=rja&uact=8&ved=2ahUKEwjZwaeZYn1AhWYk4kEHQKYATwQFnoECAQQAQ&url=https%3A%2F%2Fwww.health.ny.gov%2Fhealth_care%2Fmedicaid%2Fredesign%2Fbehavioral_health%2Fchildren%2Fdocs%2F2017-09-29_transition_plan.pdf&usg=AOvVaw1YljjPttEViG2q20WPGSDC
- 11. New York State Department of Health Children's Health and Behavioral Health Benefit Administration Medicaid Managed Care Organization Children's System Transition Requirements and Standards, February 1, 2017. Available: final draft childs mc plan req.pdf (ny.gov)
- 12. Langhorne P, Ramachandra S. Organised inpatient (stroke unit) care for stroke: network meta-analysis. Cochrane Database of Systematic Reviews 2020, Issue 4. Art. No.: CD000197. DOI: 10.1002/14651858.CD000197.pub4.
- 13. U.S. Department of Veterans Affairs. VA/DoD Clinical Practice Guidelines: the management of stroke rehabilitation. Version 4, 2019. Accessed Dec 24, 2020. Available at URL address: https://www.healthquality.va.gov/index.asp
- 14. Ward D, Severs M, Dean T, Brooks N. Care home versus hospital and own home environments for rehabilitation of older people (Cochrane Review). In: The Cochrane Library, Issue 3, 2004. Updated 2008, Oct 8. Oxford: Update Software.
- 15. Winstein CJ, Stein J, Arena R, et al. Guidelines for Adult Stroke Rehabilitation and Recovery: A Guideline for Healthcare Professionals From the American Heart Association/American Stroke Association. Stroke. 2016 Jun;47(6):e98-e169.

Customer Product	Medical Management Requirements*
New York Products	
НМО	Prior Auth
PPO in Plan	Prior Auth
PPO OOP	Prior Auth
POS in Plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Prior Auth
MVP Child Health Plus	Prior Auth
MVP Harmonious Health Care Plan	Prior Auth
MVP Medicare Complete Wellness	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth naviHealth Inc.
MVP Medicare Secure HMO POS	Prior Auth naviiHealth Inc.
MVP Medicare Secure Plus HMO POS	Prior Auth naviiHealth Inc.
MVP Medicare WellSelect PPO	Prior Auth navii Health Inc.
MVP Medicare WellSelect Plus PPO	Prior Auth navii Health Inc.
MVP Patriot Plan PPO	Prior Auth naviiHealth Inc.
MVP DualAccess D-SNP HMO	Prior Auth naviHealth Inc.
MVP DualAccess Complete D-SNP HMO	Prior Auth navi Health Inc.
MVP DualAccess Plus D-SNP HMO	Prior Auth navi Health Inc.
UVM Health Advantage Select PPO	Prior Auth navi Health Inc.
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	300 3. 2
POS in Plan	Prior Auth
POS OOP	Prior Auth Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth Prior Auth naviHealth Inc.
MVP Medicare Preferred Gold HMO POS MVP Medicare Secure Plus HMO POS	Prior Auth naviHealth Inc. Prior Auth naviHealth Inc.
MVP VT HMO	Prior Auth Navineauth Inc. Prior Auth
MVP VT HIMO MVP VT HDHP HMO	Prior Auth Prior Auth
MVP VT Plus HMO	Prior Auth Prior Auth
MVP VT Plus HDHP HMO	Prior Auth Prior Auth
MVP V1 Plus HDHP HMO MVP Secure	Prior Auth Prior Auth
ASO ASO	See SPD
ASU	266 2hD

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review.

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Revision History:

04/01/2022 – Annual review; added that policy applies to all ages, eliminated under three-hour therapy coverage criteria, added criteria that would preclude a lower level of care. Updated references and websites section.

08/01/2023 – updated criteria for non-physician practitioners and group therapy.

12/01/2023 - Policy was updated to indicate that criteria applied to pediatric customers as well as adults and that rehabilitation was required for children based on being appropriate for customers age, development and cognition.



Adult Day Health Care (ADHC) Services and AIDS Adult Day Health Care (AIDS ADHC) Services for MVP Medicaid Managed Care Customers

Type of Policy: Medical

Prior Approval Date: 12/06/2021

Approval Date: 12/04/2023

Effective Date: 02/01/2024

Related Polices: Personal Care and Consumer Directed Services

for MVP Medicaid Managed Care Customers

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

HCPCS Codes: S5102 – Day care services, adult; per diem

Codes Requiring Retrospective Review

N/A

Experimental/Investigational

N/A

Common Diagnosis Codes

N/A

Common Procedure Codes

N/A

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are

subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

Adult Day Health Care (ADHC) and AIDS Adult Day Health Care Program (AIDS ADHC) provide health care services and activities to qualified Medicaid recipients who may need assistance with activities of daily living, help with medications, or specialized services for those with human immunodeficiency virus (HIV), acquired immune deficiency syndrome (AIDS), or are part of a high-need population that, regardless of their HIV status, would benefit from receiving these adult day health care services.

AIDS Adult Day Health Care Programs are designed to assist individuals with AIDS, HIV disease or customers who are considered to be part of a high-need population, regardless of their HIV status, to live more independently in the community or to eliminate the need for residential health care services. The program targets services to high need individuals with HIV and co-morbidities such as substance abuse and mental illness, and to those who may need assistance with managing other chronic conditions such as diabetes and hypertension.

Indications/Criteria

Adult Day Health Care (ADHC) or AIDS Adult Day Health Care (AIDS ADHC) services will be provided for qualified MVP Medicaid Managed Care Customers when **all** the following criteria have been met: [1,2]

- ordered by a physician or other medical practitioner;
- provided to eligible beneficiaries, as determined by a patient assessment;
- included in, or consistent with, a plan of care;
- requested for a customer who:
 - is not a resident of a residential health care facility;
 - o is functionally impaired;
 - o is not homebound;
 - requires supervision, monitoring, preventive, diagnostic, therapeutic, rehabilitative or palliative care or services;
 - o does not require continuous 24 hour per day inpatient care and services;
 - whose assessed social and health care needs can satisfactorily be met in whole or in part by the delivery of appropriate services in a community setting; and
 - o requires a minimum of at least one visit per week to the program;

- documentation that includes an interdisciplinary comprehensive assessment, customer's functional impairment and the frequency and duration of particular services that must be provided to a participant.
- documentation for reassessment must include:
 - o an interdisciplinary comprehensive assessment;
 - o appropriateness of customer's continued stay in the program;
 - o the customer's needs:
 - o the necessity and suitability of services provided; and
 - the potential for transferring responsibility for the care of the customer to other more appropriate agencies or service providers.

The following services will be covered for ADHC when all of the above criteria listed under Indications\Criteria of this policy have been met:

- case management, including health education;
- interdisciplinary care planning;
- nursing services;
- nutrition;
- social services;
- assistance and supervision with the activities of daily living, such as toileting, feeding, ambulation, bathing including routine skin care, care of hair and nails; oral hygiene; and supervision and monitoring of personal safety, restorative rehabilitative and maintenance therapy services;
- planned therapeutic or recreational activities that reflect the interests, cultural backgrounds, and the communities of the registrants and provide the registrants with choices;
- pharmaceutical services;
- referrals for necessary dental services and sub-specialty care; and
- religious services and pastoral counseling.

The following services will be covered for AIDS ADHC when all of the criteria listed under Indications\Criteria of this policy have been met:

- HIV general medical services, including gynecologic services;
- sick call visits for registrants presenting with a new problem, which may result in coordination with the primary care physician and/or MCO to address conditions that require immediate or further medical intervention;

- case management services;
- food and nutrition services;
- social services;
- assistance with and/or supervision of activities of daily living such as toileting, feeding, ambulation, bathing including routine skin care, care of hair and nails, and oral hygiene;
- rehabilitation therapy services as the registrant's needs indicate;
- an activities program involving community, interpersonal and self care functions appropriate and sufficient in scope to the needs and interests of each registrant to sustain physical and psychosocial functioning;
- nursing services;
- pastoral counseling;
- counseling for HIV risk reduction;
- pharmaceutical services;
- substance abuse services;
- mental health and psychiatric services;
- ancillary services commensurate with the level of medical care delivered on-site; and
- referrals for dental services and sub-specialty care.

Exclusions

- Not meeting criteria listed under Indications\Criteria of this policy.
- Social Adult Day Care Services (SADS) are not covered.
- Services that constitute only meals and recreation will be denied as not medically necessary.

References (Updated 2023)

- NY Department of Health. Office of Health Insurance Programs. Division of Health Plan Contracting and Oversight. Guidelines for the Transition of Adult Day Health Care and AIDS Adult Day Health Care Services in Medicaid Managed Care. August 1, 2013. Available:
 - https://www.health.ny.gov/health_care/medicaid/redesign/adhc_aids_adhc_man_care_htm.
- 2. New York State Rules and Regulations Title 10 NYCRR §425.1 and 759.

3. New York State Codes, Rules and Regulations. Title: Part 425 – Adult Day Health Care. Effective Date: 06/14/2017. <u>Title: Part 425 - Adult Day Health Care | New York Codes, Rules and Regulations (ny.gov)</u>

Customer Product	Medical Management Requirements*
New York Products	-
HMO	Not Covered
PPO in Plan	Not Covered
PPO OOP	Not Covered
POS in Plan	Not Covered
POS OOP	Not Covered
Essential Plan	Not Covered
MVP Medicaid Managed Care	Prior Auth
MVP Child Health Plus	Not Covered
MVP Harmonious Health Care Plan	Prior Auth
MVP Medicare Complete Wellness	Not Covered
MVP Medicare Preferred Gold HMO POS	Not Covered
MVP Medicare Secure HMO POS	Not Covered
MVP Medicare Secure Plus HMO POS	Not Covered
MVP Medicare WellSelect PPO	Not Covered
MVP Medicare WellSelect Plus PPO	Not Covered
MVP Medicare Patriot Plan	Not Covered
MVP DualAccess D-SNP HMO	Not Covered
MVP DualAccess Complete D-SNP HMO	Not Covered
MVP DualAccess Plus D-SNP HMO	Not Covered
UVM Health Advantage Select PPO	Not Covered
USA Care	Not Covered
Healthy NY	Not Covered
MVP Premier	Not Covered
MVP Premier Plus	Not Covered
MVP Premier Plus HDHP	Not Covered
MVP EPO	Not Covered
MVP EPO HDHP	Not Covered
MVP PPO	Not Covered
MVP PPO HDHP	Not Covered
Student Health Plans	Not Covered
ASO	See SPD
Vermont Products	
POS in Plan	Not Covered
POS OOP	Not Covered
MVP Medicare Preferred Gold HMO POS	Not Covered
MVP Medicare Secure Plus HMO POS	Not Covered
MVP VT HMO	Not Covered
MVP VT HDHP HMO	Not Covered
MVP VT Plus HMO	Not Covered
MVP VT Plus HDHP HMO	Not Covered
MVP Secure	Not Covered
ASO	See SPD

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Revision History:

02/01/2022 – Annual Review with no changes to the indications or criteria for coverage.

02/01/2024 - Annual Review with no changes to the indications or criteria for coverage. Reviewed references, added reference for Part 425 – Adult Day Health Care.



Air Medical Transport

Type of Policy: Medical

Prior Approval Date: 11/07/2022

Approval Date: 11/04/2024

Effective Date: 02/01/2025

Related Polices: Ground Ambulance

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

HCPCS Codes:

Prior authorization is required only for non-emergency transport.

A0140 - Nonemergency transportation and air travel (private or commercial) intra- or interstate

A0430 - Ambulance service, conventional air services, transport, one way (fixed wing)

A0431- Ambulance service, conventional air services, transport, one way (rotary wing)

A0435 - Fixed wing air mileage, per statute mile

A0436 - Rotary wing air mileage, per statute mile

S9960- Ambulance service, conventional air services, nonemergency transport, one way (fixed wing)

S9961 - Ambulance service, conventional air service, nonemergency transport, one way (rotary wing)

Codes Subject to Retrospective Review

N/A

Experimental/Investigational

N/A

Common Diagnosis Codes

N/A

Common Procedure Codes

N/A

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy.

Overview

Air Medical Transport/ambulance is a service performed by either a helicopter or fixed wing aircraft to rapidly transfer those who are critically ill to a facility capable of caring for them. Transfer can be between two acute care facilities or from an emergency scene to an appropriate level acute care facility.

Policy Criteria

Air Medical Transport will be covered on a case-by-case basis for the following indications:

- Transport from the scene of an accident or remote critical medical emergency to the
 nearest acute care facility capable of caring for the customer's medical needs when
 the condition (see below for examples of clinical situations for scene triage to air
 transport) of the customer is such that the time needed to transport by land or the
 instability of transportation by land endangers the health or survival of the customer;
 the ground transport time must be 30-60 minutes or longer from the time the call is
 dispatched to the arrival time at the appropriate facility; or
- Transport from one acute facility to the geographically closest higher level of care
 acute facility capable of providing the necessary care related to the customer's
 condition (e.g., burn unit, cardiac care unit, trauma units, neonatal units). Coverage
 decisions do not allow for referral hospital preference based upon network referral
 patterns. Coverage is also not available for transport from a hospital capable of
 treating the patient because the patient and/or the patient's family prefer a specific
 hospital or physician; or
- The point-of-pickup is inaccessible by a ground/land vehicle.

The patient requires advanced lifesaving skills and technology during transportation to the nearest acute care facility, which is not present with the available ground-based EMS responders. This determination should be based upon an assessment utilizing the 2011

Air Medical Transport Page 2 of 7

Guidelines for Field Triage of Injured Patients from the CDC and the National Center for Injury Prevention and Control, Division of Injury Response. Prior authorization is required only for non-emergency transport.

Examples of clinical situations for scene triage to air medical transport include, but are not limited to:

- Intracranial bleeding requiring prompt neurosurgical intervention;
- Cardiogenic shock (e.g., due to acute myocardial infarction);
- Extensive burns requiring specialized treatment;
- Catastrophic, life-threatening illness or trauma with signs and/or symptoms suggesting:
 - Multiple orthopedic injuries, including multiple pelvic fracture,
 - Vascular compromise:
 - Arterial, interruption with arterial flow (e.g., hemorrhagic ischemia)
 - Venous, major vessel obstruction (e.g., acute thrombosis)
 - Spinal cord injury with neurological deficits,
 - Open injury with cerebrospinal fluid leak,
 - Major chest wall damage including flail chest or open sucking chest wounds.

Exclusions

- Air Medical Transport will not be covered for any situation when trauma or critical condition cannot be substantiated.
- Transport to a facility other than the geographically closest facility capable of caring for the customer.
- Coverage is not available for transport from a hospital capable of treating the patient because the patient and/or the patient's family prefer a specific hospital or physician.
- Coverage decisions do not allow for referral hospital preference based upon network referral patterns.
- Air ambulance services are not covered for transport to a facility that is not an acute care hospital, such as a nursing facility, physician's office, or a beneficiary's home.

Medicare Variation

Non-emergent air transport will not be reimbursed if prior authorization is not obtained. When prior authorization is not required, the air transport will be reimbursed at the ground ambulance rate if the air transport does not meet policy criteria for coverage.

Air Medical Transport Page 3 of 7

Medically appropriate air ambulance transportation is a covered service if the Medicare customer's medical condition is such that transportation by either basic or advanced life support ground ambulance is not appropriate.

Full coverage and limitation details are available in the Medicare Benefit Policy Manual, Chapter 10.4 Air Ambulance Services. Available: www.cms.gov/Regulations-and-Guidance/Manuals/downloads/bp102c10.pdf

MVP Medicaid Managed Care Variation

Emergency transportation, including Air Medical Transport, is not covered by MVP for Medicaid Managed Care Plans. Air Medical Transport is covered by NYS Medicaid Feefor-Service (FFS).

References (Updated 2025)

- American College of Emergency Physicians and National Association of EMS Physicians. Guidelines for air medical dispatch. Position Statement. 2002 May. Prehosp Emerg Care 2003 Apr-Jun;7(2):265-71 Available: https://www.tandfonline.com/doi/abs/10.1080/10903120390936923#.Vdt6PvlViko.
- 2. American College of Emergency Physicians and National Association of EMS Physicians. Guidelines for air medical dispatch. Policy resource and education paper. 2006 Jan Available: https://www.acep.org/globalassets/uploads/uploaded-files/acep/clinical-and-practice-management/resources/emergency-medical-services/quidelinesforairmeddisp.pdf.
- 3. Centers for Disease Control and Prevention. Guidelines for Field Triage of Injured Patients: Recommendations of the National Expert Panel on Field Triage, 2011

 Available: https://www.cdc.gov/mmwr/preview/mmwrhtml/rr6101a1.htm
- Centers for Medicare & Medicaid (CMS). Medicare Benefit Policy Manual. Chapter 10, Ambulance Services. Section 10.4. Available: www.cms.gov/manuals/downloads/bp102c10.pdf.
- 5. Centers for Medicare & Medicaid (CMS). National Government Services, Inc. Medicare Local Coverage Decision (LCD) for Air Ambulance Services (L36749) Effective Date: 11/01/2016. RETIRED: 02/28/2018.
- 6. Doucet J, Bulger E, Sanddaj N, Fallat M, Bromberg W, Gestring M; Emergency Medical System Subcommittee, Committee on Trauma, American College of Surgeons. Appropriate use of helicopter emergency medical services for transport of trauma patients. J Trauma Acute Care Surg. 2013 Oct; 75(4): 734-41.
- 7. Flocare DJ, Stuhlmiller DF, Braithwaite SA, Thomas SH, Madden JF, Hankins DG, et al. Appropriate and Safe Utilization of Helicopter Emergency Medical Services: A Joint

Air Medical Transport Page 4 of 7

- Position Statement with Resource Document. Prehosp Emerg Care 2013. Oct-Dec; 17(4): 521-525I
- 8. Galvagno Jr SM, Sikorski R, Hirshon JM, Floccare D, Stephens C, Beecher D, et al. Helicopter emergency medical services for adults with major trauma. Cochrane Database Syst Rev 2015 Dec 15; (12):CD009228.
- New York State Department of Health. Bureau of Emergency Medical Services and Trauma Systems. Revised 2021 Jan. Available: http://www.health.ny.gov/professionals/ems/.
- 7. New York State Department of Health. eMedNY. Provider Manuals. Transportation Manual, Policy Guidelines. Available: https://www.emedny.org/ProviderManuals/Transportation/index.aspx.
- 10. United States Federal law [42 USC 1396b (v) (3), SSA 1903(v) (3) and 42 CFR 440.255].

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Customer Product	Medical Management Requirements*
New York Products	•
НМО	Prior Auth
PPO in Plan	Prior Auth
PPO OOP	Prior Auth
POS in Plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Carved out to Medicaid FFS
MVP Child Health Plus	Prior Auth
MVP Harmonious Health Care Plan	Carved out to Medicaid FFS
MVP Medicare Complete Wellness	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP Medicare WellSelect PPO	Prior Auth
MVP Medicare WellSelect Plus PPO	Prior Auth
MVP Medicare Patriot Plan PPO	Prior Auth
MVP DualAccess D-SNP HMO	Prior Auth
MVP DualAccess Complete D-SNP HMO	Prior Auth
MVP DualAccess Plus D-SNP HMO	Prior Auth
UVM Health Advantage Select PPO	Prior Auth
USA Care	Potential for Retrospective Review
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	
POS in Plan	Prior Auth
POS OOP	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP VT HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD

[♦] Note: Prior authorization requirements for HDHP products are the same as the base product (e.g., HDHP HMO auth requirements are the same as listed for HMO).

*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro ReviewRetrospective Review RequiredNot CoveredService is not a covered benefitSee SPDSee Specific Plan Design

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Revision History:

12/01/2022 – Annual review; no changes to indications or criteria; added Medicaid Managed Care variation, references updated.

01/01/2023 – Coverage added to Child Health Plus (CHP).

02/01/2025 – Annual review with no changes to the indications or criteria, references reviewed.

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Allergy Testing and Allergen Immunotherapy

Type of Policy: Medical

Prior Approval Date: 12/05/2022

Approval Date: 06/03/2024

Effective Date: 08/01/2024

Related Polices: Allergy Testing and Serum

Preparation Claims Payment

Policy

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

N/A

Codes Requiring Retrospective Review

N/A

Experimental/Investigational

N/A

Common Diagnosis Codes

ICD-10- CM Diagnosis Codes: J45.902, T63.001A, T63.014A, T63.023A, T63.031A, T63.034A, T63.041A, T63.044A, T63.061A, T63.064A, T63.071A, T63.074AT63.084A, T63.091A, T63.094A, T63.301A, T63.441A, T63.444A, T63.451A, T63.461A, T63.621A, T63.691A, T63.711A, T63.811A, T63.822A, T63.831A, T63.891A, T78.40xA, T78.49xA

Common Diagnosis Codes associated with this policy have been provided for informational purposes only. The list of codes may not be all-inclusive and may be updated to reflect any applicable revisions to the ICD-10 code set and/or medical necessity guidelines applied in this policy.

Common Procedure Codes

CPT Codes: 86003, 86332, 86343, 95004, 95024, 95027, 95028, 95044, 95052, 95056, 95060, 95065, 95070, 95115, 95117, 95120, 95125, 95130, 95131, 95132, 95133, 95134, 95144, 95145, 95146, 95147, 95148, 95149, 95165, 95170, 95180, 95076, 95079

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior authorization for some products may require retrospective review for plans that do not require prior authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

Allergy testing is necessary to confirm the presence of IgE antibodies directed toward inhalants, foods, hymenoptera, venoms* (Refer to MVP Skin Endpoint Titration Policy), and pharmaceutical allergens implicated by the customer's history. Although there are a variety of methods for assessing the presence of specific IgE antibodies, skin testing is preferred. Allergy skin testing may be performed by the percutaneous (prick testing) or the intracutaneous route (intradermal testing). Standardized allergen extracts should be used in diagnostic skin testing along with appropriate positive and negative controls. Fresh fruits and vegetables may be used as a source of skin testing extracts by a specialist when indicated.

Provocative challenge tests can help diagnose adverse reactions to allergens when skin prick tests (SPT) or intradermal tests are considered equivocal or are unreliable. Challenge tests may be categorized into inhalation challenge tests for testing those with significant breathing reactions to allergens, and ingestion challenge tests for those who may react to food or drug allergens.

The primary tools available to evaluate patients' adverse reactions to foods include history (including diet records), physical examination, prick/puncture skin tests, serum tests for food specific IgE antibodies, trial elimination diets, and oral food challenges. Prick/puncture tests and serum assays are techniques used to detect the presence of antibody in suspected food allergies. However, they do not necessarily indicate, by themselves, that ingestion would result in a clinical reaction. Serologic analysis may indicate that a negative test result rules out IgE-mediated reactions to a tested food but that a positive test result may not be associated with true clinical reactions. Intracutaneous skin tests for foods are potentially dangerous, are overly sensitive, increase the chance of a false positive test result, and are not recommended. [7, 17] Although these tests may assist in the assessment of allergic reaction, they are not considered diagnostic.

Graded oral food challenge is performed by having the patient ingest increasing amounts of the suspected food under physician observation. This represents a definitive test for

tolerance since ingestion of a relevant amount of food with no reaction excludes the diagnosis of an adverse reaction to a tested food.

Indications/Criteria

Allergy Testing

Allergy skin testing may be considered when the customer's history and physical examination indicate that allergic mechanisms may be the underlying cause of some of the following chronic conditions:

- asthma;
- allergic rhinitis;
- eczematous eruptions, including atopic dermatitis and contact dermatitis;
- urticaria/angioedema;
- anaphylaxis caused by food, pharmaceuticals, or insects;
- gastrointestinal reactions;
- severe conjunctivitis;
- non-behavioral adverse reactions to food and drugs; or
- stinging insects* (refer to the MVP Skin End Point Titration Policy).

Patch Testing

Patch testing is used to determine the causative agent in contact eczematous dermatitis. Indications for patch testing include:

- dermatitis that is suspected to be contact induced;
- chronic occupational dermatitis; or
- when clinical evaluations suggest that a specific allergen may be implicated in a clinical setting, patch testing can be used to confirm the diagnosis.

Provocative Challenge Tests

Provocative challenge tests (inhalation or ingestion tests) are used to identify causative or provocative allergens when symptoms and signs suggest an IgE mediated allergic reaction to inhaled or ingested substances. A skin prick test (SPT) may be suggestive of an IgE mediated food or drug-induced allergic disorder, but this testing is often equivocal and is considered unreliable. Inhalation or ingestion challenge tests expose the appropriate mucosal surface to the potential allergen in a controlled setting, and patients are observed for their clinical reactions. Such testing can determine if a patient is actually allergic to a particular substance and needs to avoid it, or if the substance may be inhaled or ingested without triggering illness. Provocative challenge tests will be covered when all of the following criteria have been met:

Inhalation Challenge Tests

- Bronchoprovocation tests are considered medically necessary to evaluate new allergens and to substantiate the role of allergens in patients with significant symptoms. Results of these tests are ordinarily evaluated by objective measures of pulmonary function and by characterization of bronchoalveolar lavage samples.
- Bronchoprovocation with methacholine, histamine, cold air, or exercise challenge may be covered when asthma is suspected, and spirometry is normal.
- Bronchoprovocation should be performed as a dose-response assay wherein provocation concentration thresholds can be determined based on the allergen concentration required to cause a 20% decrease of the forced expiratory volume (FEV1).
- For safety reasons, bronchoprovocation testing should be carried out by a trained individual in an appropriate facility and is not recommended if the FEV1 is <65 percent predicted.
- All inhalation challenge tests should be preceded by a control test with diluent and, if possible, the procedure should be performed on a double-blind basis or at least a single-blind basis.

Ingestion Challenge Test

- Ingestion challenge testing materials are applied to the mucosae of the mouth or GI tract.
- Double-blind, placebo-controlled, ingestion challenge tests are required to confirm suspected gastrointestinal or systemic symptoms occurring after ingestion of a food additive, or drug.
- There is a history of allergy to a particular drug.
- Treatment with that drug class is absolutely essential.

Exclusions

Allergy Testing

The following are examples of allergy testing that have not demonstrated efficacy and will not be considered for coverage at this time:

- grain mill dust;
- tobacco smoke;
- golden rod;
- orris root;
- pyrethrum;

- dandelion;
- marigold;
- soybean dust;
- honey suckle;
- processed wool;
- phenol;
- alcohol; or
- sugar and yeast; or
- office air

Allergy Tests

The following allergy tests have not been proven to be effective in peer-reviewed studies and are considered not medically necessary: (This list may not be all inclusive)

- qualitative multi-allergen screens (via dipstick, paddle, or disk);
- cytotoxic food testing, leukocytotoxic testing or Bryan's test;
- provocation neutralization testing (subcutaneous, sublingual or intradermal), or Rinkel test;
- organ challenge testing to the conjunctivae (eyes) and nares (nose);
- basophil histamine release/activation;
- lymphocyte stimulation;
- facial thermography;
- gastric juice analysis;
- endoscopic allergen provocation;
- hair analysis;
- allergen specific lgG4;
- bronchial provocation/challenge testing for common allergens (e.g. dust, ragweed);
- medicator release test (MRT);
- leukocyte histamine release test (LHRT);
- ophthalmic mucous membrane tests;
- Prausnitz-Kustner test;
- SAGE test for food delayed hypersensitivity;
- in vitro metal allergy testing;

- antigen leukocyte cellular antibody test (ALCAT) automated food allergy testing;
- urine auto injection (autogenous urine immunization);
- food immune complex assay (FICA);
- pulse test;
- rebuck skin window;
- rhinomanometry;
- electrodermal testing;
- muscle response testing (applied kinesiology);
- chemical analysis of body tissue;

Allergen Immunotherapy

Allergen immunotherapy is considered not medically necessary for the following:

- non-IgE mediated allergies;
- food allergenic extract immunotherapy;
- management of skin and mucous membrane disease such as atopic dermatitis, uticaria and candida vulvovaginitis. As with all of the medical policies, exceptional cases will be considered for medical necessity on an individual basis;
- unsuccessful allergen immunotherapy that was administered within the past three (3) years by credentialed physicians within the same practice;
- the customer has had no significant reduction in symptoms after two years of allergen immunotherapy;
- when allergen immunotherapy has been given longer than 24 months without appropriate re-evaluation.

Allergen immunotherapy will be considered on an individual basis for children less than three (3) years of age. [6]

Out-of-area allergen immunotherapy may be covered on a case-by case basis.

Length of Therapy

Treatment duration and the benefits of immunotherapy must be documented in the customer's chart. The duration of all forms of immunotherapy must be individualized. A presumption of failure can be made when, after 24 months of therapy, a person does not experience a noticeable decrease of symptoms, an increase in tolerance to the offending allergen and a reduction in medication usage.

Treatment will not be reimbursed after a two-year period when there is no apparent clinical benefit.

Medicaid Products Variation

Allergy testing (in vivo/in vitro) may be covered only for the following conditions:

- Suspected food allergies;
- Suspected stinging insect allergies;
- Chronic rhinitis or conjunctivitis where the cause is suspected environmental allergies and the patient has been nonresponsive to avoidance and pharmacologic therapy;
- Suspected medication allergy, when no alternative is available, and treatment is medically necessary;
- Suspected allergic dermatitis.

Oral Ingestion Challenge Testing

The addition of oral ingestion challenge testing may be medically necessary for those patients for whom a diagnosis of a food allergy or allergy to an oral drug has been inconclusive or inconsistent with clinical symptoms. In general, oral ingestion challenge testing should not be used as first-line testing for allergies. Oral ingestion challenge testing should only be performed in a carefully supervised allergy specialist setting, with emergency support immediately available. Oral ingestion challenge testing is a covered service when considered medically necessary to confirm a positive in vivo/in vitro test result or to test for an allergic response to:

- Foods/ingested substances when in vivo/in vitro testing is inconclusive or inconsistent with clinical symptoms; or
- Oral medications, when all of the following are met:
 - o Patient has a history of allergy to a specified drug; and
 - o There is no effective alternative or equivalent drug; and
 - o Patient requires treatment with the drug class.

MVP Medicare Products Variation

For full coverage details refer to the National Government Services Local Coverage Determination (LCD) for RAST Type Tests (L33591). Revision Effective Date: 11/07/2019. Available: MCD Search (cms.gov)

References (Reviewed 2024)

 National Government Services Inc. Local Coverage Determination (LCD) for RAST Type Tests (L33591). Revision Effective Date November 07, 2019. Available: https://www.cms.gov/medicare-coverage-database/search.aspx.

- 2. Joint Council of Allergy, Asthma & Immunology. Practice parameters for allergen immunotherapy: Algorithm for the diagnosis and management of asthma: a practice parameter update (2016). Available: https://www.allergyparameters.org.
- 3. Joint Council of Allergy, Asthma & Immunology. Practice parameters for allergy diagnostic testing. Available: https://www.allergyparameters.org/.
- 4. National Institute of Allergy and Infectious Diseases. Guidelines for the Diagnosis and Management of Food Allergy in the United States: Report of the NIAID-Sponsored Expert Panel. U.S. Department of Health and Human Services. National Institutes of Health. October 13, 2010.
- 5. American Academy of Allergy, Asthma and Immunology. (1983). Skin testing and radioallergosorbent testing (RAST) for diagnosis of specific allergens responsible for IgE-mediated diseases. *Journal of Allergy and Clinical Immunology, 72,* 515-517. (AAAAI Position Statement #10). Available: https://www.jacionline.org/article/0091-6749%2892%2990081-C/fulltext.
- 6. American Academy of Allergy, Asthma & Immunology and the American College of Allergy, Asthma & Immunology. Allergen Immunotherapy: A Practice Parameter Third Update (Sept 2010). © 2010 American Academy of Allergy, Asthma & Immunology. Available: https://www.allergyparameters.org/published-practice-parameters/.
- 7. American Academy of Allergy, Asthma & Immunology and the American College of Allergy, Asthma & Immunology. Allergy Diagnostic Testing: An Updated Practice Parameter. Annals of Allergy, Asthma, & Immunology. March 2008; Volume 100, Number 3, Supplement 3.
- 8. Centers for Medicare and Medicaid Services. National Coverage Determination (NCD) for Food Allergy Testing and Treatment (110.11). Effective Date: 10/31/1988.
- 9. American Academy of Allergy, Asthma & Immunology and the American College of Allergy, Asthma & Immunology. The Diagnosis and Management of Anaphylaxis Practice Parameter: 2010 Update. August 21, 2010.
- 10. American Academy of Allergy, Asthma & Immunology, the American College of Allergy, Asthma & Immunology and the Joint Council of Allergy, Asthma and Immunology. Drug Allergy: An Updated Practice Parameter. Annals of Allergy, Asthma & Immunology. Volume 105. October, 2010.
- 11. National Heart, Lung, and Blood Institute. National Asthma Education and Prevention Program. Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma. Full Report 2007.
- 12. Irvin, C.G. Bronchoprovocation Testing. UpToDate®. ©2014. Available: www.uptodate.com.

- 13. Malo J.L., Lemiere C., Cartier A and Chan-Yeung M. Occupational Asthma: Clinical Features and Diagnosis. UpToDate®. ©2014. Available: www.uptodate.com.
- 14. American Academy of Allergy, Asthma & Immunology. Workgroup on Practice Parameters for Diagnostic Testing. Practice Parameters for Allergy Diagnostic Testing. ©2013 American Academy of Allergy, Asthma & Immunology.
- 15. U.S. Food and Drug Administration. Food Allergies: What you Need to Know. September 2018. Available: www.fda.gov/.
- 16. Warrington R. and Silviu-Dan F. Drug Allergy. Allergy, Asthma & Clinical Immunology November 10, 2011.
- 17. Boyce JA, Assa,ad A, Burks AW, et al. Guidelines for the Diagnosis and Management of Food Allergy in the United States: Report of the NIAD-Sponsored Expert Panel. J Allergy Clin Immunol. December 2010.
- 18. New York State Department of Health New York State Medicaid Update. May 2016. Volume 32. Number 5. Available: http://www.health.ny.gov/health_care/medicaid/program/update/2016/2016-05.htm#allergy.
- 19. Sampson, H.A., et al. Food allergy: Joint Task Force on Practice Parameters, representing the American Academy of Allergy, Asthma & Immunology (AAAAI); the American College of Allergy, Asthma & Immunology (ACAAI); and the Joint Council of Allergy, Asthma & Immunology (JCAAI). A practice parameter update-2014. J Allergy Clin Immunol 2014;134:1016-25.).

Customer Product	Medical Management Requirements*
New York Products	
НМО	Potential for Retrospective Review
PPO in Plan	Potential for Retrospective Review
PPO OOP	Potential for Retrospective Review
POS in Plan	Potential for Retrospective Review
POS OOP	Potential for Retrospective Review
Essential Plan	Potential for Retrospective Review
Healthy NY	Potential for Retrospective Review
MVP Medicaid Managed Care	Potential for Retrospective Review
MVP Child Health Plus	Potential for Retrospective Review
MVP Harmonious Health Care Plan	Potential for Retrospective Review
MVP Medicare Complete Wellness	Potential for Retrospective Review
MVP Medicare Preferred Gold HMO POS	Potential for Retrospective Review
MVP Medicare Secure HMO POS	Potential for Retrospective Review
MVP Medicare Secure Plus HMO POS	Potential for Retrospective Review
MVP Medicare WellSelect PPO	Potential for Retrospective Review
MVP Medicare WellSelect Plus PPO	Potential for Retrospective Review
MVP Medicare Patriot Plan PPO	Potential for Retrospective Review
MVP DualAccess D-SNP HMO	Potential for Retrospective Review
MVP DualAccess Complete D-SNP HMO	Potential for Retrospective Review
MVP DualAccess Plus D-SNP HMO	Potential for Retrospective Review
UVM Health Advantage Select PPO	Potential for Retrospective Review
USA Care	Potential for Retrospective Review
Healthy NY	Potential for Retrospective Review
MVP Premier	Potential for Retrospective Review
MVP Premier Plus	Potential for Retrospective Review
MVP Premier Plus HDHP	Potential for Retrospective Review
MVP Secure	Potential for Retrospective Review
MVP EPO	Potential for Retrospective Review
MVP EPO HDHP	Potential for Retrospective Review
MVP PPO	Potential for Retrospective Review
MVP PPO HDHP	Potential for Retrospective Review
Student Health Plans	Potential for Retrospective Review
ASO	See SPD
Vermont Products	
POS in Plan	Potential for Retrospective Review
POS OOP	Potential for Retrospective Review
MVP Medicare Preferred Gold HMO POS	Potential for Retrospective Review
MVP Medicare Secure Plus HMO POS	Potential for Retrospective Review
MVP VT HMO	Potential for Retrospective Review
MVP VT HDHP HMO	Potential for Retrospective Review
MVP VT Plus HMO	Potential for Retrospective Review
MVP VT Plus HDHP HMO	Potential for Retrospective Review
MVP Secure	Potential for Retrospective Review
ASO	See SPD
AJO	Jee Jr D

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Revision History

02/01/2023 – Annual review; no changes to the indications and criteria; added provider testing using office air as an exclusion.

08/01/2024 – Allergen immunoassay blood and in-vitro tests (CPT Codes 82784, 86021, 88184, 86001, 86005) now managed in the Allergen Testing Payment Policy.



Alopecia Treatment

Type of Policy: Medical

Prior Approval Date: 02/06/2023

Approval Date: 12/02/2025

Effective Date: 04/01/2025

Related Polices: Phototherapy, Photochemotherapy,

and Excimer Laser Therapy for

Dermatologic Conditions

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

CPT Codes: N/A

Codes Subject to Retrospective Review

CPT Codes:

11900 - Injection, intralesional; up to and including 7 lesions

11901 - Injection, intralesional; more than 7 lesions

15775 - Punch graft for hair transplant; 1 to 15 punch grafts

15776 - Punch graft for hair transplant; more than 15 punch grafts

Experimental/Investigational

N/A

Diagnosis Codes

ICD-10-CM Diagnosis Codes that Support Medical Necessity: L63.0, L63.1, L63.2, L63.8, L63.9, L66, L66.0, L66.1, L66.2, L66.3, L66.4, L66.8, L66.9

ICD-10-CM Diagnosis Codes that Do Not Support Medical Necessity

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Common Procedure Codes

N/A

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy.

Overview

Alopecia, or hair loss, affects millions of people including children. The cause of alopecia is complex and includes hormonal imbalance, endocrine abnormalities, genetics, medications, stress, severe illness, malnourishment, infections and autoimmune diseases.

- Alopecia Areata (non-scarring) is believed to be caused by an autoimmune reaction and is manifested as hair falling out in patches. It is subdivided into three categories based on the extent of hair loss.
 - Alopecia Areata is considered a mild form of the disease and only a few spots become bald.
 - Alopecia Totalis is total loss of hair on the scalp.
 - Alopecia Universalis is complete hair loss of all hair on the scalp and body including eyelashes, brows, and pubic hair.
- Scarring Alopecia results from infection and inflammation of the hair follicles and is characterized by extensive follicular destruction. Some examples of scarring alopecia include, but are not limited to:
 - lichen planopilaris;
 - o discoid lupus erythematosus;
 - o folliculitis declavans/pseudopelade; and
 - follicular degeneration syndrome.

Indications/Criteria

Medical Treatment for Alopecia

Treatment with intralesional corticosteroids (11900, 11901) is only covered for underlying inflammatory medical conditions resulting in hair loss. This includes alopecia areata and scarring alopecia.

Treatment with high potency topical corticosteroids are only covered when used to treat alopecia areata and scarring alopecia.

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One consultation for the evaluation to determine the underlying cause of alopecia is covered unless it is known to be androgenic alopecia.

Exclusions

Drugs (e.g., Minoxidil/Rogaine, Finasteride/Propecia and other over-the-counter hair growth medications or products) are considered cosmetic and not a covered pharmacy benefit.

Opzelura for alopecia treatment is considered cosmetic and not medically necessary.

Hair transplantation (86.83); and surgical treatments, e.g., punch grafts, rotation flaps, scalp reduction (15775, 15776) are considered cosmetic and not medically necessary.

Hair loss due to all other conditions including inherited baldness trait, androgenic alopecia (male pattern baldness), malnutrition or other disorders not specified under the criteria is considered cosmetic and not medically necessary.

Medicare

Based upon review, there is no National or Local Medicare coverage determination or policy specifically addressing alopecia.

References (Reviewed 2024)

- 1. Delamere, FM, et al Interventions for alopecia areata. Cochrane Database System Review. 2008 Apr 16; (2): CD004413.
- 2. Bissonnette, R., Shapiro, J., Zeng, H., McLean, D.I., Lui, H., (2000), Topical photodynamic therapy with 5-aminolaevulinic acid does not induce hair regrowth in patients with extensive alopecia areata. British Journal of Dermatology 143(5): 1032-1035.
- 3. Gupta AK, et al. Platelet-rich plasma as a treatment for androgenetic alopecia. Dermatol Surg. 2019 Oct;45(10):1262- 1273.
- 4. Hordinsky M, et al. Alopecia areata: an evidence-based treatment update. Am J Clin Dermatol. 2014 Jul;15(3):231-46.
- 5. Mesinkovska NA. Emerging unconventional therapies for alopecia areata. Journal of Investigative Dermatology Symposium Proceedings (2018) 19, S32eS33.
- 6. MacDonald Hull, SP., et al. Guidelines for the management of alopecia areata. British Journal of Dermatology 2003; 149: 692-699.
- 7. Shapiro J, et al. Evaluation of platelet-rich plasma as a treatment for androgenetic alopecia: A randomized controlled trial. J Am Acad Dermatol. 2020 Nov;83(5):1298-1303.
- 8. van Zuuren EJ, et al. Interventions for female pattern hair loss. Cochrane Database Syst Rev 2016 May 26;(5):CD007628.

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Customer Product	Medical Management Requirements*
New York Products	-
НМО	Retrospective Review
PPO in Plan	Retrospective Review
PPO OOP	Retrospective Review
POS in Plan	Retrospective Review
POS OOP	Retrospective Review
Essential Plan	Retrospective Review
MVP Medicaid Managed Care	Retrospective Review
MVP Child Health Plus	Retrospective Review
MVP Medicare Complete Wellness	Retrospective Review
MVP Medicare Preferred Gold HMO POS	Retrospective Review
MVP Medicare Secure HMO POS	Retrospective Review
MVP Medicare Secure Plus HMO POS	Retrospective Review
MVP Medicare WellSelect PPO	Retrospective Review
MVP Medicare WellSelect Plus PPO	Retrospective Review
MVP Medicare Patriot Plan PPO	Retrospective Review
MVP DualAccess D-SNP HMO	Retrospective Review
MVP DualAccess Complete D-SNP HMO	Retrospective Review
MVP DualAccess Plus D-SNP HMO	Retrospective Review
UVM Health Advantage Select PPO	Retrospective Review
USA Care PPO	Potential for Retrospective Review
Healthy NY	Retrospective Review
MVP Premier	Retrospective Review
MVP Premier Plus	Retrospective Review
MVP Premier Plus HDHP	Retrospective Review
MVP Secure	Retrospective Review
MVP EPO	Retrospective Review
MVP EPO HDHP	Retrospective Review
Student Health Plans	Retrospective Review
ASO	See SPD
Vermont Products	
POS in Plan	Retrospective Review
POS OOP	Retrospective Review
MVP Medicare Preferred Gold HMO POS	Retrospective Review
MVP Medicare Secure Plus HMO POS	Retrospective Review
WellSelect PPO	Retrospective Review
USACare PPO	Potential for Retrospective Review
MVP VT HMO	Retrospective Review
MVP VT HDHP HMO	Retrospective Review
MVP VT Plus HMO	Retrospective Review
MVP VT Plus HDHP HMO	Retrospective Review
MVP Secure	Retrospective Review
ASO	See SPD

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Alopecia Treatment Page 4 of 5

Revision History:

12/01/2022 - Annual review; added term androgenic alopecia to exclusions, added Medicare section, updated references.

04/01/2023 – Added diagnosis codes that support and do not support medical necessity, deleted codes S0138, S0139 as they are not applicable to policy, added exclusion for Opzelura.

04/01/2024- Annual review, no changes to criteria.

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Ambulatory Holter Monitors and Other Cardiac Monitors

Type of Policy: Medical

Prior Approval Date: 05/06/2024

Approval Date: 03/28/2025

Effective Date: 06/01/2025

Related Polices: N/A

Holter Monitor

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

N/A

Codes Subject to Retrospective Review

N/A

Experimental/Investigational

33289 – Transcatheter implantation of wireless pulmonary artery pressure sensor for long-term hemodynamic monitoring, including deployment and calibration of the sensor, right heart catheterization, selective pulmonary catheterization, radiological supervision and interpretation, and pulmonary artery angiography, when performed

93264- Remote monitoring of a wireless pulmonary artery pressure sensor for up to 30 days, including at least weekly downloads of pulmonary artery pressure recordings, interpretation(s), trend analysis, and report(s) by a physician or other qualified health care professional

Common Diagnosis Codes

ICD-10 Diagnosis Codes: A18.84, E63.9, G45.1, G45.2, G45.8, G46.0, G46.1, G46.2, I20.0, I20.1, I20.8, I20.9, I21.09, I21.11, I21.3, I21.4, I22.8, I21.19, I21.21, I21.29, I22.0, I22.1, I22.2,

122.8, 122.9, 124.4, 124.8, 124.9,125.110, 125.111, 125.118, 125.119, 125.700, 125.701, 125.708, 125.709, 125.710, 125.711, 125.718, 125.719, 125.720, 125.721, 125.728, 126.729, 125.730, 125.731, 125.738, 125.739, 125.750, 125.751, 125.758, 125.759, 125.760, 125.761, 125.768, 125.769, 125.791, 125.798, 125.799, 126.09, 126.991, 26.790, 141, 140.0, 140.1, 140.8, 140.9, 142.0, 142.1, 142.2, 142.3, 142.4, 142.5, 142.6, 142.7, 142.8, 142.9, 143, 144.0, 144.1, 144.2, 144.30, 145.5, 145.6, 145.81, 145.89, 145.9, 146.2, 146.8, 146.9, 147.1, 147.9, 148.0, 148.1, 148.2, 148.3, 148.4, 148.92, 149.01, 149.02, 149.1, 149.3, 149.40, 149.49, 149.5, 149.8, 149.9, 151.4, 163.40, 163.411, 163.412, 163.419, 163.21, 163.429, 163.431, 163.432, 163.429, 163.431, 163.432, 163.439, 163.441, 163.442, 163.449, 163.49166.01, 166.02, 166.03, 166.09, 166.11, 166.12, 166.13, 166.19, 166.21, 166.23, 166.23, 166.29, 166.3, 166.9, R00.0, R00.1, R00.2, R42, R55, T82.110A, T82.111A, T82.118A, T82.119A, T82.120A, T82.121A, T82.128A, T82.129A, T82.190A, T82.198A, T82.199A

Common Procedure Codes

CPT Codes: 93224, 93225, 93226, 93227, 93241, 93242, 93243, 93244, 93245, 93246, 93247, 93248

30-Day Cardiac Event Recorders

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

N/A

Codes Subject to Retrospective Review

N/A

Experimental/Investigational

N/A

Common Diagnosis Codes

ICD-10 Diagnosis Codes: G45.9, I45.6, I45.89, I47.0, I47.1, I47.2, I47.9, I48.0, I48.1, I48.2, I48.3, I48.4, I48.91, I48.92, I49.01, I49.02, I49.2, I49.8, I67.941, I67.848, I67.841, I67.848, R00.1, R00.2, R06.00, R06.09, R06.3, R06.83, R06.89, R42, R55

Common Procedure Codes

CPT Codes: 93268, 93270, 93271, 93272

Mobile Cardiac Outpatient Telemetry (MCOT)

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

N/A

Codes Subject to Retrospective Review

CPT Codes:

93228- External mobile cardiovascular telemetry with electrocardiographic recording, concurrent computerized real time data analysis and greater than 24 hours of accessible ECG data storage (retrievable with query) with ECG triggered and patient selected events transmitted to a remote attended surveillance center for up to 30 days; review and interpretation with report by a physician or other qualified health care professional.

93229 - External mobile cardiovascular telemetry with electrocardiographic recording, concurrent computerized real time data analysis and greater than 24 hours of accessible ECG data storage (retrievable with query) with ECG triggered and patient selected events transmitted to a remote attended surveillance center for up to 30 days; technical support for connection and patient instructions for use, attended surveillance, analysis and transmission of daily and emergent data reports as prescribed by a physician or other qualified health care professional.

Experimental/Investigational

CPT Codes:

93228- External mobile cardiovascular telemetry with electrocardiographic recording, concurrent computerized real time data analysis and greater than 24 hours of accessible ECG data storage (retrievable with query) with ECG triggered and patient selected events transmitted to a remote attended surveillance center for up to 30 days; review and interpretation with report by a physician or other qualified health care professional.

93229 - External mobile cardiovascular telemetry with electrocardiographic recording, concurrent computerized real time data analysis and greater than 24 hours of accessible ECG data storage (retrievable with query) with ECG triggered and patient selected events transmitted to a remote attended surveillance center for up to 30 days; technical support for connection and patient instructions for use, attended surveillance, analysis and transmission of daily and emergent data reports as prescribed by a physician or other qualified health care professional.

Common Diagnosis Codes

ICD-10 Diagnosis Codes: G45.9, I45.6, I45.89, I47.0, I47.1, I48.0, I48.1, I48.2, I48.3, I48.4, I48.91, I48.92, I49.01, I49.02, I49.2, I49.8, I49.9, I67.841, I67.848, R00.1, R00.2, R06.00, R06.3, R06.83, R06.89, R42, R55

Common Procedure Codes

N/A

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-

authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy.

Overview

Holter Monitors are portable electrocardiograph devices that record and store up to 24 hours of the patient's cardiac activity. The test is done in an ambulatory setting. A 24-hour Holter monitor is useful in diagnosing cardiac arrhythmias that occur daily and that might not be recorded in a standard electrocardiogram. The recording is completed either on a magnetic cassette, a digitized recorder, or by specialized "real time" recorder.

Cardiac Event Recorders involve the use of long-term monitoring to evaluate patients with symptoms suggestive of cardiac arrhythmias such as palpitations, chest pain, dizziness, syncope, lightheadedness, or shortness of breath for up to a 30-day period. These are patient activated devices that permit the patient to record an EKG upon manifestation of symptoms. These devices may also be patient activated or in response to a physician's order (e.g., immediately following strenuous physical activity).

There are several types of Cardiac Event Recorders/Monitors:

- Non-continuous external loop devices: These are devices that are carried by the patient and applied to the lower part of the chest area when symptoms occur.
- Continuous external memory loop devices: These devices are worn continuously and can store EKG data. When symptoms occur, the patient activates the device or a sensing element within the device activates the device and the EKG is recorded from the memory loop for the preceding 30-90 seconds and for approximately one minute after.
- Implantable/Insertable continuous memory loop devices: These devices are implanted under the skin in the chest area as an outpatient procedure. When symptoms occur, the patient activates the device with a hand-held activator over the recorder to activate the storage of the EKG or the device is activated from a sensing element within the device. This device may be used for more than one year with a battery life of 14 months. After the year, the device has to be surgically removed.
- Home-based, real-time cardiac surveillance system (Zio AT): This is also known as "Mobile Cardiac Outpatient Telemetry." Mobile Cardiac Outpatient Telemetry is an ambulatory EKG arrhythmia detector with alarm and extended memory. The device includes an automatic arrhythmia detector and cellular telephone transmission so that abnormal EKG waveforms can be transmitted immediately to a remote monitoring center. There is insufficient peer reviewed literature at this time that assesses the medical effectiveness of this service since there needs to be a large well-designed clinical trial to assess the use of MCOT and its value in improving clinical outcomes.

- External electrocardiographic recording for more than 48 hours up to 21 days by
 continuous rhythm recording: The Zio™ XT is a long-term cardiac rhythm monitor
 that provides continuous monitoring for up to 14 days. This device does not require
 patient activation and, therefore, is indicated for use on patients who may be
 asymptomatic or who may suffer from transient symptoms such as palpitations,
 dizziness, lightheadedness, or syncope.
- Implantation and Monitoring of pulmonary artery pressure (e.g., CardioMEMs) is proposed for the management of heart failure. A sensor is implanted into the pulmonary artery and monitors heart rate and pressure within the pulmonary artery.

Indications/Criteria

Holter Monitors and External Electrographic Recording Devices

Continuous 24-hour through 14-day monitoring (e.g., Zio™XT) of an electrocardiogram in a symptomatic patient who is ambulatory or potentially ambulatory when ordered by a physician for one of the following reasons:

- detecting transient episodes of cardiac dysrhythmia, permitting correlation of these episodes with cardiovascular symptomology;
- evaluation of the patient with symptoms of obscure etiology suggestive of cardiac arrhythmias;
- evaluation of arrhythmias in the patient with documented coronary artery disease, including the assessment of the immediate post-myocardial infarction patient; or
- monitoring the effectiveness of anti-arrhythmic therapy; or
- monitoring customers who have had surgical or ablative procedures for arrhythmias;
 or
- to identify asymptomatic atrial fibrillation as a potential source of cryptogenic stroke, or
- assessment of customers with implanted pacemakers or defibrillators, but only when customers have symptoms suggestive of arrhythmia not revealed by standard EKG or defibrillator event recordings, or analysis of pacemaker or defibrillator devices.

Insertable Loop Recorders (ILR)

An Insertable Loop Recorder (ILR) is indicated for customers with syncope who have undergone recurrent but infrequent syncopal episodes which have defied diagnosis by conventional means and when all of the following are met:

- a cardiac arrhythmia is suspected as the cause of the symptoms; and
- non-invasive ambulatory monitoring consisting of two (2) negative or nondiagnostic 30-day pre-symptom memory loop customer demand recordings fail to

establish a definitive diagnosis because the symptoms occur so infrequently and unpredictably that the monitoring period may not have been long enough to capture a diagnostic ECG; and

• tilt table testing is negative or non-diagnostic.

These customers will frequently have a history of injury or even hospitalization directly attributed to prior syncopal events. (Syncope here is defined as a sudden but transient total loss of consciousness with spontaneous resolution.)

Cardiac Event Recorders

Documentation submitted should include:

- complete history and physical;
- diagnosis; and
- clinical indication for use of this device such as:
 - o monitoring for the purpose of regulating anti-arrhythmic medication;
 - monitoring patients who have had a recent surgical ablative procedure for arrhythmias;
 - assess pacemaker or defibrillator device functioning and programming for patients experiencing arrhythmic symptoms; or
 - assessment of symptoms that may be related to cardiac arrhythmias when not diagnosed by other modalities (e.g., Holter monitor, stress test, standard EKG's).

Exclusions

The coverage of home based, real time cardiac surveillance systems is considered experimental and investigational as there is insufficient evidence to support Mobile Cardiac Outpatient Telemetry (MCOT) improves health outcomes.

Invasive Congestive Heart Failure Monitoring (33289, 93264)

Due to the lack of evidence from peer-reviewed literature, an implantable wireless pulmonary artery pressure monitor (CardioMEMS) is considered investigational.

Medicare Variation:

Mobile Cardiac Outpatient Telemetry (MCOT) is a covered benefit for Medicare plans according to the Medicare Novitas Solutions, Inc. Local Coverage Determination (LCD) Real-Time, Outpatient Cardiac Telemetry (L34997):

Medicare coverage for this service is limited to patients who have demonstrated a specific need for this type of cardiac telemetry service. The ordering physician must have determined and documented that patients who require this service are at low risk for a life-threatening cardiac event. In addition, the medical record must clearly demonstrate

that the results of this testing will provide diagnostic and/or treatment information useful in the ongoing management of the patient.

The following uses of real-time, outpatient cardiac telemetry are considered medically reasonable and necessary:

- 1. Detection, characterization and documentation of symptomatic transient or paroxysmal dysrhythmia when the frequency of the symptoms is limited and the use of a 24-hour ambulatory ECG is documented in the medical record to be unlikely to capture and record the dysrhythmia, or
- Other testing and/or monitoring/recording/telemetry has been unrevealing. The
 ordering physician must document the prior testing performed and the results.
 This information must be maintained in the patient's medical record and be
 available upon request, or
- 3. Prolonged monitoring is required specifically to ensure the absence of atrial fibrillation prior to the discontinuation of anticoagulation therapy.

Implantable Pulmonary Artery Pressure Sensor (IPAPS – CardioMEMS 33289, 93264)

Implantable pulmonary artery pressure sensor (PAPS) for heart failure management is a covered benefit for Medicare plans according to the National Coverage Analysis Implantable Pulmonary Artery Pressure Sensors for Heart Failure Management CAG-00466N; when performed under a CMS- approved Coverage with Evidence Development (CED) study and meets all of the following criteria:

- Diagnosis of chronic heart failure of at least 3 months duration and in New York Heart Association (NYHA) functional Class II or III within the past 30 days, prior to PAPS implantation, regardless of left ventricular ejection fraction (LVEF); and
- History of heart failure hospitalization or urgent HF visit (emergency room or other outpatient visit requiring intravenous diuretic therapy) within the past 12 months, or elevated natriuretic peptides within the past 30 days; and
- The customer is on guideline-directed medical therapy (GDMT) for at least 3 months with the goal of achieving optimal or maximally-tolerated GDMT prior to PAPS implantation; and
- Customer has been evaluated for, and received if appropriate, an implantable cardioverter defibrillator (ICD), cardiac resynchronization therapy (CRT)-Pacemaker (CRT-P), or CRT-Defibrillator (CRT-D). Implantation of the device must occur at least 3 months prior to PAPS implantation; and
- There is no major cardiovascular event (e.g., unstable angina, myocardial infarction, percutaneous coronary intervention, open heart surgery, or stroke) within the last 3 months prior to PAPS implantation; and
- The customer has access to reliable connectivity to ensure daily collection and submission of IPAPS data; and

- PAPS implantation cannot occur during a hospital admission for an acute HF episode; and
- Physician referring the customer and managing them post implantation must be a cardiologist with training and experience in heart failure management; and
- The physician implanting the PAPS must have training and experience in pulmonary arterial catheterization and intervention.

References (Updated 2025)

- Crawford, MH, et al. ACC/AHA guidelines for ambulatory electrocardiography: executive summary and recommendations: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee to Revise the Guidelines for Ambulatory Electrography). Circulation. 1999; 100:886-93.
- 2. Hindricks, G., et al. XPECT Trial Investigators. Performance of a new leadless implantable cardiac monitor in detecting and quantifying atrial fibrillation: Results of the XPECT trial. Circulation: Arrhythmia and Electrophysiology. 2010 April 1; 3(2):141-7.
- 3. Giada, F., et al. Recurrent unexplained palpitations (RUP) study comparison of implantable loop recorder versus conventional diagnostic strategy. Journal of American College Cardiology. 2007 May 15; 49(19):1951-6.
- 4. Rothman, SA, et al. The diagnosis of cardiac arrhythmia: a prospective multi-center randomized study comparing mobile cardiac outpatient telemetry versus standard loop event monitoring. Journal of Cardiovascular Electrophysiology. 2007; 18 (3): 1-7.
- 5. HAYES Health Technology Assessment Mobile Cardiac Outpatient Telemetry (MCOT) (CardioNet Ambulatory ECG Monitor; CardioNet.) for Home Monitoring of Cardiac patients. HAYES, Inc. September 23, 2011. <u>Annual</u> Review October 16, 2013.
- Centers for Medicare and Medicaid Services (CMS) National Coverage Decision for Electrocardiographic Services 100-3 Section 20.15, August 26, 2004. Available: www.cms.gov/
- 7. National Government Services, LCD for Category III CPT® Codes Local Coverage Determination (LCD) (L33392). Revision Effective Date: October 3, 2019. Available: www.ngsmedicare.com
- 8. <u>Novitas Solutions, Inc. Local Coverage Determination (LCD): Real-Time, Outpatient Cardiac Telemetry (L34997) Revision Effective Date: October 17, 2019. Available: https://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx.</u>
- 9. Novitas Solutions, Inc. Local Coverage Article: Billing and Coding: Real-Time, Outpatient Cardiac Telemetry (A52995) Revision Effective Date: 10/01/2019.

<u>Available:</u> https://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx.

- 10. Strickberger, S.A., et al. ACC/ACCF Scientific Statement on the evaluation of syncope; From the American Heart Associations on Clinical Cardiology, Cardiovascular Nursing, Cardiovascular Disease in the Young, and Stroke, and the Quality of Care and Outcomes Research Interdisciplinary Working Group; and the American College of Cardiology Foundation in Collaboration with the Heart Rhythm Society. Journal of American College of Cardiology. 2006; 47; 473-484.
- 11. Zipes, DP, et al. ACC/AHA/ESC 2006 Guidelines for Management of Patients with Ventricular Arrythmias and the Prevention of Sudden Cardiac Death. A Report of the American College of Cardiology/American Heart Association Task Force and the European Society of Cardiology Committee for Practice Guidelines. Circulation. 2006; 114:e385-e484.
- 12. Blomstrom-Lundqvist C., et al. European Society of Cardiology Committee, NASPE-Heart Rhythm Society. ACC/AHA/ESC guidelines for the management of patients with supraventricular arrhythmias-executive summary. A report of the American college of cardiology/American heart association task force on practice guidelines and the European society of cardiology committee for practice guidelines developed in collaboration with NASPE-Heart Rhythm Society. Journal of American College of Cardiology. 2003 October 15; 42(8):1493-531.
- 13. iRhythm Technologies, Inc. Available: www.irhythmtech.com.
- 14. Zimetbaum, P., et al. Ambulatory Arrhythmia Monitoring: Choosing the right device. Circulation. 2010, 122:1629-1636.
- 15. Rosenberg, MA, et al. Use of noninvasive continuous monitoring device in the management of atrial fibrillation: A pilot study. PACE Pacing and Clinical Electrophysiology. 2013, 36(3): 328-333.
- 16. Mittal, S. et al. Ambulatory external electrocardiographic monitoring: Focus on atrial fibrillation. Journal of the American College of Cardiology. 2011, 58 (17): 1741-1749.
- 17. U.S. Food and Drug Administration. Center for Devices and Radiological Health (CDRH). Device Approval. Zio® Patch K121319 Jul 2012. Available: www.fda.gov/.
- 18. Turakhia MP, Hoang DD, Zimetbaum P, et al. Diagnostic utility of a novel leadless arrhythmia monitoring device. Am J Cardiol. 2013;112(4):520-524.
- 19. Higgins SL. A novel patch for heart rhythm monitoring: Is the Holter monitor obsolete? Future Cardiol. 2013;9(3):325-333.
- 20. HAYES Health Technology Brief™. Zio Patch (iRhythm Technologies Inc.) Long-Term Ambulatory Cardiac Rhythm Monitoring. Lansdale, PA: HAYES, Inc.; © Winifred S. Hayes, Inc. November 5, 2015. Available: www.hayesinc.com.

- 21. Hayes, Inc. Health Technology Assessment. CardioMEMS implantable hemodynamic monitor (Abbott) for managing patients with heart failure. Published July 28, 2022.
- 22. Heidenreich PA, et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: a report of the American College of Cardiology/American Heart Association Joint Committee on clinical practice guidelines. Circulation 2022 May 3;145(18):e895-e1032.
- 23. Centers for Medicare and Medicaid Services (CMS) National Coverage Analysis (NCA) for Implantable Pulmonary Artery Pressure Sensors for Heart Failure Management CAG-00466N, January 13, 2025. Available: www.cms.gov/

Customer Product	Medical Management Requirements*
New York Products	-
НМО	Retrospective Review
PPO in Plan	Retrospective Review
PPO OOP	Retrospective Review
POS in Plan	Retrospective Review
POS OOP	Retrospective Review
Essential Plan	Retrospective Review
MVP Medicaid Managed Care	Retrospective Review
MVP Child Health Plus	Retrospective Review
MVP Harmonious Health Care Plan	Retrospective Review
MVP Medicare Complete Wellness	Retrospective Review
MVP Medicare Preferred Gold HMO POS	Retrospective Review
MVP Medicare Secure HMO POS	Retrospective Review
MVP Medicare Secure Plus HMO POS	Retrospective Review
MVP Medicare WellSelect PPO	Retrospective Review
MVP Medicare WellSelect Plus PPO	Retrospective Review
MVP Medicare Patriot Plan PPO	Retrospective Review
MVP DualAccess D-SNP HMO	Retrospective Review
MVP DualAccess Complete D-SNP HMO	Retrospective Review
MVP DualAccess Plus D-SNP HMO	Retrospective Review
UVM Health Advantage Select PPO	Retrospective Review
USA Care	Potential for Retrospective Review
Healthy NY	Retrospective Review
MVP Premier	Retrospective Review
MVP Premier Plus	Retrospective Review
MVP Premier Plus HDHP	Retrospective Review
MVP Secure	Retrospective Review
MVP EPO	Retrospective Review
MVP EPO HDHP	Retrospective Review
MVP PPO	Retrospective Review
MVP PPO HDHP	Retrospective Review
Student Health Plans	Retrospective Review
ASO	See SPD
Vermont Products	
POS in Plan	Retrospective Review
POS OOP	Retrospective Review
MVP Medicare Preferred Gold HMO POS	Retrospective Review
MVP Medicare Secure Plus HMO POS	Retrospective Review
MVP VT HMO	Retrospective Review
MVP VT HDHP HMO	Retrospective Review
MVP VT Plus HMO	Retrospective Review
MVP VT Plus HDHP HMO	Retrospective Review
MVP Secure	Retrospective Review
ASO	See SPD

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Revision History

08/01/2022 – Annual Review, eliminated requirement for Cardiologist to order cardiac monitors, updated references and websites.

08/01/2024 – Annual Review, no changes to indications or criteria, references updated.

06/01/2025 – moved CardioMems (33289, 93264) from Investigational Policy with new Medicare Variation.



Applied Behavior Analysis

Type of Policy: Behavioral Health/Medical

Prior Approval Date: 02/05/2024

Approval Date: 03/28/2025

Effective Date: 06/01/2025

Related MVP Polices Speech Generating Devices and Other: Speech Therapy (Outpatient)

Autism Spectrum Disorders - New York State (N.Y. ISC

Law § 3216)

Applied Behavior Analysis - Vermont

Codes Requiring Prior Authorization

Because requirements for Prior Authorization vary by plan types, the below codes may be specific to one product or apply to all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

97151	Behavior identification assessment, administered by a physician or other qualified health care professional, each 15 minutes of the physician's or other qualified health care professional's time face-to-face with patient and/or guardian(s)/caregiver(s) administering assessments and discussing findings and recommendations, and non-face-to-face analyzing past data, scoring/interpreting the assessment, and preparing the report/treatment plan	
97152	Behavior identification-supporting assessment, administered by one technician under the direction of a physician or other qualified health care professional, face-to-face with the patient, each 15 minutes	
97153	- 	
97154	Group adaptive behavior treatment by protocol, administered by technician under the direction of a physician or other qualified health care professional, face-to-face with two or more patients, each 15 minutes	

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97155	Adaptive behavior treatment with protocol modification, administered by physician or other qualified health care professional, which may include simultaneous direction of technician, face-to-face with one patient, each 15 minutes	
97156	Family adaptive behavior treatment guidance, administered by physician or other qualified health care professional (with or without the patient present), face-to-face with guardian(s)/caregiver(s), each 15 minutes	
97157	Multiple-family group adaptive behavior treatment guidance, administered by physician or other qualified health care professional (without the patient present), face-to-face with multiple sets of guardians/caregivers, each 15 minutes	
97158	Group adaptive behavior treatment with protocol modification, administered by physician or other qualified health care professional, face to-face with multiple patients, each 15 minutes	
0362T	Behavior identification supporting assessment	
0373T	Adaptive behavior treatment with protocol modification, each 15 minutes	

Codes Requiring Retrospective Review

N/A

Experimental/Investigational

N/A

Common Diagnosis Codes

Common Diagnosis Codes associated with this policy have been provided for informational purposes only and is not an exhaustive list. These codes may be updated to reflect any applicable revisions to the ICD-10 Clinical Modification or CPT code sets adopted by CMS and/or medical necessity criteria.

F84.0	Autistic disorder	
F84.2	Rett's syndrome	
F84.3	Other childhood disintegrative disorder	
F84.5	Asperger's syndrome	
F84.8	Other pervasive developmental disorders	
F84.9	Pervasive developmental disorder, unspecified	

Common Procedure Codes

N/A

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring authorization for some products may require retrospective review for plans that do not require authorization.

Overview

Applied Behavior Analysis (ABA) is a behavior therapy that utilizes various behavioral stimuli and consequences to produce meaningful outcomes in human behavior ABA focuses on developing practical skills and decreasing problematic behaviors. Treatment can occur in a variety of settings, including the home, community, school, etc., with the goal of generalization of skills across all settings and locations. A qualified ABA professional will conduct a thorough assessment, develop and implement a treatment plan, and provide direct training and support to the behavioral technicians, family members, and other involved professionals. ABA is an evidenced based treatment for Autism Spectrum Disorder (ASD).

Autism Spectrum Disorder (ASD) is a neurodevelopmental disorder characterized by persistent impairment in social communication and social interaction and restricted, repetitive patterns of behavior, interests, or activities, as defined by the American Psychiatric Association in its Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5).

Indications/Criteria

ABA is considered Medically Necessary as a behavioral intervention for serious behavior impairments associated with ASD and is covered when medically necessary for members who:

- 1. are diagnosed with ASD by a Licensed Physician ((including psychiatrists and behavioral/developmental pediatricians), Licensed Nurse Practitioner (including psychiatric or pediatric NPs), or Licensed Psychologist; **and**
- 2. meets diagnostic criteria for ASD according to the DSM-5; and
- 3. has been recommended for and referred to ABA treatment; and
- 4. has been assessed by a Licensed Behavior Analyst (LBA) and determined to be appropriate for ABA.

MVP takes a multidisciplinary approach to ensure a member receives appropriate covered services for ABA treatment as outlined in MVP Protocols and the guidelines put forth by The Council for Autism Service Providers (CASP).

Documentation Requirements When Submitting Authorization Requests for ABA Assessment:

The following documentation must be submitted by the member or appropriate provider to determine the medical necessity of ABA:

- 1. A copy of the completed diagnostic evaluation that resulted in a diagnosis of ASD and was conducted by a Licensed Physician, Licensed Nurse Practitioner, or Licensed Psychologist. This evaluation must include:
 - a) direct clinical observation of the member; and

- b) developmental, medical, family, and social history; and
- c) physical exam assessing medical causes and/or associations to the behavioral presentation; **and**
- d) consideration of other disorders that may overlap or mimic the ASD symptoms; and
- e) completion of a validated ASD diagnostic tool (i.e. ADOS, CARS, or ADI-R)
- 2. The completed diagnostic evaluation should describe how diagnostic criteria for ASD is met according to the DSM-5, to include:
 - a) the existence of the following specifiers, as applicable; and
 - i. With or without intellectual impairment
 - ii. With or without language impairment
 - iii. Associated with a known medical or genetic condition or environmental factor
 - iv. Associated with another neurodevelopment, mental, or behavioral disorder
 - v. With or without catatonia
 - b) a description of the level of severity of social communication and interaction impairments and restricted, repetitive patterns of behavior
- 3. A copy of the referral(s) for ABA Assessment and/or Treatment that includes the current (within the last two (2) years) recommendation for ABA assessment and/or treatment made by a Licensed Physician), Licensed Psychologist, or Licensed Nurse Practitioner.
- 4. A copy of the comprehensive annual physical, or a school health examination form which includes a completed physical exam, by the member's Primary Care Provider (PCP) and/or specialty physician that evaluated the member's medical, vision, hearing, genetic, developmental, and/or behavioral health conditions
- 5. The requested number of hours planned for completion of the ABA Assessment. The ABA assessment for initial development of the ABA treatment plan can take up to twenty (20) hours to complete.
 - a) The presence of severe, problematic behaviors may require longer durations of assessment.
 - b) Initial assessments that involve a small number of uncomplicated goals require fewer than 20 hours to complete.

Documentation Requirements hen Submitting Authorization Requests for ABA treatment:

In addition to the documentation requirements (1-4) above for requesting an ABA assessment, the following documentation must be provided when requesting ABA treatment.

- 6. <u>ABA Assessment</u>. A copy of the official ABA Assessment (as defined by The Council of Autism Service Providers (CASP) guidelines), including the certification/credentials of the assessor.
- 7. <u>ABA Treatment Plan</u>. A copy of the current ABA Treatment Plan (as defined by CASP guidelines) that details the frequency, duration, and location of the requested ABA treatment and the treatment to be applied in targeting the member's identified core symptoms of ASD. The Treatment Plan should support the assessed number of hours needed and any clinical supervision hours. Specific parent/ caregiver training procedures should also be included to support the treatment goals. The Treatment Plan should also include the transition plan, discharge plan, and crisis intervention plan.
- 8. <u>Treatment Dosage</u>. Treatment dosage or intensity is identified as the number of direct treatment hours per week and varies based on whether ABA is part of a Focused or Comprehensive Treatment plan.
 - a) Focused ABA Treatment is appropriate when treatment is needed for a limited number of core functional skills or when acute problem behaviors are the priority. Focused ABA Treatment intensity includes approximately 10 hours per week, with higher intensity indicated depending on the nature of the target behaviors and other considerations, all individual to the customer. Examples of behaviors requiring higher intensity include a need to reduce maladaptive behaviors which place the customer at risk of harm and/or adaptive behaviors needing to be developed in order to strengthen or enhance a customer's health, safety, and overall functioning.
 - b) Comprehensive ABA Treatment is appropriate when treatment is needed for multiple affected developmental domains, such as cognitive, communicative, social, emotional, and adaptive functioning, as well as maladaptive behaviors. Comprehensive Treatment intensity includes approximately 30 hours per week when it is necessary to achieve meaningful improvements in a large number of treatment goals.
 - c) Intensity of treatment must be individualized to the customer's needs, developmentally appropriate, and take into consideration the wide range of behavioral, academic, social, and communication needs of the customer.
 - d) An individual's ability to tolerate and participate in treatment should be considered when prescribing service intensity. Less hours may be indicated when an individual is unable to tolerate treatment for extended periods of time.
 - e) ABA service intensity should also include consideration for an individual's other developmental and treatment needs, allowing time to participate in other necessary services and treatments.
- 9. <u>Dosage of Case Supervision.</u> Case supervision and clinical direction, completed by the LBA, should occur for 1-2 hours per every 10 hours (1-2:10) of direct treatment.

When direct treatment is 10 hours per week or less, a minimum of 1-2 hours per week of case supervision is usually necessary. Clinical direction, which occurs concurrently with the delivery of direct treatment, generally accounts for 50% or more of case supervision.

Authorization for ABA treatment, if approved, will be for 6 months.

Clinical Criteria for Medical Necessity for Continued Treatment:

Criteria to authorize the continuation of ABA treatment include all clinical criteria to establish medical necessity as indicated above and the following, as applicable:

- 1. Documentation from the treating ABA provider that measures the member's clinical progress to support that the treatment approach is effective and reasonably expected to result in significant improvements for the member in at least two settings (i.e., home, school, community) and not making the symptoms persistently worse.
- 2. Documentation of parent training progress.
- 3. Documentation that the member's attendance is appropriate and consistent.
- 4. Documentation of monthly assessment of progress for each targeted goal.
- 5. When there has been inadequate progress in a targeted goal or a goal has not been achieved in the estimated timeframes, the ABA provider must provide an evaluation of the reasons for the inadequate progress.
- 6. If the previously set treatment plan is not reaching a targeted goal, the treatment plan must be reevaluated and modified accordingly.

Clinical Criteria for Medical Necessity for Discharge:

Services should be considered no longer medically necessary and discharge planning should begin when at least one of the following criteria is met:

- 1. The member has achieved treatment goals; OR
- 2. The member no longer meets the diagnostic criteria for ASD (see above ABA clinical criteria for medical necessity that resulted in original ASD Diagnosis); OR
- 3. The member does not demonstrate progress towards goals for successive authorization periods; OR
- 4. The member, parent(s), caregiver(s) and/or legal guardian decides to discontinue services; OR
- 5. The family and provider are unable to reconcile important issues in treatment planning and delivery.

Provider Requirements

ABA Providers in New York must be licensed under Article 167 of the New York State Education Law as a Licensed Behavior Analyst ("LBA").

Members have coverage for ABA therapy when provided by:

- Licensed Behavioral Analyst (LBA);
- Certified Behavioral Analyst Assistant (CBAA) under the supervision of an LBA; or

Other unlicensed professionals acting under the supervision and direction of a licensed LBA under Article 167 of NYS Education Law.

Exclusions

- 1. ABA treatment will not be covered as a substitute for an Early Intervention Program for developmental delays that do not meet the DSM-5 criteria for ASD.
- 2. Services that are provided in a school setting.
- 3. Services that are deemed as primarily educational or vocational training in nature to improve academic or job performance, or to correct a learning disability are not considered Medically Necessary.
- 4. Services that are provided pursuant to an Individualized Education Plan (IEP) under the New York State Education Law are not Covered Services.
- 5. Pharmaceutical drugs not meeting MVP's Experimental and Investigational Policy criteria are excluded from coverage.
- 6. Neuropsychological testing is not included in the American Academy of Pediatrics Guidelines for the Identification, Evaluation, and Management of Children with Autism Spectrum Disorders and, therefore, is considered not medically necessary. See Neuropsychological Testing Medical Policy for additional coverage criteria.
- 7. Coverage of complementary and alternative medicine is not supported in the American Academy of Pediatrics Guidelines for the Identification, Evaluation, and Management of Children with Autism Spectrum Disorders due to insufficient scientific evidence that demonstrates their use as effective treatments for ASD and will be administratively denied as experimental/investigational. Examples of complementary and alternative medicine include but are not limited to:
 - a. auditory integration training
 - b. behavioral optometry
 - c. craniosacral manipulation
 - d. detoxification therapies (e.g., chelation therapy)
 - e. dolphin therapy
 - f. equine therapy

- g. holding therapy
- h. hippotherapy
- 8. Time spent traveling between service locations, when not actively working on skill development or goal objectives, is not covered.
- 9. Periods of rest (i.e. member is not alert) during sessions are not covered.

State of Vermont Variation

The diagnosis and treatment of early childhood developmental disorders is covered in accordance with the Vermont state mandate, including applied behavior analysis supervised by a nationally board-certified behavior analyst, for children beginning at birth and continuing until the child reaches age 21.

MVP Medicaid Managed Care Plans

MVP Medicaid Managed Care Plan members have coverage for Applied Behavior Analysis (ABA) therapy, regardless of age, when they have a diagnosis of autism spectrum disorder and/or Rett Syndrome as defined by the American Psychiatric Association in its Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5); and when medically necessary.

Applied Behavior Analysis (ABA) therapy must be provided by:

- Licensed Behavioral Analyst (LBA),
- Certified Behavioral Analyst Assistant (CBAA) under the supervision of an LBA, or
- Other individuals specified under Article 167 of NYS Education Law.

Members may be eligible for Applied Behavior Analysis (ABA) if:

- Have a diagnosis of autism spectrum disorder and/or Rett Syndrome as defined by the American Psychiatric Association in its the Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5); and
- Referred by a NYS licensed and NYS Medicaid enrolled physician (including psychiatrists and developmental/behavioral pediatricians), psychologist, or psychiatric nurse practitioner, pediatric nurse practitioner, or physician assistant.

Applied Behavior Analysis (ABA) coverage includes:

- assessment and treatment by a physician, licensed behavioral analyst, or certified behavior analyst assistant, or another qualified health professional,
- individual treatments delivered in the home or other setting, and
- training and support to family and caregivers.

Settings for ABA Services will include anywhere LBA/CBAAs may legally provide ABA services:

- Private/group practice settings where patients/clients reside full-time or parttime, clinics, hospitals, residences, and community settings.
- ABA services are not considered primary care services and thus will not be provided in School-Based Health Centers.
- ABA services are not covered as part of an Individual Education Plan (IEP); ABA Services are not included in SSHSP.

Medicaid Coverage Exclusions:

The following procedures are excluded from Medicaid Managed Care (MMC) plan coverage and are not covered:

- Behavior identification supporting assessment (CPT 0362T)
- Adaptive behavior treatment with protocol modification (0373T)

MVP Medicare Advantage Plans:

ABA services are not covered for MVP Medicare Advantage Plans.

References (Updated 2025)

- 1. American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders, 5th Edition, (DSM-V)*. Washington, DC: American Psychiatric Publishing; 2013.
- 2. The Council of Autism Service Providers (CASP). Applied Behavior Analysis Treatment of Autism Spectrum Disorder: Practice Guidelines for Healthcare Funders and Managers, Second Edition. Copyright © 2014, 2020 by The Council of Autism Service Providers ("CASP"). Ver. 2.0
- 3. Volkmar F, Siegel M, et al. Practice parameter for the assessment and treatment of children and adolescents with autism spectrum disorder. *Journal of the American Academy of Child and Adolescent Psychiatry*. 2014; 53(2).
- 4. Hyman, SL, Levy, SE, Myers, SM. American Academy of Pediatrics Clinical report identification, evaluation and management of children with autism spectrum disorder. *Pediatrics*. 2020; 145(1).
- 5. Myers, SM, Plauche´ Johnson C. The Council on Children with Disabilities. Management of Children with Autism Spectrum Disorders. American Academy of Pediatrics. *Pediatrics*. 2007; 120(5).
- 6. Johnson CP, Myers SM; American Academy of Pediatrics, Council on Children with Disabilities. Identification and Evaluation of Children with Autism Spectrum Disorders. *Pediatrics*. 2007; 120.
- 7. New York State Health Insurance Law S.4005A/A.6305A. Available: https://www.nysenate.gov/legislation/bills/2011/s5845.

- 8. New York State Department of Financial Services. Insurance Circular Letter No. 6 (2014). October 10, 2014. Available: https://www.dfs.ny.gov/insurance/circltr/2014/cl2014_06.htm.
- 9. Behavior Analyst Certification Board. Professional and Ethical Compliance Code for Behavior Analysts. Behavior Analyst Certification Board, Inc. 2014.
- 10. Centers for Disease Control and Prevention. Autism Spectrum Disorder. Accessed at: https://www.cdc.gov/ncbddd/autism/index.html.
- 11. Office of the Professions. Applied Behavior Analysis. Accessed at: <u>Article 167, Licensed Behavior Analysts | Office of the Professions (nysed.gov)</u>
- 12. UpToDate. Autism Spectrum Disorder. Available: http://www.uptodate.com.
- 13. Best Practice Guidelines for the Diagnosis of Pervasive Developmental Disorders 2009, State of Vermont. <u>A (vermont.gov).</u>
- 14. NYS Department of Health. (2021-3) Clinical Practice Guideline on Assessment and Intervention Services for Young Children with Autism Spectrum Disorders (ASD). Publication No. 20152. Version 2021-3 October 2021.
- 15. eMedNY New York State Medicaid Provider Policy Manual, Applied Behavior Analysis Policy Manual. Update February 1, 2024. <u>ABA Policy.pdf</u>
- 16. New York State Department of Health Bureau of Early Intervention. Best Practice Protocol for Early Screening of Young Children for Autism Spectrum Disorders (ASDs) by Pediatric Primary Care Providers. July 2013, Updated January 2019.

Member Product	Medical Management Requirements*
New York Products	
HMO	Prior Authorization
PPO in Plan	Prior Authorization
PPO OOP	Prior Authorization
POS in Plan	Prior Authorization
POS OOP	Prior Authorization
Essential Plan	Prior Authorization
MVP Medicaid Managed Care	Prior Authorization
MVP Child Health Plus	Prior Authorization
MVP Harmonious Health Care Plan	Prior Authorization
MVP Medicare Complete Wellness	Not Covered
MVP Medicare Preferred Gold HMO POS	Not Covered
MVP Medicare Secure HMO POS	Not Covered
MVP Medicare Secure Plus HMO POS	Not Covered
MVP Medicare WellSelect PPO	Not Covered
MVP Medicare WellSelect Plus PPO	Not Covered
MVP Medicare Patriot Plan PPO	Not Covered
MVP DualAccess D-SNP HMO	Not Covered
MVP DualAccess Complete D-SNP HMO	Not Covered
MVP DualAccess Plus D-SNP HMO	Not Covered
UVM Health Advantage Select PPO	Not Covered
Healthy NY	Prior Authorization
MVP Premier	Prior Authorization
MVP Premier Plus	Prior Authorization
MVP Premier Plus HDHP	Prior Authorization
MVP Secure	Not Covered
MVP EPO	Prior Authorization
MVP EPO HDHP	Prior Authorization
MVP PPO	Prior Authorization
MVP PPO HDHP	Prior Authorization
Student Health Plans	Prior Authorization
ASO	See SPD
Vermont Products	
POS in Plan	Prior Authorization
POS OOP	Prior Authorization
MVP Medicare Preferred Gold HMO POS	Not Covered
MVP Medicare Secure Plus HMO POS	Prior Authorization
MVP VT HMO	Prior Authorization
MVP VT HDHP HMO	Prior Authorization
MVP VT Plus HMO	Prior Authorization
MVP VT Plus HDHP HMO	Prior Authorization
MVP Secure	Not Covered
ASO	See SPD

♦ Note: Authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Authorization Required

Potential for Retrospective Review No Authorization Required. May be subject to Retrospective Review.

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Revision History:

03/01/2021 – New policy effective date.

10/01/2021 – Updated clinical criteria for the comprehensive evaluation requirements and for ABA treatment. Added clinical criteria for continued treatment and discharge. Policy updated to reflect the delay for MMC carve-in for ABA.

01/01/2023 - Applied Behavior Analysis (ABA) services carved into the Medicaid Managed Care (MMC) benefit package.

07/01/2023 - overview rewrite, updated indications/criteria for coverage, updated documentation requirements for authorization requests, added documentation requirements for treatment dosage and intensity, exclusions added for time spent traveling and periods of rest. Added coverage to Medicaid Managed Care Plans for group adaptive behavior treatment (CPT 97154) and multiple-family treatment (CPT 97157), references updated. Expanded ABA services provided by New York State Licensed Behavior Analysts to all Medicaid eligible individuals, regardless of age.

06/01/2025 - Added exclusion for ABA services provided in the school setting.



Artificial Intervertebral Disc Cervical and Lumbar

Type of Policy: Surgical

Prior Approval Date: 02/07/2022

Approval Date: 09/11/2023

Effective Date: 12/01/2023

Related Polices: N/A

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

CPT Codes: N/A

Codes Requiring Retrospective Review

CPT Codes: 0095T, 0098T, 0164T, 0165T, C1831

Experimental/Investigational

CPT Codes: 0095T, 0098T, 0163T, 0164T, 0165T, 22860, C1831

Common Diagnosis Codes

ICD-10- CM Diagnosis Codes: M51.36, M51.37

Common Procedure Codes

CPT Codes: 22857, 22862, 22864, 22865

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

Chronic back or neck pain may be due to degenerative disc disease which occurs with aging causing the intervertebral discs in the spine to lose their shock absorbing characteristics. The discs become stiff and rigid, restricting movement and are painful in the areas of deterioration.

If conservative medical treatment has failed to relieve the pain, surgical intervention may be necessary. The ultimate goal of surgical management is to significantly decrease or eliminate the pain and to restore as much function as possible.

Indications/Criteria

Lumbar Artificial Disc

The lumbar artificial disc replacement (LADR) with an FDA approved prosthesis for single-level disc replacement (including the In Motion artificial disc (formerly known as The Charité® Artificial Disc), the ProDisc®-L Lumbar, and activL® Artificial Disc will be considered medically necessary when all of the following criteria have been met:

- the lumbar artificial disc is indicated for spinal arthroplasty in skeletally mature patients with degenerative disc disease (DDD)* at one level from L4-S I; and
- DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies; and
- these DDD patients should have no more than 3mm of spondylolisthesis at the involved level; and
- patients receiving the lumbar artificial disc should have failed at least six months of conservative treatment (e.g., reduced activities, exercise, analgesics, physical therapy), prior to implantation.

Cervical Artificial Disc

Cervical artificial total disc replacement via an open anterior approach with an FDA approved implant is medically necessary for the treatment of degenerative disc disease at a single level (including the Pro-Disc C, Prestige® Cervical Disc, and Bryan® Cervical Disc) or two contiguous levels (MOBI-C cervical disc, Prestige Lp Cervical Disc) between one or two level degenerative disc disease from C3-C4 to C6-C7 in skeletally mature patients when all of the following criteria have been met: [4,5,6]

 documentation in the patient's record indicates that the patient has intractable symptomatic radiculopathy and/or intractable symptomatic myelopathy resulting in disability and/or neurological deficit that is refractory to at least six weeks of conservative management (e.g., reduced activities, exercise, analgesics, physical therapy); and

- the patient has one of the following conditions producing symptomatic nerve root and/or spinal cord compression:
 - o herniated disc; or
 - o osteophytes formation; and
- single-level or two-level disc degeneration has been confirmed on complex imaging studies (i.e., computerized tomography [CT] scan, magnetic resonance imaging [MRI]); and
- the planned implant will be used in the reconstruction of a cervical disc at C3-C7, following single-level or two-level discectomy; and
- the individual is a candidate for single-level anterior cervical decompression and interbody fusion.

Exclusions

The following are exclusions for implantation of the **lumbar artificial disc**:

The lumbar artificial disc should not be implanted in patients with any of the following conditions:

- The planned procedure includes the combined use of a prosthesis and spinal fusion (i.e. hybrid surgery); or
- The individual has a history of lumbar disc replacement at any lumbar level; or
- Simultaneous multilevel implantation is planned; or
- active systemic infection or infection localized to the site of implantation; or
- osteoporosis; or
- osteomalacia; or
- osteopenia; or
- bony lumbar stenosis; or
- allergy or sensitivity to implant materials; or
- isolated radicular compression syndromes, especially due to disc herniation; or pars defect; or

Non-FDA-approved lumbar intervertebral disc.

The following are exclusions for implantation of the **cervical intervertebral artificial disc**:

The cervical artificial disc should not be implanted in patients with any of the following conditions:

- the planned procedure includes the combined use of a prosthesis and spinal fusion;
 or
- more than two cervical levels; or
- non-FDA approved cervical disc prosthesis; or
- FDA approved cervical disc prosthesis used for other than the FDA approved and intended, manufacturer specific use of the device; orthe individual had prior fusion at an adjacent cervical level; or
- the individual had prior surgery at the treated level; or
- osteopenia, osteomalacia, or osteoporosis (T-score of -3.5, or -2.5, with vertebral crush fracture); or
- neck or arm pain of unknown etiology; or
- absence of neck and/or arm pain; or
- progressive neurological deficit or deterioration; or
- infection, systemic or local; or
- allergy to stainless steel; or
- rheumatoid arthritis or other autoimmune disease; or
- chronic or acute renal failure or history of renal disease; or
- paget's disease, osteomalacia or any other metabolic bone disease; or
- the customer is pregnant; or
- severe insulin dependent diabetes; or
- taking medications known to potentially interfere with bone or soft tissue healing (e.g., steroids); or
- there is radiological evidence of any of the following:
 - clinically significant cervical instability, such as kyphotic deformity or spondylolisthesis (e.g., > 3.5 mm subluxation or >11 degrees angulation); or
 - significant cervical anatomical deformity or compromised vertebral bodies at the index level (e.g., ankylosing spondylitis, rheumatoid arthritis, or compromise due to current or past trauma); or
 - o multilevel degenerative disc; or
 - spinal metastases.

Personalized (i.e., customized, patient-specific 3D printed) anterior and lateral interbody cage (implantable) (CPT code C1831) are experimental, investigational, and unproven for all indications for the cervical, thoracic, or lumber spine.

Medicare Variation

Lumbar artificial disc replacement (LADR) is not reasonable and necessary for the Medicare population over 60 years of age; therefore, LADR is non-covered for Medicare beneficiaries over 60 years of age.

There is a Medicare National Coverage Decision (NCD) for Lumbar Artificial Disc Replacement LADR) (150.10) Effective Date: 08/14/2007. For full Medicare coverage details please refer to the following LCD website for Medicare customers. Available: www.cms.hhs.gov/

References (Updated 2023)

- Centers for Medicare & Medicaid Services, Coverage Decision Memorandum for Lumbar Artificial Disc Replacement (CAG-00292N). 2006 May 16. Available: www.cms.hhs.gov/.
- Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for Lumbar Artificial Disc Replacement (LADR) (150.10). Aug 14, 2007. Available: www.cms.hhs.gov/.
- 3. Blue Cross Blue Shield Technology Evaluation Center. Artificial Intervertebral Disc Arthroplasty for Treatment of Degenerative Disc Disease of the Cervical Spine. Assessment Program Volume 26, No. 5, November 2011.
- 4. Medtronic. Indications, Contraindications, and Warnings for the Prestige Cervical Disc. Last updated: May 2016. © 2016 Medtronic, Inc. Available: http://www.medtronic.com/us-en/index.html.
- 5. North American Spine Society (NASS). Coverage Policy Recommendations. Cervical Artificial Disc Replacement. Published November 2015.
- 6. U.S. Food and Drug Administration (FDA). PRESTIGE® Cervical Disc System P060018 [Labeling]. July 16, 2007. Available: http://www.fda.gov/.
- 7. U.S. Food and Drug Administration (FDA). PRESTIGE® LP Cervical Disc System P090029. July 2014. Available: http://www.fda.gov/.
- 8. U.S. Food and Drug Administration (FDA). CHARITÉ™ Artificial Disc P040006 [Labeling]. Oct 26, 2004. Available: http://www.fda.gov/.
- 9. U.S. Food and Drug Administration (FDA). ProDisc™ C Total Disc Replacement P070001. 12/17/2007. Available: http://www.fda.gov/.

- 10. U.S. Food and Drug Administration (FDA). BRYAN® Cervical Disc P060023 05/12/2009. Available: http://www.fda.gov/.
- 11. U.S. Food and Drug Administration (FDA). SECURE® C Artificial Cervical Disc P100003 09/28/2012. Available: http://www.fda.gov/.
- 12. U.S. Food and Drug Administration (FDA). PCM Cervical Disc System P100012 10/26/2012. Available: http://www.fda.gov/.
- 13. U.S. Food and Drug Administration (FDA). Mobi-C® Cervical Disc Prosthesis (two-level). P110009 08/23/2013. Available: http://www.fda.gov/.
- 14. U.S. Food and Drug Administration (FDA). activL® Artificial Disc. P120024. 06/11/15. Available: http://www.fda.gov/.
- 15. U.S. Food and Drug Administration (FDA). In-Motion Lumbar Artificial Disc P040006 [Labeling]. Feb 08, 2011. Available: http://www.fda.gov/.
- 16. HAYES Comparative Effectiveness Review[™]. Lumbar Total Disc Replacement for Degenerative Disc Disease. HAYES, Inc.; © 2021 Hayes, a symplr company.April 1, 2019. Annual Review May 24, 2021.
- 17. HAYES Comparative Effectiveness Review. Multilevel Artificial Disc Replacement for Cervical Degenerative Disc Disease. HAYES, Inc.; © 2021 Hayes, a symplr company. October 3, 2017. Annual Review: February 12, 2021.
- 18. HAYES Comparative Effectiveness Review. Comparative Effectiveness Review Of Single-Level Artificial Disc Replacement For Cervical Degenerative Disc Disease. HAYES, Inc.; © 2021 Hayes, a symplr company. August 21, 2017. Annual Review: November 20, 2020.
- 19. HAYES Health Technology Assessment. Expandable Interbody Cages for Cervical Spinal Fusion. HAYES, Inc. © 2023 Hayes, a symplr company. May 28, 2020 Annual Review: June 8, 2023
- 20. HAYES Health Technology Assessment. Expandable Interbody Cages for Lumbar Spinal Fusion. HAYES, Inc.; © 2023 Hayes, a symplr company. May 5, 2020 Annual Review: May 25, 2023

Customer Product	Medical Management Requirements*
New York Products	
НМО	Retrospective Review
PPO in Plan	Retrospective Review
PPO OOP	Retrospective Review
POS in Plan	Retrospective Review
POS OOP	Retrospective Review
Essential Plan	Retrospective Review
MVP Medicaid Managed Care	Retrospective Review
MVP Child Health Plus	Retrospective Review
MVP Harmonious Health Care Plan	Retrospective Review
MVP Medicare Complete Wellness	Retrospective Review
MVP Medicare Preferred Gold HMO POS	Retrospective Review
MVP Medicare Secure HMO POS	Retrospective Review
MVP Medicare Secure Plus HMO POS	Retrospective Review
MVP Medicare WellSelect PPO	Retrospective Review
MVP Medicare WellSelect Plus PPO	Retrospective Review
MVP Medicare Patriot Plan PPO	Retrospective Review
MVP DualAccess D-SNP HMO	Retrospective Review
MVP DualAccess Complete D-SNP HMO	Retrospective Review
MVP DualAccess Plus D-SNP HMO	Retrospective Review
	·
UVM Health Advantage Select PPO USA Care PPO	Retrospective Review Potential for Retrospective Review
Healthy NY	Retrospective Review
MVP Premier MVP Premier Plus	Retrospective Review Retrospective Review
MVP Premier Plus HDHP	Retrospective Review
MVP Secure	Retrospective Review
MVP EPO	Retrospective Review
MVP EPO HDHP	Retrospective Review
MVP PPO	Retrospective Review
MVP PPO HDHP	Retrospective Review
Student Health Plans	Retrospective Review
ASO	See SPD
Vermont Products	
POS in Plan	Retrospective Review
POS OOP	Retrospective Review
MVP Medicare Preferred Gold HMO POS	Retrospective Review
MVP Medicare Secure Plus HMO POS	Retrospective Review
MVP VT HMO	Retrospective Review
MVP VT HDHP HMO	Retrospective Review
MVP VT Plus HMO	Retrospective Review
MVP VT Plus HDHP HMO	Retrospective Review
MVP Secure	Retrospective Review
ASO	See SPD

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

*Medical Management Requirements

Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review Retrospective Review Required

Not Covered Service is not a covered benefit See SPD See Specific Plan Design

Revision History

04/01/2022 - Annual Review; added coverage for two level cervical artificial total disc replacement.

12/01/2023 - C1831 added to exclusions as experimental.

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MVP Health Care Behavioral Health Medical Necessity Criteria

Assertive Community Treatment (ACT)

Type of Policy: Behavioral Health

Prior Approval Date: 05/22/2023

Approval Date: 08/02/2023

Effective Date: 10/01/2023

Related Polices: Home and Community Based Services – Pediatric

Home and Community Based Services – Adult

Children's Family Treatment and Support Services (CTFSS)

Personalized Recovery Oriented Services (PROS)

Codes Requiring Authorization

Authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

N/A

Common Procedure Codes

H0040, H0040U5, H0040U1U5

Overview

ACT teams deliver comprehensive services to adults with Serious Mental Illness (SMI) and children/youth with Serious Emotional Disorder (SED) whose needs have not been met by traditional service delivery approaches or are at risk of entering, or returning home from high intensity services, such as inpatient settings or residential services. ACT is an evidence-based practice that incorporates treatment, rehabilitation, case management, and support services delivered by a mobile, multi-disciplinary mental health team. ACT supports individual recovery through an individualized approach that provides individuals with the tools to obtain and maintain housing, employment, relationships and relief from symptoms and medication side effects. Youth ACT Team interventions are focused on enhancing family functioning to foster health and wellbeing, stability, and re-integration for the child/youth. Services are delivered using a

family-driven, youth guided and developmentally appropriate approach that comprehensively addresses the needs of the child/youth with the family, educational, medical, behavioral, psychosocial, and community domains. The nature and intensity of ACT services are developed through a person-centered service planning process and adjusted as needed in daily ACT team meetings.

Individuals admitted to ACT Teams may have a treatment history that has been characterized by frequent use of psychiatric hospitalization and emergency rooms, involvement with the criminal justice system, addiction disorder, and lack of engagement in traditional outpatient services. The ACT model is designed to serve a small subset of high-need individuals with SMI or SED who require complex multifaceted care. Most individuals will not need the intensive services offered by ACT programs.

The ACT program is an intensive service with limited capacity. ACT should be utilized appropriately as a specific service within the larger continuum of care. As HARPs begin to manage Behavioral Health Home and Community Based Services (BH HCBS), these and other behavioral health services will help transition individuals off of ACT teams, creating access for other individuals who need ACT services. The ACT Institute, in partnership with the State Office of Mental Health, provides supports and training to ACT teams with emphasis on a transitional model of care.

For children, Youth ACT is target is targeted towards those returning from impatient hospitalization, residential treatment, or a community residence to provide ample support for a successful transition home, or for those in the community and at risk of out of home care or placement due to significant functional deficits impeding their ability to remain in the community without intensive in home-services and supports. It is expected that children admitted to youth ACT will continue to receive services until their complex needs are adequately met are no longer at risk of out of home care and can successfully transition to a lower level of service that will meet their needs.

Indications/Criteria

Admission Guidelines:

- Severe and persistent mental illness listed in the diagnostic nomenclature (the most recent version of DSM) that seriously impairs their functioning in the community.
- Priority is given to people with schizophrenia, other psychotic disorders (e.g., schizoaffective disorder), bipolar disorder or major/chronic depression, because these illnesses more often cause long-term psychiatric disability.
- Priority is also given to individuals with continuous high service needs that are not being met in more traditional service settings.

- Assisted Outpatient Treatment (AOT) individuals with ACT in their order will get admission priority.
- Recipients with continuous high service needs should demonstrate one or more of the following conditions:
 - o Inability to participate in traditional, office-based treatment services or case management;
 - o Two (2) or more psychiatric inpatient admissions over a 12-month period or one (1) long-term hospitalization of 60 calendar days or more;
 - o Excessive use of psychiatric emergency or crisis services;
 - o Persistent severe major symptoms (e.g., affective, psychotic, suicidal or significant impulse control issues);
 - o Co-existing substance abuse disorder (duration greater than 6 months);
 - Repeat arrests, incarceration, or recent prison release for offenses directly related to mental illness;
 - Court ordered to participate in Assisted Outpatient Treatment (AOT);
 - Inability to meet basic survival needs or homeless or at imminent risk of becoming homeless;
 - Residing in an inpatient bed or in a supervised community residence, but clinically assessed to be able to live in a more independent setting if intensive community services are provided;
 - Currently living independently but clinically assessed to be at immediate risk of requiring a more restrictive living situation (e.g., community residence or psychiatric hospital) without intensive community services;
 - o Are active clients of the ACT provider.

Young Adult ACT Eligibility

Young Adult ACT serves only individuals age 18 to 25 with SMI that impairs functioning in the community, have continuous high service needs, who lack engagement in and whose needs have not been met in traditional outpatient services. The individuals may work or need assistance developing a productive vocational or educational plan. Many of these young adults have very limited family or social support networks, or networks that may be insufficient to meet their needs. Moreover, these individuals often lack many of the real world skills needed to be successful, independent adults, such as financial literacy, self-care/well-being, time management and decision-making.

Continuous high service needs, which include:

• Two (2) or more psychiatric hospitalizations or one (1) hospitalization of 60+ days in a 12-month period;

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- Four (4) or more psychiatric emergency room visits in the last 12 months;
- Co-occurring SUD for six (6) months or more;
- High risk of justice involvement;
- Homelessness or imminent risk of homelessness or inability to meet basic survival needs;
- Residing in inpatient bed, residential program or CR and assessed to be able to live independently with intensive community services;
- At risk of requiring more restrictive living situation without increased community services.

Continuing Stay Guidelines

• Initial eligibility criteria continue to be met.

Discharge Guidelines

- ACT recipients meeting any of the following criteria may be discharged:
 - Individuals who demonstrate, over a period of time, an ability to function in major life roles (i.e., work, social, self-care) and can continue to succeed with less intensive service.
 - Individuals who move outside the geographic area of the ACT team's
 responsibility. The ACT team must arrange for transfer of mental health
 service responsibility to an appropriate provider and maintain contact with
 the recipient until the provider and the recipient are engaged in this new
 service arrangement.
 - o Individuals who need a medical nursing home placement, as determined by a physician or have been admitted to another program (Community Residence, Residential Treatment).
 - Individuals who are hospitalized or locally incarcerated for three months or longer. However, an appropriate provision must be made for these individuals to return to the ACT program upon their release from the hospital or jail.
 - o Individuals who request discharge, despite the team's best, repeated efforts to engage them in service planning. Special care must be taken in this situation to arrange alternative treatment when the recipient has a history of suicide, assault or forensic involvement.
 - Individuals who are lost to follow-up for a period of greater than 3 months after persistent efforts to locate them, including following all local policies and procedures related to reporting individuals as "missing persons."
- For all persons discharged from ACT to another service provider within the team's primary service area or county, there is a three-month transfer period during

- which recipients who do not adjust well to their new program may voluntarily return to the ACT program. During this period, the ACT team is expected to maintain contact with the new provider, to support the new provider's role in the recipient's recovery and illness management goals.
- The decision not to take medication is an insufficient reason for discharging an individual from an ACT program.
- If a recipient of ACT services is under a court order to receive Assisted Outpatient Treatment, any discharge must be planned in coordination with the County's AOT program administrator.

Young Adult ACT Discharge (in addition to above):

- 1. Individuals who are no longer within the eligible age range for Young Adult ACT, which serves young adults ages 18 to 25, must be transferred to an appropriate provider. The Young Adult ACT team must maintain contact with the individual until the provider and individual are engaged in this new service arrangement.
- 2. Individuals who move outside the geographic area of the Young Adult ACT team's responsibility. The Young Adult ACT team must arrange for transfer of mental health service responsibility to an appropriate provider and maintain contact with the individual until the provider and the individual are engaged in this new service arrangement.
- 3. Young adults are expected to be served by Young Adult ACT for two (2) to three (3) years depending upon their needs, goals, and progress.

Exclusions Criteria:

Individuals with a primary diagnosis of a personality disorder(s), substance use disorder (SUD), intellectual/developmental disabilities, an IQ below 70, or also being served by the Office for People with Developmental Disabilities (OPWDD) are not appropriate for Assertive Community Treatment (ACT) or Young Adult ACT.

References (2023)

- New York State Office of Mental Health Assertive Community Treatment. Available: https://omh.ny.gov/omhweb/act/
- 2. New York State Office of Mental Health Utilization Management (UM) Guidelines for New York State Medicaid Managed Care Organizations (MMCO) updated 3/2023. Available: https://omh.ny.gov/omhweb/bho/policy-guidance/nys-act-um-guidance.pdf
- 3. New York State Office of Mental Health ACT Program Guidelines (updated 3/2023) Available: https://omh.ny.gov/omhweb/act/act-program-guidelines.pdf

Customer Product	Management Requirements*
New York Products	
HMO	Not A Covered Benefit
PPO in Plan	Not A Covered Benefit
PPO OOP	Not A Covered Benefit
POS in Plan	Not A Covered Benefit
POS OOP	Not A Covered Benefit
Essential Plan	Not A Covered Benefit
MVP Medicaid Managed Care	Potential for Retrospective Review
MVP Child Health Plus	Potential for Retrospective Review
MVP Harmonious Health Care Plan	Potential for Retrospective Review
MVP Medicare Complete Wellness	Not A Covered Benefit
MVP Medicare Preferred Gold HMO POS	Not A Covered Benefit
MVP Medicare Secure HMO POS	Not A Covered Benefit
MVP Medicare Secure Plus HMO POS	Not A Covered Benefit
MVP Medicare WellSelect PPO	Not A Covered Benefit
MVP Medicare WellSelect Plus PPO	Not A Covered Benefit
MVP Medicare Patriot Plan PPO	Not A Covered Benefit
MVP DualAccess D-SNP HMO	Not A Covered Benefit
MVP DualAccess Complete D-SNP HMO	Not A Covered Benefit
MVP DualAccess Plus D-SNP HMO	Not A Covered Benefit
UVM Health Advantage Select PPO	Not A Covered Benefit
USA Care	Not A Covered Benefit
Healthy NY	Not A Covered Benefit
MVP Premier	Not A Covered Benefit
MVP Premier Plus	Not A Covered Benefit
MVP Premier Plus HDHP	Not A Covered Benefit
MVP Secure	Not A Covered Benefit
MVP EPO	Not A Covered Benefit
MVP EPO HDHP	Not A Covered Benefit
MVP PPO	Not A Covered Benefit
MVP PPO HDHP	Not A Covered Benefit
Student Health Plans	Not A Covered Benefit
ASO	Not A Covered Benefit
Vermont Products	
POS in Plan	Not A Covered Benefit
POS OOP	Not A Covered Benefit
MVP Medicare Preferred Gold HMO POS	Not A Covered Benefit
MVP Medicare Secure Plus HMO POS	Not A Covered Benefit
MVP VT HMO	Not A Covered Benefit
MVP VT HDHP HMO	Not A Covered Benefit
MVP VT Plus HMO	Not A Covered Benefit
MVP VT Plus HDHP HMO	Not A Covered Benefit
MVP Secure	Not A Covered Benefit
ASO	Not A Covered Benefit
A Note: Authorization vancinoments for UDUD un	

♦ Note: Authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Management Requirements

Authorization Authorization Required

Potential for Retrospective Review No Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Revision History:

12/01/2021 – Annual Review; removed age restrictions for eligibility.

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01/01/2023 – Added coverage and authorization to Child Health Plus (CHP) plans.

06/01/2023 – Authorization not required. Updated with coverage for Youth ACT. Updated references.



Atrial Fibrillation Ablation, Catheter based

Type of Policy: Surgical/Medical

Prior Approval Date: 12/01/2022

Approval Date: 05/06/2024

Effective Date: 08/01/2024

Related Polices:

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

93656 - Comprehensive electrophysiologic evaluation including transseptal catheterizations, insertion and repositioning of multiple electrode catheters with induction or attempted induction of an arrhythmia including left or right atrial pacing/recording when necessary, right ventricular pacing/recording when necessary, and His bundle recording when necessary with intracardiac catheter ablation of atrial fibrillation by pulmonary vein isolation

93657 - Additional linear or focal intracardiac catheter ablation of the left or right atrium for treatment of atrial fibrillation remaining after completion of pulmonary vein isolation

Codes Requiring Retrospective Review

33255 -Operative tissue ablation and reconstruction of atria, extensive (e.g., maze procedure); without cardiopulmonary bypass [hybrid Maze procedure]

33258 Operative tissue ablation and reconstruction of atria, performed at the time of other cardiac procedure(s), extensive (eg, maze procedure), without cardiopulmonary bypass (List separately in addition to code for primary procedure)

33265: Endoscopy, surgical; operative tissue ablation and reconstruction of atria, limited (e.g., modified maze procedure), without cardiopulmonary bypass

33266: Endoscopy, surgical; operative tissue ablation and reconstruction of atria, extensive (eq. maze procedure), without cardiopulmonary bypass

Experimental/Investigational

33255 -Operative tissue ablation and reconstruction of atria, extensive (e.g., maze procedure); without cardiopulmonary bypass [hybrid Maze procedure]

33258 Operative tissue ablation and reconstruction of atria, performed at the time of other cardiac procedure(s), extensive (eg, maze procedure), without cardiopulmonary bypass (List separately in addition to code for primary procedure)

33265: Endoscopy, surgical; operative tissue ablation and reconstruction of atria, limited (e.g., modified maze procedure), without cardiopulmonary bypass

33266: Endoscopy, surgical; operative tissue ablation and reconstruction of atria, extensive (eg, maze procedure), without cardiopulmonary bypass

Common Diagnosis Codes

148, 148.0, 148.1, 148.19, 148.9, 148.91

Codes excluded from coverage

148.11, 148.2, 148.20, 148.21.

Common Diagnosis Codes associated with this policy have been provided for informational purposes only. The list of codes may not be all-inclusive and may be updated to reflect any applicable revisions to the ICD-10 code set and/or medical necessity guidelines applied in this policy.

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

Atrial fibrillation (AF) is the most common heart rhythm disturbance, and the incidence increases as people age. It is highly associated with poorly or untreated hypertension, obesity, sleep apnea, congestive heart failure, mitral valvular disease, and moderate to heavy alcohol use. Atrial fibrillation can be associated with symptoms such as palpitations, fatigue, lightheadedness, and shortness of breath. Stroke is a well-defined potential complication of atrial fibrillation, which management with anticoagulants has an evidence-based benefit. In addition, if poorly managed, atrial fibrillation can lead to cardiomyopathy and heart failure.

Atrial fibrillation ablation has been performed for decades during open cardiac procedures, but within the last 15 years, the procedure has evolved into treatments that may include Pulmonary Vein Isolation and/or focal ablation. The evidence of benefit at

this time is purely related to symptom relief, with no evidence that the stroke, heart failure, or mortality risk, nor need for anticoagulation therapy is significantly affected.

Term Definition

Paroxysmal AF: AF that terminates spontaneously or with intervention within 7 d of onset. Episodes may recur with variable frequency.

Recurrent symptomatic paroxysmal atrial fibrillation: more than one episode, with four or fewer episodes in the previous six months. These episodes need to be demonstrated by ECG or clinically administered and supervised monitoring, rather than by symptoms alone.

Persistent AF: Continuous AF that is sustained >7 d.

Long-standing persistent AF: Continuous AF > 12 mo in duration.

Permanent AF: The term "permanent AF" is used when the patient and clinician make a joint decision to stop further attempts to restore and/or maintain sinus rhythm. Acceptance of AF represents a therapeutic attitude on the part of the patient and clinician rather than an inherent pathophysiological attribute of AF.

"Chronic" atrial fibrillation (I48.20) is a new code that is a non-specific term indicating that atrial fibrillation of any type has been present for more than three months.

Symptoms refractory to medical therapy require 6 months of adequate dosing of a class I or III antiarrhythmic medication.

Indications/Criteria

Atrial fibrillation ablation by Pulmonary Vein Isolation (PVI) and/or focal ablation is considered **medically necessary** when the clinical criteria, as outlined below are met:

a) Symptomatic paroxysmal atrial fibrillation:

- as an initial therapy to improve symptoms and reduce progression to persistent atrial fibrillation; OR
- refractory to or intolerant of at least 1 class I or III antiarrhythmic medication (see list below)

b) Symptomatic persistent atrial fibrillation, either:

- As a rhythm-control strategy for symptomatic atrial fibrillation in whom anti-arrhythmic medications are ineffective, contraindicated or not preferred, OR
- refractory to an adequate trial or intolerance of at least 1 class I or III antiarrhythmic medication. (see list below) OR
- For diagnosis of heart failure, classification of NYHA II, III, or IV, and ejection fraction < 40; as an initial rhythm-control strategy for

symptomatic **persistent** atrial fibrillation, before therapeutic trials of antiarrhythmic drug therapy, after weighing the risks and outcomes of drug and ablation therapy.

c) Recurrent symptomatic paroxysmal atrial fibrillation:

 more than one episode, with four or fewer episodes in the previous six months. These episodes need to be demonstrated by ECG or monitoring, rather than by symptoms alone.

One additional atrial fibrillation ablation may be considered **medically necessary** in patients with recurrence of atrial fibrillation following the initial procedure.

If additional atrial fibrillation ablation is being requested due to recurrence, electrocardiographic documentation meeting the original definition of paroxysmal or persistent atrial fibrillation, is required.

Atrial fibrillation must be documented by ECG or clinically administered and supervised monitoring, rather than by symptoms alone.

Class I Anti Arrhythmic Agent (AAA) medications include moricizine, disopyramide, phenytoin, propafenone, flecainide, mexiletine, quinidine, procainamide, or tocainide.

Class III Anti Arrhythmic Agent (AAA) medications include amiodarone, dofetilide, dronedarone, sotalol.

Exclusions

- Atrial fibrillation ablation for any other indication not listed in the Indications/Criteria section is considered not medically necessary.
- Ablation of chronic atrial fibrillation is not supported by evidence in the literature as improving health outcomes and, therefore, is considered not medically necessary.
- A diagnosis of Permanent atrial fibrillation is used when the patient and clinician make a joint decision to stop further attempts to restore and/or maintain sinus rhythm. Therefore, attempts at ablation in this situation are not medically necessary.
- Atrial fibrillation catheter ablation is not indicated for patients who cannot be treated with anticoagulant therapy during and after the procedure.
- Atrial fibrillation catheter ablation is not medically necessary to eliminate the need for chronic anticoagulation.
- Atrial fibrillation ablation is considered not medically necessary when the patient has significant mitral valve disease and is being considered for mitral valve surgery.
- Off-pump Maze procedures (including the hybrid Maze and the Convergent hybrid procedure) (33255, 33258, 33265, 33266), also known as thoracoscopic off-pump surgical ablation (TOPS), experimental and investigational for atrial fibrillation or flutter because there is insufficient evidence of their effectiveness.

Medicare Variation

Based on review there are no National or Local Determination Coverage for this region.

References (Updated 2024)

- Skelly A, Hashimoto R, Al-Khatib S, Sanders-Schmidler G, Fu R, Brodt E, McDonagh M. Catheter Ablation for Treatment of Atrial Fibrillation. Technology Assessment. (Prepared by the Pacific Northwest Evidence-based Practice Center under Contract No. HHSA 290-2012-00014-I.) AHRQ Publication. Rockville, MD: Agency for Healthcare Research and Quality; April 2015.
- 2. January CT, Wann LS, Alpert JS, Calkins H, Cigarroa JE, Cleveland JC Jr, Conti JB, Ellinor PT, Ezekowitz MD, Field ME, Murray KT, Sacco RL, Stevenson WG, Tchou PJ, Tracy CM, Yancy CW. 2014 AHA/ACC/HRS guideline for the management of patients with atrial fibrillation: executive summary: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the Heart Rhythm Society. J Am Coll Cardiol 2014; 64: 2246–80.
- 3. January CT, Wann LS, Calkins H, Chen LY, Cigarroa JE, Cleveland JC Jr, Ellinor PT, Ezekowitz MD, Field ME, Furie KL, Heidenreich PA, Murray KT, Shea JB, Tracy CM, Yancy CW. 2019 AHA/ACC/HRS focused update of the 2014 AHA/ACC/HRS guideline for the management of patients with atrial fibrillation: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. J Am Coll Cardiol 2019; 74:104–132.
- 4. UpToDate: Atrial fibrillation: Catheter ablation. Author: Rod Passman, MD, MSCE. Section Editors: Bradley P Knight, MD, FACC, N A Mark Estes, III, MD. Deputy Editor: Gordon M Saperia, MD. All topics are updated as new evidence becomes available and our peer review process is complete. Literature review current through: May 2020. | This topic last updated: Feb 25, 2020.
- 5. Nishimura RA, Otto CM, Bonow RO, Carabello BA, Erwin JP III, Guyton RA, O'Gara PT, Ruiz CE, Skubas NJ, Sorajja P, Sundt TM III, Thomas JD. 2014 AHA/ACC guideline for the management of patients with valvular heart disease: executive summary: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. Circulation. 2014; 129:2440–2492.
- 6. Calkins H, Reynolds MR, Spector P, et al. Treatment of atrial fibrillation with antiarrhythmic drugs or radiofrequency ablation: two systematic literature reviews and meta-analyses. Circ Arrhythm Electrophysiol 2009; 2:349–61.
- 7. Bonanno C, Paccanaro M, La Vecchia L, et al. Efficacy and safety of catheter ablation versus antiarrhythmic drugs for atrial fibrillation: a meta-analysis of randomized trials. J Cardiovasc Med (Hagerstown) 2010; 11:408–18.

- 8. Nair GM, Nery PB, Diwakaramenon S, et al. A systematic review of randomized trials comparing radiofrequency ablation with antiarrhythmic medications in patients with atrial fibrillation. J Cardiovasc Electrophysiol 2009; 20:138–44.
- 9. Parkash R, Tang AS, Sapp JL, et al. Approach to the catheter ablation technique of paroxysmal and persistent atrial fibrillation: a meta-analysis of the randomized controlled trials. J Cardiovasc Electrophysiol 2011; 22:729–38.
- 10. Piccini JP, Lopes RD, Kong MH, et al. Pulmonary vein isolation for the maintenance of sinus rhythm in patients with atrial fibrillation: a meta-analysis of randomized, controlled trials. Circ Arrhythm Electrophysiol 2009; 2:626–33.
- 11. Jais P, Cauchemez B, Macle L, et al. Catheter ablation versus antiarrhythmic drugs for atrial fibrillation: the A4 study. Circulation 2008; 118:2498–505.
- 12. Wilber DJ, Pappone C, Neuzil P, et al. Comparison of antiarrhythmic drug therapy and radiofrequency catheter ablation in patients with paroxysmal atrial fibrillation: a randomized controlled trial. JAMA 2010; 303:333–40.
- 13. Stabile G, Bertaglia E, Senatore G, et al. Catheter ablation treatment in patients with drug-refractory atrial fibrillation: a prospective, multi-centre, randomized, controlled study (Catheter Ablation For The Cure Of Atrial Fibrillation Study). Eur Heart J 2006; 27:216–21.
- 14. Oral H, Pappone C, Chugh A, et al. Circumferential pulmonary-vein ablation for chronic atrial fibrillation N Engl J Med 2006; 354:934–41.
- 15. Mont L, Bisbal F, Hernandez-Madrid A, et al. Catheter ablation vs. antiarrhythmic drug treatment of persistent atrial fibrillation: a multicentre, randomized, controlled trial (SARA study) 2014; 35:501–7.
- 16. Wazni OM, Marrouche NF, Martin DO, et al. Radiofrequency ablation vs antiarrhythmic drugs as first-line treatment of symptomatic atrial fibrillation: a randomized trial. JAMA 2005; 293:2634–40.
- 17. Morillo C, Verma A, Kuck K, et al. Radiofrequency ablation vs antiarrhythmic drugs as first-line treatment of paroxysmal atrial fibrillation (RAAFT 2): a randomized trial. JAMA 2014; 311:692–700.
- 18. Cosedis NJ, Johannessen A, Raatikainen P, et al. Radiofrequency ablation as initial therapy in paroxysmal atrial fibrillation. N Engl J Med 2012; 367:1587–95.
- 19. Haissaguerre M, Hocini M, Sanders P, et al. Catheter ablation of long-lasting persistent atrial fibrillation clinical outcome and mechanisms of subsequent arrhythmias. J Cardiovasc Electrophysiol 2005;16:1138–47.
- 20. HAYES Health Technology Assessment. Hybrid Maze Procedure for Atrial Fibrillation. HAYES, Inc.; © 2021 Hayes, a symplr company July 15, 2019. Annual Review August 25, 2021

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♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Auth

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review.

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Revision History

12/01/22 – Annual review; removed 12-month duration from criteria and exclusions, added Maze procedures (33255, 33258, 33265, 33266) to exclusions.

08/01/2024- Updated criteria to cover as an initial therapy for symptomatic paroxysmal afib.



Autism Spectrum Disorders New York State

Type of Policy: Medical/Behavioral Health

Prior Approval Date: 11/08/2022

Approval Date: 11/04/2024

Effective Date: 02/01/2025

Related Polices: Applied Behavior Analysis

Early Childhood Developmental

Disorders Vermont

Speech Generating Devices
Speech Therapy (Outpatient)

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

MVP Health Care may require prior authorization for the services that are covered in this policy. See those policies for specific medical management requirements.

Codes Requiring Retrospective Review

N/A

Experimental/Investigational

N/A

Common Diagnosis Codes

ICD-10 Diagnosis Codes: F84.0

F84.0 – Autistic disorder

F84.2 – Rett's syndrome

F84.3 – Other childhood disintegrative disorder

F84.5 – Asperger's syndrome

F84.8 – Other pervasive developmental disorders

Autism Spectrum Disorders NYS

F84.9 – Pervasive developmental disorder, unspecified

Common Procedure Codes

N/A

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

This medical policy applies only to MVP plans that are required to follow the New York State Health Insurance Law for autism spectrum disorder treatment. Refer to the customer's individual plan certificate for benefit coverage for applied behavioral analysis.

Autism Spectrum Disorder (ASD) is a neurodevelopmental disorder characterized by persistent impairment in social communication and social interaction and restricted, repetitive patterns of behavior, interests, or activities, as defined by the American Psychiatric Association in its Diagnostic and Statistical Manual of Mental Disorders, 5th Edition, Text Revision (DSM-5-TR). The primary goals of treatment are to maximize the child's ultimate functional independence and quality of life by minimizing the core autism spectrum disorder features, facilitating development and learning, promoting socialization, reducing maladaptive behaviors, and educating and supporting families.

Indications/Criteria

MVP will cover the following services, consistent with the requirements of the New York State Health Insurance Law for the coverage of autism spectrum disorders when prescribed or ordered by a licensed Physician or a licensed Psychologist, when necessary to develop, maintain, or restore, to the maximum extent practicable, the functioning of an individual and when deemed medically necessary:

- assessments, evaluations, and tests to determine whether someone has autism spectrum disorder
- a formal evaluation by a speech-language pathologist to determine the need for an assistive communication device
- the rental or purchase of assistive communication devices for an individual diagnosed with ASD, when prescribed or ordered by a licensed physician or a licensed psychologist when the customer has met the criteria listed in the MVP Medical Policy for Speech Generating Devices;
- behavioral health treatment for counseling and treatment programs, including applied behavior analysis (ABA), when provided by a licensed Provider.;

- psychiatric and psychological care provided by a psychiatrist, psychologist or a licensed clinical social worker;
- medical care provided by a licensed health care provider;
- therapeutic care and services provided by licensed or certified speech therapists (ST), occupational therapists (OT), physical therapists (PT), and social workers when provided to develop, maintain or restore, to the greatest extent practicable, functioning of the individual;
- pharmacy care when prescribed by a provider legally authorized to prescribe under
 Title 8 of the New York Education Law

Exclusions

- Services that are considered primarily educational or training in nature to improve academic or work performance or to correct a learning disability are not medically necessary.
- Services or treatments that are provided pursuant to an individualized education plan under the New York State Education Law are not covered.
- Neuropsychological testing is not included in the American Academy of Pediatrics Guidelines for the Identification, Evaluation, and Management of Children with Autism Spectrum Disorders and, therefore, is considered not medically necessary.
- Complementary and alternative medicine is not supported in the American Academy
 of Pediatrics Guidelines for the Identification, Evaluation, and Management of
 Children with Autism Spectrum Disorders because there is not enough scientific
 evidence to support their use as treatments for ASDs. The following therapies are
 considered not medically necessary. This list is not considered to be all inclusive:
 - auditory integration training;
 - o behavioral optometry;
 - o craniosacral manipulation;
 - o detoxification therapies (e.g., chelation therapy);
 - o dolphin therapy;
 - o equine therapy (hippotherapy); and
 - holding therapy.
- Drugs not meeting MVP's Experimental and Investigational policy criteria are excluded from coverage.

Variations

MVP Managed Care Medicaid Products

MVP Medicaid Managed Care Plan customers have coverage for Applied Behavior Analysis (ABA) therapy when they have a diagnosis of autism spectrum disorder and/or Rett Syndrome as defined by the American Psychiatric Association in its Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5) when medically necessary in accordance with the criteria in the Applied Behavior Analysis Behavioral Health Policy.

Applied Behavior Analysis is a covered benefit for Child Health Plus (CHP) plans when medically necessary in accordance with the criteria in the Applied Behavior Analysis Behavioral Health Policy.

MVP Medicare Advantage Plans:

Applied behavior analysis (ABA) is not covered for MVP Medicare Advantage Plans.

References (Updated 2024)

- 1. New York State Health Insurance Law S.4005A/A.6305A. Available: https://www.nysenate.gov/legislation/bills/2011/s5845
- 2. New York State Department of Financial Services. Insurance Circular Letter No. 6 (2014). October 10, 2014. Available: https://www.dfs.ny.gov/insurance/circltr/2014/cl2014_06.htm
- 3. New York State Department of Health eMedNY Provider Manuals Applied Behavior Analysis Policy Manual. Available: https://www.emedny.org/ProviderManuals/ABA/
- 4. NYS Department of Health. (2017) Clinical Practice Guideline on Assessment and Intervention Services for Young Children with Autism Spectrum Disorders (ASD). Publication No. 20152
- 5. New York State Department of Health Bureau of Early Intervention. Best Practice Protocol for Early Screening of Young Children for Autism Spectrum Disorders (ASDs) by Pediatric Primary Care Providers. July 2013, Updated January 2019.
- 6. MVP Health Care customer Certificate of Coverage (COC) documents.

Revision History

04/01/2022 – Annual Review; References were reviewed and updated for NYS Regulations. Updated Medicaid variation to match Applied Behavior Analysis Behavioral Health Policy. Removed medical management grid.

01/01/2023 – Annual review, indicated that Applied Behavior Analysis (ABA) services have been carved in to the Medicaid Managed Care (MMC) benefit package.

02/01/2025 – Annual review, updated overview with definition for ASD according to DSM-5, updated indications/criteria to be consistent with NYS, updated references.



Autologous Chondrocyte Implantation Osteochondral Allograft Transplantation Osteochondral Autograft Transfer System (OATS)

Type of Policy: Surgical

Prior Approval Date: 12/05/2022

Approval Date: 03/28/2025

Effective Date: 06/01/2025

Related Polices: Knee Arthroscopy

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

N/A

Codes Requiring Retrospective Review

N/A

Experimental/Investigational

N/A

Common Diagnosis Codes

ICD-10-CM Diagnosis Codes: M23.011, M23.012, M23.019, M23.211, M23.212, M23.219, M23.311, M23.312, M23.319, M23.021, M23.022, M23.029, M23.221, M23.222, M23.229, M23.321, M23.322, M23.329, M23.031, M23.032, M23.039, M23.203, M23.204, M23.205, M23.231, M23.232, M23.239, M23.303, M23.304, M23.305, M23.331, M23.332, M23.339, M23.202, M23.041, M23.042, M23.049, M23.241, M23.242, M23.249, M23.341, M23.342, M23.349, M23.051, M23.052, M23.059, M23.251, M23.252, M23.259, M23.351, M23.352, M23.359, M23.000, M23.001, M23.002, M23.003, M23.004, M23.005, M23.006, M23.007, M23.009, M23.206, M23.207, M23.209, M23.306, M23.307, M23.309, Q68.6, M23.40, M23.41, M23.42, M22.40, M22.41, M22.42, M23.50, M23.51, M23.52, M23.50, M23.51,

Autologous Chondrocyte Implantation and Osteochondral Allograft Transplantation

M23.52, M23.50, M23.51, M23.52, M23.50, M23.51, M23.52, M23.50, M23.51, M23.52, M22.90, M22.91, M22.92, M23.90, M23.91, M23.92

Common Diagnosis Codes associated with this policy have been provided for informational purposes only. The list of codes may not be all-inclusive and may be updated to reflect any applicable revisions to the ICD-10 code set and/or medical necessity guidelines applied in this policy.

Common Procedure Codes

27412, 27415, 27416, 29866, 29867, J7330, S2112

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

Autologous Chondrocyte Implantation (ACI) is a two-step procedure utilizing the patient's own cartilage cells to repair traumatic damage to the articular cartilage of the femoral condyle of the knee caused by acute or repetitive trauma.

An arthroscopy is performed to harvest healthy cartilage cells from the patient. The cells are then prepared for culturing through a washing technique in a buffered solution and then placed in a medium for cultivation over a 3- to 5-week period. At a second operative procedure, an arthrotomy is performed and a periosteal flap is surgically created at the site of the defect. The cultured cartilage is implanted beneath the flap before closure where it proliferates and repairs the defect.

Osteochondral Allograft Transplantation involves transferring a piece of articular cartilage and subchondral bone cartilage from a cadaver donor to a damaged region of the articular surface of a joint. An allograft is typically larger than an autograft. It can be shaped to fit the exact contour of the defect and then pressed into place.

Osteochondral Autograft Transfer System (OATS) is a type of osteochondral autografting. Cartilage is transferred from one part of the joint to another joint. A cartilage tissue graft is taken from an area of the bone that does not carry weight (non-weight bearing). The graft is taken as a cylindrical plug of cartilage and subchondral bone. It is then matched to the surface area of the defect and impacted into place. This leaves a smooth cartilage surface in the joint. Typically, a single plug of cartilage is used.

Mosaicplasty is a type of osteochondral autografting. This procedure is similar to the osteochondral autograft transfer system (OATS) procedure; however, it involves the use of multiple small osteochondral cylinders.

The Modified Outerbridge Classification is a system that has been developed for judging articular cartilage injury to the knee. This system allows delineation of varying areas of

Autologous Chondrocyte Implantation and Osteochondral Allograft Transplantation

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chondral pathology, based on the qualitative appearance of the cartilage surface, and can assist in identifying those injuries that are suitable for repair techniques. The characterization of cartilage in this system is as follows:

- Grade I Softening with swelling
- Grade II Fragmentation and fissuring less than one square centimeter (1 cm2)
- Grade III Fragmentation and fissuring greater than one square centimeter (1 cm2)
- Grade IV Subchondral bone exposed.

Indications/Criteria

Osteochondral allograft, osteochondral autografts (osteochondral autograft transfer system (OATS) or mosaicplasty) are considered medically necessary when **one** the following are met:

- Osteochondral autograft transplants and mosaicplasty is considered medically necessary in an individual with ≤ 2.5 cm² chondral defects with normal appearing hyaline cartilage surrounding the border of the defect;
- Osteochondral allograft transplants is considered medically necessary in an individual with ≤10.0 cm² chondral defects normal appearing hyaline cartilage surrounding the border of the defect; and

And all of the following criteria are met:

- The customer has disabling symptoms limiting the ability to perform activities of daily living (ADLs) that has not been relieved by 3 months of conventional medical treatment (physical therapy and /or bracing); and
- The customer is skeletally mature with documented closure of growth plates (e.g., 15 years or older); and
- The customer has focal, full thickness (Modified Outerbridge Scale as Grade grade III or IV) unipolar lesions on the weight bearing surface of the femoral condyles (medial or lateral) or trochlea; and
- Previous arthroscopic or other traditional surgical procedure (i.e., microfracture, drilling, abrasion,) which has resulted in an inadequate response; and
- The customer has normal alignment or correctable varus or valgus deformities; and
- The customer is not considered a candidate for total knee replacement (i.e., customer is under 55 years of age).

Autologous chondrocyte implantation is considered medically necessary when ALL of the following criteria are met:

Autologous Chondrocyte Implantation and Osteochondral Allograft Transplantation

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- treatment of a single symptomatic articular cartilage defect of the femoral condyle of the knee (medial, lateral or trochlear) caused by acute or repetitive trauma;
- age 15–55 years;
- body mass index (BMI) of ≤ 35;
- the customer has disabling knee pain which interferes with the ability to perform activities of daily living (ADLs) that has not been relieved by 3 months of conventional medical treatment;
- failure of surgical interventions (i.e., microfraction, drilling, abrasion, or osteochondral autograft)
- femoral condyle defect size of 1–10 cm² in an area that affects a weight-bearing surface of the femoral condyle, as demonstrated by magnetic resonance imaging (MRI) or arthroscopy^[30];
- articular cartilage defect classified as Modified Outerbridge Scale grade III or IV (full thickness) that involves only cartilage;
- knee is stable with intact, fully functional ligaments ACL or PCL), has normal joint space, and normal alignment;
- customer is willing and able to comply with post-operative physical rehabilitation program;
- no corresponding tibial or patellar lesion ("kissing" lesion) with a Modified
 Outerbridge Scale grade III or IV chondromalacia or exposed bone chondromalacia;
- no osteoarthritis of the knee; and
- normal articular cartilage at lesion border.

Exclusions

The following exclusions apply to all MVP contracts:

- any indication not listed in the Indications/Criteria section.
- Osteochondral autografts (OATS, mosaicplasty) of other joints (ankle, elbow, hip, patella, shoulder);

References (Reviewed 2025)

- 1. Memon, AR, and Quilan, JF. Surgical treatment of articular cartilage defects in the knee: are we winning? Advances in Orthopedics. Volume 2012, Article ID 528423. 6 March 2012.
- 2. Minas, T., MD, Gomoll, A.H., MD, Rosenberg, R., MD et al. Increased Failure Rate of Autologous Chondrocyte Implantation Treatment with Marrow Stimulation Techniques. The American Journal of Sports Medicine. May 2009.

Autologous Chondrocyte Implantation and Osteochondral Allograft Transplantation

Page 4 of 10

- 3. Bartlett, W., Gooding, C.R., Carrington, R. W. J., et al. Autologous Chondrocyte Implantation at the Knee Using a Bilayer Collagen Membrane with Bone Graft. The Journal of Bone and Joint Surgery. April 13, 2004.
- 4. Chahal, J., MD, Gross, A.E., MD, Gross, C., MD, et al. Outcomes of Osteochondral Allograft Transplantation in the Knee. Arthroscopy: The Journal of Arthroscopic and Related Surgery. March 2013.
- 5. Washington State Health Care Authority. Osteochondral Allograft/Autograft Transplantation (OAT) Health Technology Assessment. October 17, 2011.
- 6. Mundi, R., et al. Cartilage Restoration of the Knee: A Systematic Review and Meta-Analysis of Level 1 Studies. Am J. Sports Med. 2015 Jul 2
- 7. Li, Z., et al. Osteochondral autograft transplantation or autologous chondrocyte implantation for large cartilage defects of the knee: a meta-analysis. Cell Tissue Bank. 2015 Jun 12.
- 8. Lynch TS, Patel RM, Benedick A, et al. Arthroscopy. 2015 Jan 20. pii: S0749-8063(14)00936-0. doi: 10.1016/j.arthro.2014.11.018. [Epub ahead of print]. Systematic Review of Autogenous Osteochondral Transplant Outcomes.
- 9. American Academy of Orthopaedic Surgeons (AAOS). Clinical Practice Guideline. Diagnosis and Treatment of Osteochondritis Dissecans. December 2010. Available: https://www.aaos.org/quality/quality-programs/lower-extremity-programs/osteochondritis-dissecans/.
- 10. Chambers HG, Shea KG, Anderson AF, et al. American Academy of Orthopaedic Surgeons clinical practice guideline on: the diagnosis and treatment of osteochondritis dissecans. J Bone Joint Surg Am. 2012;94(14):1322-1324. PMID 22810404.
- 11. American Academy of Orthopaedic Surgeons (AAOS). Use of Musculoskeletal Tissue Allografts. 1991. Revised 2011. Position and advisory statements. Available: https://www.aaos.org/uploadedFiles/PreProduction/About/Opinion_Statements/advistmt/1011%20Use%20of%20Musculoskeletal%20Tissue%20Allografts.pdf.
- 12. Bentley, G, Biant, LC, Carrington, RW, et al. A prospective, randomised comparison of autologous chondrocyte implantation versus mosaicplasty for osteochondral defects in the knee. J Bone Joint Surg Br. 2003;85(2):223-230.
- 13. Briggs T, Mahroof S, David L, et al. Histological evaluation of chondral defects after autologous chondrocyte implantation of the knee. J Bone Joint Surg Br. 2003;85(7):1077-1083.

- 14. Dozin B, Malpeli M, Cancedda R, et al. Comparative evaluation of autologous chondrocyte implantation and mosaicplasty: A multicentered randomized clinical trial. Clin J Sport Med. 2005;15(4):220-226.
- 15. Henderson I, Tuy B, Connell D, et al. Prospective clinical study of autologous chondrocyte implantation and correlation with MRI at three and 12 months. J Bone Joint Surg Br. 2003;85(7):1060-1066.
- 16. Ruano-Ravina A, Jato Diaz M. Autologous chondrocyte implantation: a systematic review. Osteoarthritis Cartilage. 2006;14(1):47-51.
- 17. Sharpe J, Ahmed S, Fleetcroft J, Martin R. The treatment of osteochondral lesions using a combination of autologous chondrocyte implantation and autograft: Three-year follow-up. J Bone Joint Surg Br. 2005;87(5):730-735.
- 18. Hangody L, Füles P: Autologous osteochondral mosaicplasty for the treatment of full-thickness defects of weight-bearing joints: Ten years of experimental and clinical experience. J Bone Joint Surg Am 2003;85(suppl2):25-32.
- 19. Hangody L, Dobos J, Baló E, et al. Clinical experiences with autologous osteochondral mosaicplasty in an athletic population: a 17-year prospective multicenter study. Am J Sports Med. 2010 Jun;38(6):1125-33.
- 20. National Institute for Health and Clinical Excellence (NICE). Mosaicplasty for knee cartilage defects. Interventional Procedure Guidance 162. London, UK: NICE; March 2006.
- 21. Aubin PP, et al. Long-term follow-up of fresh femoral osteochondral allografts for posttraumatic knee defects. Clin Orthopaed Rel Res 2001;(2):S218-327
- 22. Bekkers JE, et al. Treatment selection in articular cartilage lesions of the knee: a systematic review. Am J Sports Med 2009 Nov;37 Suppl 1:148S-55S.
- 23. Hangody L, et al. Mosaicplasty for the treatment of articular defects of the knee and ankle. Clin Orthopaed Rel Res 2001 Oct;1(391):S328-36.
- 24. Hangody L, et al. Autologous osteochondral grafting- technique and long-term results. Injury 2008 Apr; 39 (Suppl)1:S32-9.
- 25. Hettrich CM, et al. Cartilage repair: third-generation cell-based technologies- basic science, surgical techniques and clinical outcomes. Sports Med Arthrosc 2008 Dec;16(4):230-5.
- 26. Ma HL, et al. Osteochondral autografts transfer for post-traumatic osteochondral defect of the knee- 2-5 years follow-up. Injury 2004 Dec;35(12):1286-92.
- 27. Gudas R, Gudaite A, Pocius A, et al: Ten-year follow-up of a prospective,randomized clinical study of mosaic osteochondral autologous transplantation versus

Autologous Chondrocyte Implantation and Osteochondral Allograft Transplantation

- microfracture for the treatment of osteochondral defects in the knee joint of athletes. Am J Sports Med 2012;40(11):2499-2508.
- 28. Safaran, MR., Seiber, K. The evidence for surgical repair of articular cartilage in the knee. Journal of the American Academy of Orthopaedic Surgeons. May 2010, Vol 18. No 5: 259-266.
- 29. Marcacci M, Kon E, Delcogliano M, Filardo G, Busacca M, Zaffagnini S:Arthroscopic autologous osteochondral grafting for cartilage defects of the knee:Prospective study results at a minimum 7-year follow-up. Am J Sports Med 2007;35(12):2014-2021
- 30. Winthrop, Z., et al. Surgical treatment for osteochondritis dessicans of the knee.Curr Rev Musculoskelet Med. 2015 Dec; 8(4): 467-475.
- 31. Gross, A.E., et al. Long-term followup of the use of fresh osteochondral allografts for post traumatic knee defects. Clinical Orthopaedics and Related Research. No. 435, 79-87.
- 32. Bartha L, Vajda A, Duska Z, et al. Autologous osteochondral mosaicplasty grafting. J Orthop Sports Phys Ther. 2006;36(10):739-750.
- 33. Henderson I, Tuy B, Connell D, et al. Prospective clinical study of autologous chondrocyte implantation and correlation with MRI at three and 12 months. J Bone Joint Surg Br. 2003;85(7):1060-1066.
- 34. Jakob R, Franz T, Gautier E, Mainil-Varlet P. Autologous osteochondral grafting in the knee: Indication, results, and reflections. Clin Orthop. 2002;(401):170-184.
- 35. Karataglis D, Green M, Learmonth D. Autologous osteochondral transplantation for the treatment of chondral defects of the knee. Knee. 2006;13(1):32-35.
- 36. Karataglis D, Learmonth D. Management of big osteochondral defects of the knee using osteochondral allografts with the MEGA-OATS technique. Knee. 2005;12(5):389-393.
- 37. Peterson L, Minas T, Brittberg M, Lindahl A. Treatment of osteochondritis dissecans of the knee with autologous chondrocyte transplantation. J Bone Joint Surg Am. 2003;85(Suppl 2):17-24.
- 38. Sherman SL, Garrity J, Bauer K, Cook J et al. Fresh osteochondral allograft transplantation for the knee: current concepts. J Am Acad Orthop Surg. 2014;22(2):121-33.
- 39. Adler V, Pa L, Ko J, et al. Autologous chondrocyte transplantation for the treatment of articular defects of the knee. Scr Med. 2003;76(3):241-250.
- 40. Alleyne K, Galloway M. Management of osteochondral injuries of the knee. Clin Sports Med. 2001;20(2):343-364.

Autologous Chondrocyte Implantation and Osteochondral Allograft Transplantation

Page 7 of 10

- 41. HAYES Comparative Effectiveness Review. Comparative Effectiveness Review of First-Generation Autologous Chondrocyte Implantation of the Knee. Copyright © 2022 Hayes, a symplr company. July 13, 2017. Archived July 9, 2020. Available: www.hayesinc.com/hayes/
- 42. HAYES Comparative Effectiveness Review. Comparative Effectiveness Review of Second- and Third-Generation Autologous Chondrocyte Implantation of the Knee Copyright © 2022 Hayes, a symplr company. July 13, 2017. Archived July 9, 2020. Available: www.hayesinc.com/hayes/
- 43. HAYES Comparative Effectiveness Review. Matrix-induced autologous chondrocyte implantation (MACI) for the treatment of patients with chondral defects of the knee. Copyright © 2022 Hayes, a symplr company. August 26, 2020. Annual review: August 17, 2022. Available: www.hayesinc.com/hayes/
- 44. HAYES Comparative Effectiveness Review. Comparative Effectiveness Review of Mosaicplasty for Treatment of Articular Cartilage Injuries. Copyright © © 2022 Hayes, a symplr company. May 4, 2017. Available: www.hayesinc.com/hayes/

Customer Product	Medical Management Requirements*
New York Products	
НМО	Potential for Retrospective Review
PPO in Plan	Potential for Retrospective Review
PPO OOP	Potential for Retrospective Review
POS in Plan	Potential for Retrospective Review
POS OOP	Potential for Retrospective Review
Essential Plan	Potential for Retrospective Review
MVP Medicaid Managed Care	Potential for Retrospective Review
MVP Child Health Plus	Potential for Retrospective Review
MVP Harmonious Health Care Plan	Potential for Retrospective Review
MVP Medicare Complete Wellness	Potential for Retrospective Review
MVP Medicare Preferred Gold HMO POS	Potential for Retrospective Review
MVP Medicare Secure HMO POS	Potential for Retrospective Review
MVP Medicare Secure Plus HMO POS	Potential for Retrospective Review
MVP Medicare WellSelect PPO	Potential for Retrospective Review
MVP Medicare WellSelect Plus PPO	Potential for Retrospective Review
MVP Medicare Patriot Plan PPO	Potential for Retrospective Review
MVP DualAccess D-SNP HMO	Potential for Retrospective Review
MVP DualAccess Complete D-SNP HMO	Potential for Retrospective Review
MVP DualAccess Plus D-SNP HMO	Potential for Retrospective Review
UVM Health Advantage Select PPO	Potential for Retrospective Review
USA Care PPO	Potential for Retrospective Review
Healthy NY	Potential for Retrospective Review
MVP Premier	Potential for Retrospective Review
MVP Premier Plus	Potential for Retrospective Review
MVP Premier Plus HDHP	Potential for Retrospective Review
MVP Secure	Potential for Retrospective Review
MVP EPO	Potential for Retrospective Review
MVP EPO HDHP	Potential for Retrospective Review
MVP PPO	Potential for Retrospective Review
MVP PPO HDHP	Potential for Retrospective Review
Student Health Plans	Potential for Retrospective Review
ASO	See SPD
Vermont Products	366 31 3
POS in Plan	Potential for Retrospective Review
POS OOP	Potential for Retrospective Review
MVP Medicare Preferred Gold HMO POS	Potential for Retrospective Review
MVP Medicare Secure Plus HMO POS	Potential for Retrospective Review
MVP VT HMO	Potential for Retrospective Review
MVP VT HDHP HMO	Potential for Retrospective Review
MVP VT Plus HMO	Potential for Retrospective Review
MVP VT Plus HDHP HMO	Potential for Retrospective Review
MVP Secure	Potential for Retrospective Review
ASO	See SPD
7.00	3cc 3i D

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Revision History

02/01/2023 - Annual review with no changes to the indications or criteria. References updated.

07/01/2023 - Prior authorization removed from 27412, 27415, 27416, 29866, 29867, J7330, and S2112 because procedures managed previously by Magellan Healthcare are no longer medically managed or reviewed.

06/01/2025- Annual Review no changes to indications or criteria.



Automatic External Defibrillators

Type of Policy: Durable Medical

Equipment

Prior Approval Date: 05/03/2021

Approval Date: 05/01/2023

Effective Date: 08/01/2023

Related Polices:

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

MVP Durable Medical Equipment (DME) Prior Authorization List Available:

Provider Reference Library Home (mvphealthcare.com)

Code:	Description:
E0617	External defibrillator with integrated electrocardiogram analysis
K0606	Automatic external defibrillator, with integrated electrocardiogram analysis, garment type
K0607	Replacement battery for automated external defibrillator, garment type only, each
K0608	Replacement garment for use with automated external defibrillator, each
K0609	Replacement electrodes for use with automated external defibrillator, garment type only, each

Codes Requiring Retrospective Review

Experimental/Investigational

N/A

Common Diagnosis Codes

N/A

Common Procedure Codes

N/A

Common Diagnosis Codes

ICD-10- CM Diagnosis Codes for HCPCS Code E0617

121.01 | 121.02 | 121.09 | 121.11 | 121.19 | 121.21 | 121.29 | 121.3 | 121.4 | 122.0 | 122.1 | 122.2 | 122.8

I22.9 I25.2 I42.1 I42.2 I45.81 I46.2 I46.8 I46.9 I47.0 I47.2 I49.01 I49.02 T82.110A T82.111A T82.118A T82.119A T82.120A T82.121A T82.128A T82.129A T82.190A T82.191A T82.198A T82.199A T82.6XXA T82.7XXA

ICD-10- CM Diagnosis Codes for HCPCS coded K0606-K0609

A18.84 I21.01 I21.02 I21.09 I21.11 I21.19 I21.21 I21.29 I21.3 I21.4 I22.0 I22.1 I22.2 I22.8 I22.9 I25.2 I42.0 I42.1 I42.2 I42.3 I42.4 I42.5 I42.6 I42.7 I42.8 I42.9 I43 I45.81 I46.2 I46.8 I46.9 I47.0 I47.2 I49.01 I49.02 T82.110A T82.111A T82.118A T82.119A T82.120A T82.121A T82.128A T82.129A T82.190A T82.191A T82.198A T82.199A T82.6XXA T82.7XXA

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

Automatic External Defibrillators (AEDs) are portable devices used to induce electrical stimulation to the heart muscle in the event of a potential cardiac arrest. Early access defibrillation has been recognized as a significant factor in survival from incidents of sudden cardiac arrest. Adequate preparation for responding to a life-threatening emergency can save lives.

Documentation Requirements

Medical necessity must be documented in the patient's medical record. The customer's medical records include the treating practitioner's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports. Medical record documentation must be available upon request.

Indications/Criteria

Wearable Defibrillator

A wearable defibrillator (K0606) is covered for beneficiaries if they meet one of the following criteria:

- 1. A documented episode of ventricular fibrillation or a sustained, lasting 30 seconds or longer, ventricular tachyarrhythmia. These dysrhythmias may be either spontaneous or induced during an electrophysiologic (EP) study, but may not be due to a transient or reversible cause and not occur during the first 48 hours of an acute myocardial infarction; or
- 2. Familial or inherited conditions with a high risk of life-threatening ventricular tachyarrhythmia such as long QT syndrome or hypertrophic cardiomyopathy; or
- 3. Either documented prior myocardial infarction or dilated cardiomyopathy and a measured left ventricular ejection fraction less than or equal to 0.35; or
- 4. A previously implanted defibrillator now requires explantation.

Non-wearable Automatic Defibrillator

A non-wearable automatic defibrillator (E0617) is covered for customers when they meet either (1) both criteria A and B or (2) criteria C:

- A. The customer has one of the following conditions noted below (1-8):
 - 1. A documented episode of cardiac arrest due to ventricular fibrillation, not due to a transient or reversible cause; or
 - 2. A sustained, lasting 30 seconds or longer, ventricular tachyarrhythmia, either spontaneous or induced during an electrophysiologic (EP) study, not associated with acute myocardial infarction, and not due to a transient or reversible cause; or
 - 3. Familial or inherited conditions with a high risk of life-threatening ventricular tachyarrhythmias such as long QT syndrome or hypertrophic cardiomyopathy; or
 - 4. Coronary artery disease with a documented prior myocardial infarction with a measured left ventricular ejection fraction less than or equal to 0.35, and inducible, sustained ventricular tachycardia (VT) or ventricular fibrillation (VF) during an EP study. To meet this criterion, the following must be met;
 - The myocardial infarction must have occurred more than 4 weeks prior to the external defibrillator prescription; and,
 - The EP test must have been performed more than 4 weeks after the qualifying myocardial infarction. or

- 5. Documented prior myocardial infarction and a measured left ventricular ejection fraction less than or equal to 0.30. The customer must not have any of the following:
 - Cardiogenic shock or symptomatic hypotension while in a stable baseline rhythm; or,
 - Had a coronary artery bypass graft (CABG) or percutaneous transluminal coronary angioplasty (PTCA) within past 3 months; or,
 - Had an enzyme-positive MI within past month; or,
 - Clinical symptoms or findings that would make them a candidate for coronary revascularization; or,
 - Irreversible brain damage from preexisting cerebral disease; or,
 - Any disease, other than cardiac disease (e.g. cancer, uremia, liver failure), associated with a likelihood of survival less than one year.
- 6. Customers with ischemic dilated cardiomyopathy (IDCM), documented prior myocardial infarction (MI), New York Heart Association (NYHA) Class II and III heart failure, and measured left ventricular ejection fraction (LVEF) ≤ 35%.
- 7. Customers with nonischemic dilated cardiomyopathy (NIDCM) > 3 months, NYHA Class II and III heart failure, and measured LVEF ≤ 35%
- 8. Customers who meet one of the criteria above and have NYHA Class IV heart failure
- B. Implantation surgery is contraindicated
- C. A previously implanted defibrillator now requires explantation

Exclusions

Any indication not listed in the Indications/Criteria section listed above.

Medicaid Variation

According to the New York State Medicaid Wearable Automatic External Defibrillator Guidelines (K0606), MVP Managed Medicaid customers must meet the following criteria 1 through 4:

- 1. The Medicaid customer has one of the following conditions (A or B or C):
 - A. A documented episode of ventricular fibrillation or a sustained, lasting 30 seconds or longer, ventricular tachyarrhythmia. These dysrhythmias may be spontaneous; and/or must be reproducible during an electrophysiologic (EP) study, but may not be due to a transient or reversible cause and not occur during the first 48 hours of an acute myocardial infarction, first 72 hours post coronary bypass, or within 5 days of a transplant; or

- B. Familial or inherited conditions with a high risk of life-threatening ventricular tachyarrhythmia such as long QT syndrome or hypertrophic cardiomyopathy; or
- C. Either documented prior myocardial infarction or dilated cardiomyopathy and a measured left ventricular ejection fraction less than or equal to 0.35; and
- 2. Implantation surgery is contraindicated (A or B):
 - A. Implantation surgery is contraindicated (systemic infectious process) or a temporary condition that precludes initial implantation; or
 - B. A previously implanted defibrillator now requires explantation due to infection or inflammatory process due to implant graft with waiting period before ICD reinsertion with documentation that severe infection is not due to poor patient compliance; and
- 3. The provider and ordering practitioner have assured that all less costly medically appropriate alternatives have been explored. If the alternatives are not adequate the ordering practitioner is required to provide clear documentation as to why the alternatives are not adequate; and
- 4. The ordering practitioner of the wearable defibrillator is a cardiologist and experienced in the management of patients at risk for sudden cardiac death (SCD).

Non-Covered Indications

The wearable cardioverter defibrillator (WCD) is considered investigational, not medically necessary, medically contraindicated and not covered for any condition not listed in the Indications/Criteria section, including but not limited to, the following:

- Patients with a history of an acute myocardial infarction (MI) within 30 days;
- Patients with drug-refractory class IV congestive heart failure (CHF) who are not candidates for heart transplantation;
- Patients with a history of psychiatric disorders that interfere with the necessary care and follow-up;
- Patients in whom a reversible triggering factor (by drug therapy, definitive therapy, ablation) for VT/VF can be definitely identified, such as ventricular tachyarrhythmias in evolving acute myocardial infarction or electrolyte abnormalities;
- Patients with terminal illnesses other disease processes that clearly and severely limits the patient's life expectancy.

Non-wearable Automatic Defibrillator

A non-wearable automatic defibrillator (E0617) is not covered for Medicaid Customers.

For full coverage and exclusion details refer to the New York State Department of Health Medicaid website below.

New York State Department of Health. eMedNY. Provider Manuals. DME Manual. Wearable Automatic Defibrillator Guidelines. October 2015. Available: https://www.emedny.org/ProviderManuals/DME/index.aspx

Medicare Variation

MVP follows Medicare criteria for automatic external defibrillator.

References (Updated 2023)

- 1. Noridian Healthcare Solutions Local Coverage Decision (LCD) (L33690) for Automatic External Defibrillators. Revision Effective Date: 01/01/2020 Available: https://www.cms.gov/medicare-coverage-database/
- 2. Noridian Healthcare Solutions Local Coverage Article (A52458) for Automatic External Defibrillators. Revision Effective Date: 01/01/2020 Available: https://www.cms.gov/medicare-coverage-database/
- 3. New York State Department of Health. eMedNY. Provider Manuals. DME Manual. Wearable Automatic Defibrillator Guidelines. October 2015. Available: https://www.emedny.org/ProviderManuals/DME/index.aspx

Customer Product	Medical Management Requirements*
New York Products	
HMO	Prior Auth
PPO In Plan	Prior Auth
PPO OOP	Prior Auth
POS In Plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Prior Auth
MVP Child Health Plus	Prior Auth
MVP Harmonious Health Care Plan	Prior Auth
MVP Medicare Complete Wellness	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP Medicare WellSelect PPO	Prior Auth
MVP Medicare WellSelect Plus PPO	Prior Auth
MVP Patriot Plan PPO	Prior Auth
MVP DualAccess D-SNP HMO	Prior Auth
MVP DualAccess Complete D-SNP HMO	Prior Auth
MVP DualAccess Plus D-SNP HMO	Prior Auth
UVM Health Advantage Select PPO	Prior Auth
USA Care PPO	Potential for Retrospective Review
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	See SFD
POS In Plan	Prior Auth
POS OOP	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP VT HMO	Prior Auth
MVP VT Plus HMO	riioi Autii
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD
A N. 4 Dui	

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Revision History

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08/01/2021 – Annual Review. Deleted the Medicare variation because MVP follows Medicare criteria and there is no variation for Medicare customers. Updated policy to the new format. No changes to the indications or criteria.

08/01/2023 – Annual review. Updated format. No changes to indications or criteria.



Bariatric Surgery

Type of Policy: Surgical

Prior Approval Date: 03/04/2024

Approval Date: 06/01/2024

Effective Date: 08/01/2024

Related Polices: Weight Loss

Agents

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

CPT Codes: 43644, 43645, 43770, 43771, 43772, 43773, 43774, 43775, 43846, 43847, 43848, 43860, 43865 for all Commercial and ASO plans only to confirm use of a Center of Excellence (COE) per the customer's contract. Medical necessity review for the procedures is not required.

Codes Requiring Retrospective Review

CPT Codes: 43290, 43291

Experimental/Investigational

43290 - Esophagogastroduodenoscopy, flexible, transoral; with deployment of intragastric bariatric balloon

43291 - Esophagogastroduodenoscopy, flexible, transoral; with removal of intragastric bariatric balloon(s)

43659 - Unlisted laparoscopy procedure, stomach

43842 - Gastric restrictive procedure, without gastric bypass, for morbid obesity; vertical-banded gastroplasty

43843 - Gastric restrictive procedure, without gastric bypass, for morbid obesity; other than vertical-banded gastroplasty

43845 - Gastric restrictive procedure with partial gastrectomy, pylorus-preserving duodenoileostomy and ileoileostomy (50 to 100 cm common channel) to limit absorption (biliopancreatic diversion with duodenal switch)

C9784 - Gastric restrictive procedure, endoscopic sleeve gastroplasty, with esophagogastroduodenoscopy and intraluminal tube insertion, if performed, including all system and tissue anchoring components

Common Diagnosis Codes

ICD-10- CM Diagnosis Codes

E08.0, E08.00, E08.01, 08.1, E08.10, E08.11, E10.1, E10.10, E11.0, E11.00, E11.8, E11.9, E66.0, E66.01, E66.09, E66.1, E66.2, E66.3, E66.8, E66.9

Common Diagnosis Codes associated with this policy have been provided for informational purposes only. The list of codes may not be all-inclusive and may be updated to reflect any applicable revisions to the ICD-10 code set and/or medical necessity quidelines applied in this policy.

Common Procedure Codes

N/A

Please refer to the product grid for detailed authorization requirements for specific plans. Code lists may not be all inclusive. Codes requiring prior-authorization for some products may be retrospectively reviewed for plans that do not require prior-authorization. Common diagnosis and procedure codes are included for informational purposes. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

Weight loss surgery (bariatric surgery) is considered for customers with Class 3 obesity (defined as body mass index \geq 40kg/m²), without co-existing medical problems, who have failed medical and pharmacological management, and for whom bariatric surgery would not be associated with excessive risk. As well, customers with Class 2 obesity (BMI \geq 35 kg/m²) and \geq 1 severe obesity related condition remediable by weight loss are indicated for bariatric surgery. Customers with Class 1 obesity (BMI 30-34.9 kg/m²) with uncontrolled type 2 diabetes mellitus despite optimal lifestyle and medical therapy are also indicated. Bariatric surgical procedures can be identified as two general types: malabsorptive (bypassing parts of the gastrointestinal tract to limit the absorption of food) and restrictive (decreasing the size of the stomach).

Indications/Criteria

Documentation Requirements

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- Documentation of medical necessity must contain a history and physical pertinent to the indications within this policy. The medical record must clearly delineate the associated organic diseases requiring the treatment of obesity.
- documentation that the customer completed a physician-supervised medical weight loss program or a pre-surgical multidisciplinary preparatory program for chronically obese customers whose lives are endangered due to excessive weight, and that the customer has failed to maintain an adequate weight. A multidisciplinary weight management program must include nutritional counseling, exercise instruction, and behavior modification components.
- Documentation must indicate that, prior to completing the medical weight loss program, the customer has undergone a behavioral health evaluation that assesses for potential contraindications such as a significant psychiatric diagnosis which would result in non-compliance with, or the inability to follow through with, major surgical regimens; the ability of the customer to cope with major life changes and other factors pertinent to surgery, such as changes to the body with significant weight loss; potential addictions to substances; and the lack of support available in the community to help the person cope with the surgery. The Medical Director may request a comprehensive psychological evaluation at their discretion.
- Medical record documentation that customers with child-bearing potential have been informed that malnutrition during pregnancy (which could result from the surgical weight loss procedure) may impair normal fetal development and have agreed to appropriate birth control methods.

Medical Weight Loss Programs

The purpose of these programs is to document failure to achieve and maintain a desirable weight by aggressive non-surgical means. If the customer has shown substantial weight loss (customer has achieved a BMI < 35 or lost > 10% -15% of body weight) with a non-surgical approach over the time frames outlined below, continued participation in the program may be required prior to approval for surgery. A letter is required from the provider supervising the customer's weight loss program indicating that the customer would not be able to continue to lose weight and achieve their target weight without bariatric surgery.

Customers must meet criteria for a pre-surgical multidisciplinary preparatory program prior to making a decision for any covered weight-loss surgery as defined below:

Pre-surgical Multidisciplinary Preparatory Program

For at least six continuous months prior to the proposed bariatric surgery date, the customer must participate in a multidisciplinary preparatory program that meets all of the following criteria:

• nutrition consultation with a licensed dietitian or nutritionist; and

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- low calorie diet; and
- exercise program (unless contraindicated); and
- behavioral modification; and
- concurrent treatment of co-morbid conditions.

The purpose of the preparatory program is two-fold:

- To document failure to achieve and maintain a desirable weight by aggressive non-surgical means If the customer has shown substantial weight loss with this approach, continued participation in the program may be required prior to approval for surgery.
- To document that the customer is able to comply with the necessary dietary restrictions that will be required post-operatively. A letter from the provider supervising the customer's weight loss program indicating that the customer would not be able to continue to lose weight and achieved their target weight without the bariatric surgery is required.

ADULTS

Roux-en-Y Gastric Bypass or Sleeve Gastrectomy

Roux-en-Y Gastric Bypass or Sleeve Gastrectomy is considered medically necessary when <u>all</u> of the following criteria are met:

- age <u>></u> 18 years
- behavioral health evaluation with sufficient documentation to indicate all of the following:
 - customer is well informed, motivated, an acceptable operative risk, and is able to participate in treatment and long-term follow-up;
 - o customer is not addicted to drugs or alcohol;
 - absence of significant psychiatric disorders, severe depression, or cognitive impairment;
 - o customer does not meet criteria for an active, unmanaged eating disorder such as active Binge eating disorder; and
- One of the following BMI categories:
 - customer has a BMI of \geq 40kg/m²; or
 - customer has a BMI of \geq 35kg/m² with one of the below life-threatening or disabling co-morbid conditions despite optimal medical management:
 - poorly controlled Type II diabetes mellitus (HbA1c> 7);
 - poorly controlled dyslipidemia (not meeting ATP III goals);

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- poorly controlled hypertension (not meeting 2020 International Society of Hypertension Global Hypertension Practice Guidelines targets);
- serious cardiopulmonary disorder (e.g., coronary artery disease, cardiomyopathy, pulmonary hypertension);
- obstructive sleep apnea (Pickwickian Syndrome);
- severe arthritis of weight bearing joints (treatable but for the obesity);
- nonalcoholic steatohepatitis; urinary stress incontinence; or
- pseudotumor cerebri.
- customer has a BMI of 30-34.9 kg/m² with poorly controlled Type II diabetes mellitus (HbA1c> 7);
- failure of weight loss by medical management;
- negative cotinine test and documentation supporting that the customer has the ability to remain non-smoking for a period of six (6) weeks or longer prior to surgery; and
- appendectomy and/or cholecystectomy, if indicated, should be done at the same time as the bariatric procedure.

Laparoscopic Adjustable Gastric Banding

Published complications of gastric banding have indicated that stoma obstruction, band erosion, pouch dilatation, and band slippage may contribute to failure and eventual removal of the device in 40% or more of customers.

Laparoscopic adjustable gastric banding is considered medically necessary for Commercial customers who are not candidates for Roux-en-Y Gastric Bypass surgery and Sleeve Gastrectomy and meet all criteria under Indications/Criteria of this policy as well as the following:

- documented medical contraindication to Roux-en-Y Gastric Bypass surgery and/or Sleeve Gastrectomy
- the customer's dietary history does not indicate a large consumption of high caloric liquids or sweets; and
- the customer must have a BMI < 50 kg/m².

Removal of Adjustable Gastric Band

Removal of a gastric band will be considered when the customer is symptomatic (e.g., nausea, vomiting, inability to eat or drink, abdominal pain, dysphagia, heartburn/reflux) or there are complications (e.g., intractable dumping syndrome, syncope, life-threatening hypoglycemia, malabsorption/malnutrition, obstruction, infection, stricture or esophageal dilation) or technical failure (e.g., displaced band, port dislocation, too

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tight a band creating food passage problems, band erosion, band intolerance, port and/or catheter leakage, or staple disruption) of the prior surgery. Band removal will also be allowed when performed as part of an approved second bariatric procedure (see below).

A different second procedure after band removal will be considered when:

- A. Primary procedure was initially successful in inducing weight loss; and
- B. Customer has remained compliant with the prescribed nutrition and exercise program and
- C. Customer has documented routine follow-up appointments with bariatric program; and
- D. Customer has developed additional obesity associated comorbidities as noted above

Two-stage Bariatric Surgery

A planned two-stage procedure consisting of an initial sleeve gastrectomy followed by Roux-en-Y may be appropriate for super obese (BMI > 50) customers. Procedures will be approved separately; approval of the second stage requires documentation of satisfactory weight loss and compliance with nutritional and exercise program in addition to the customer not having achieved their target weight.

Revisional Bariatric Surgery (e.g., 43848, 43860, 43659)

Revision of previous bariatric surgical procedures will only be considered in adults > 18 years of age for requests to convert a prior surgery to Roux-en-Y gastric bypass OR perform specific revision of the gastrojejunal anastomosis (gastrojejunostomy).

Revisional procedure requests must include a copy of the clinic's revisional assessment approach and standardized clinical pathways from the Bariatric surgical center requesting the procedure.

These revisional procedures are considered medically necessary when ALL of the following are met:

- Customer has documented significant clinical complications (e.g., intractable dumping syndrome, syncope, life-threatening hypoglycemia, malabsorption/malnutrition, obstruction, infection, stricture, or esophageal dilation); AND
- For customers with significant clinical complications of severe/uncontrollable gastroesophageal reflux disease (GERD)or endoscopic findings documenting the presence of severe GERD, as well as clinical documentation of the frequency of symptoms and the maximal dose anti-reflux medical therapy that has been tried and failed: AND

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• the customer has endoscopically documented post-surgical changes which may include but are not limited to pouch dilatation.

Surgical reversal (i.e., takedown,) revision, or both of a previous bariatric surgical procedure or conversion to another bariatric surgical procedure for ANY other indication is considered not medically necessary.

Customers experiencing no medical complications with documented inadequate weight loss expected for the associated initial bariatric surgical intervention are considered for additional surgeries on a case-by-case basis, based on the level of continued obesity-associated medical co-morbidity. Individuals ≥ two years following a primary bariatric surgery procedure must meet all of the initial medical necessity criteria for surgery.

ADOLESCENTS

Roux-en-Y Gastric Bypass or Sleeve Gastrectomy

The requesting surgeon must confirm participation with a bariatric surgical center of excellence with accreditation to perform bariatric surgery in pediatric and adolescent customers.

Open or laparoscopic Roux-en-Y Gastric Bypass surgery or Sleeve Gastrectomy will be considered medically necessary for adolescents when all of the following criteria are met:

- Adolescent (age 12–17 years) with:
 - o BMI of \geq 35kg/m² or \geq 120% of the 95th percentile (whichever is lower) with one or more of the following major comorbidities:
 - type 2 diabetes mellitus;
 - moderate-to-severe sleep apnea;
 - pseudotumor cerebri, or
 - severe nonalcoholic steatohepatitis.
 - o BMI \geq 40kg/m² or ≥ 140% of the 95th percentile (whichever is lower)
- ≥6 months organized attempts at weight management without success that includes all of the following:
 - a recommendation for bariatric surgery from a physician/physician assistant/nurse practitioner other than the requesting surgeon or associated staff
 - behavioral health evaluation of customer and family with whom customer resides, with sufficient documentation to indicate all of the following:
 - customer is well informed, motivated, an acceptable operative risk, and is able to participate in treatment and long-term follow-up;

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- customer is not addicted to drugs or alcohol;
- absence of significant psychiatric disorders, severe depression, or cognitive impairment;
- customer does not meet criteria for an active, unmanaged eating disorder such as active Binge eating disorder; and
- a recommendation for bariatric surgery by a mental health provider, including assessment of family supports and involvement in the process.
- Negative cotinine test and documentation supporting that the customer has the ability to remain non-smoking for a period of six (6) weeks or longer prior to surgery;
- Medical record documentation that an adolescent capable of becoming pregnant has agreed to appropriate birth control methods; and
- For at least six (6) continuous months prior to the proposed bariatric surgery date, the customer must participate in a multidisciplinary preparatory program that meets all of the following criteria:
 - o nutrition consultation with a licensed dietitian or nutritionist; and
 - low calorie diet; and
 - o exercise program (unless contraindicated); and
 - behavioral modification; and
 - o concurrent treatment of co-morbid conditions.

Exclusions

- Not meeting criteria under Indications/Criteria in this policy.
- Customers with any of the following:
 - o prior reversal of jejuno-ileal bypass with hepatic dysfunction; or
 - o alcohol and/or chemical dependency in the past 12 months; or
 - previous significant history of non-compliance with medical and/or surgical treatment;
 - Active binge eating disorder.
- Bariatric surgery is contraindicated in pregnancy.
- Customers who are unable or unwilling to comply with post-surgical dietary restrictions that are necessary to allow the surgery to be successful.

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- Revisional bariatric surgery is considered not medically necessary for those customers who no longer meet criteria for bariatric surgery based on BMI and comorbidities.
- Revisional bariatric surgery (not related to technical failure or surgical complication) in adolescents (< 18 years).
- There is inadequate evidence that the following procedures are reasonable and necessary; therefore, they are considered experimental and investigational:
 - Single anastomosis duodenal switch (SADI-S)
 - open vertical banded gastroplasty (43842);
 - laparoscopic vertical banded gastroplasty;
 - o open adjustable gastric banding (43843);
 - intestinal bypass surgery (44238, 44799);
 - o gastric balloon (43290, 43291, 43999);
 - endoscopic sleeve gastroplasty (C9784); and
 - o open and laparoscopic biliopancreatic diversion with duodenal switch.

Medicare Variation

Medicare customers are covered according to the Centers for Medicare & Medicaid Services National Coverage Determination (NCD) for Bariatric Surgery for Treatment of Morbid Obesity (100.1). [(Below is a partial description of the indications listed in the NCD):

The following procedures for surgical management of morbid obesity will be covered for customers who have a body mass index \geq 35 kg/m², have at least one (1) comorbidity related to obesity, and have been previously unsuccessful with medical treatment of obesity:

- open and laparoscopic Roux-en Y gastric bypass (RYGBP);
- laparoscopic adjustable gastric banding (LAGB); open and laparoscopic biliopancreatic diversion with duodenal switch (BPD/DS);
- gastric reduction duodenal switch (BPD/GRDS);
- stand-alone laparoscopic sleeve gastrectomy

Medicare Exclusions

Treatments for obesity alone remain non-covered.

Supplemented fasting is not covered as a general treatment for obesity (see section D below for discretionary local coverage).

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The following bariatric surgery procedures are non-covered:

- Open adjustable gastric banding;
- Open sleeve gastrectomy;
- Open and laparoscopic vertical banded gastroplasty;
- Intestinal bypass surgery;
- Endoscopic sleeve gastroplasty; and,
- Gastric balloon for treatment of obesity.

Coverage of stand-alone laparoscopic sleeve gastrectomy (LSG) is covered for the treatment of co-morbid conditions related to obesity only when all of the following criteria are met:

- a. body-mass index (BMI) \geq 35 kg/m²,
- b. at least one co-morbidity related to obesity, and,
- c. customer has been previously unsuccessful with medical treatment for obesity.

For a complete description of the indications and limitations of coverage for bariatric surgery for Medicare customers, please refer to the National Coverage Determination (NCD) for Bariatric Surgery for Treatment of Co-Morbid Conditions Related to Morbid Obesity (100.1): www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=57&nc

References (Updated 2024)

- American Diabetes Association, Standards of medical care for members with diabetes mellitus. Diabetes Care Vol. 29, Supplement 1, Clinical Practice Recommendations, Jan, 2006. Available: https://diabetes.org/
- 2. American Society for Gastrointestinal Endoscopy (ASGE). The role of endoscopy in the bariatric surgery member. 2015. Available: https://www.asge.org/home/guidelines#upper-gi
- American Society for Metabolic and Bariatric Surgery (ASMBS). American Society for Metabolic and Bariatric Surgery and American Hernia Society consensus guideline on bariatric surgery and hernia surgery. Oct 2018. Accessed May 14, 2020. Available: Page 64 of 84 Medical Coverage Policy: 0051 <u>ASMBS and AHS Consensus Guideline on Bariatric Surgery and Hernia Surgery | American Society for Metabolic and Bariatric Surgery</u>
- 4. American Society for Metabolic and Bariatric Surgery (ASMBS). Emerging Technologies and Clinical Issues Committees of the ASMBS. Position Statement on emerging endosurgical interventions for treatment of obesity. 2009a Jan; Available:

Bariatric Surgery Page 10 of 15

- https://asmbs.org/resources/emerging-endosurgical-interventions-for-treatment-of-obesity
- 5. American Society for Metabolic and Bariatric Surgery (ASMBS). Updated position statement on bariatric surgery in class I obesity (BMI 30–35 kg/m2). May 2018. Available: ASMBS Updated Position Statement on Sleeve Gastrectomy as a Bariatric Procedure | American Society for Metabolic and Bariatric Surgery
- 6. American Society for Metabolic and Bariatric Surgery (ASMBS). Updated position statement on sleeve gastrectomy as a bariatric procedure. Oct 2017. Accessed May 14, 2020. Available: https://asmbs.org/resource-categories/position-statements
- 7. Centers for Medicare & Medicaid Services. Decision memo for bariatric surgery for the treatment of morbid obesity (CAG-0025OR). Feb 21, 2006. Available: https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=160&%3B
- 8. Centers for Medicare & Medicaid Services. NCD for Bariatric Surgery for Treatment of Co-Morbid Conditions Related to Morbid Obesity (100.1). Implementation Date: 12/17/2013 Updated May 2017. Available: https://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx
- 9. U.S Department of Health and Human Services. National Institutes of Health. National Heart, Lung, and Blood Institute. Prevention, detection, evaluation, and treatment of high blood pressure. Aug 2004. Available: www.nhlbi.nih.gov
- 10. REALIZETM Adjustable Gastric Band (Model 2200-X). Summary of safety and effectiveness data. [PMA P070009]. Available: www.accessdata.fda.gov/
- 11. Still, CD, Benotti, P, Wood, C, et al. Outcomes of preoperative weight loss in high-risk members undergoing gastric bypass surgery. *Arch Surg.* 2007; 142(10):994-998.
- 12. Himpens J, MD, Cadiere, GB, MD, Bazi, M, MD et al. Long-term Outcomes of Laparoscopic Adjustable Gastric Banding. Archives of Surgery. Vol. 146 No. 7, 7 July 2011.
- 13. Suter M, Calmes JM, Paroz A, and Giusti V. A 10-year experience with laparoscopic gastric banding for Morbid obesity: High long-term complication and failure rates. Obes Surg, 2006 Jul: 16(7):829-35.
- 14. DeMaria EJ, Sugerman HJ, Meador JG, et al. High Failure Rate After Laparoscopic Adjustable Silicone Gastric Banding for Treatment of Morbid Obesity. Ann Surg. 2001 June; 233(6):809-818.
- 15. Cherian, PT, et al. Band erosion after laparoscopic gastric banding: a retrospective analysis of 865 members over 5 years. Surg Endosc. 2010 Aug; 24(8): 2031-8.
- 16. Singhal R., et al. Band slippage and erosion after laparoscopic gastric banding: a meta-analysis. Surg Endosc 2010 Dec; 24(12):2980-6.

Bariatric Surgery Page 11 of 15

- 17. National Government Services, Inc. Article Laparoscopic Sleeve Gastrectomy (LSG) A52447. Revision Effective Date October 1, 2018. Available: www.ngsmedicare.com
- 18. Hutter, MM, et al. First report from the American College of Surgeons Bariatric Surgery Center Network: laparoscopic sleeve gastrectomy has morbidly and effectiveness positioned between the band and the bypass. Ann Surg. 2011 Sep; 254(3):410-20.
- 19. Gagner, M. Summary of the fourth international consensus summit on sleeve gastrectomy. New York City, December 6-8, 2012. Bariatric Times. 2013; 10(5 Suppl A):A26-A27.
- 20. American Society for Metabolic & Bariatric Surgery Clinical Issues Committee.

 Updated position on sleeve gastrectomy as a bariatric procedure. Revised August 2017. Surgery for Obesity and Related Diseases 8 (2012) e21-e26. Available: http://asmbs.org/2012/06/sleeve-gastrectomy-as-a-bariatric-procedure-update/
- 21. Mechanick, Jl., et al. Clinical practice guidelines for the perioperative nutritional, metabolic, and nonsurgical support of the bariatric surgery member. 2013 Update: Cosponsored by American Association of Clinical Endocrinologists, The Obesity Society, and American Society for Metabolic & Bariatric Surgery. 2013. Surgery for Obesity and Related Diseases 9 (2013) 159-181.
- 22. HAYES Medical Technology Directory™. Laparoscopic sleeve gastrectomy for Super Obesity in Adults. Lansdale, PA: HAYES, Inc.; ©Winifred S. Hayes, Inc. October 19, 2012. Available: www.hayesinc.com/
- 23. Hayes Inc. Medical Technology Directory. Bariatric surgeries for treatment of obesity in adolescents. Lansdale, PA: HAYES, Inc., ©2020 Winifred S. Hayes, Inc. May 17, 2018, updated Jan 21, 2019.
- 24. Hayes Inc. Hayes Health Technology Assessment: Single-Anastomosis Duodenal Switch For Weight Loss. Hayes © 2021 Hayes, a symplr company. February 7, 2018. (Annual review March 13, 2020) Archived March 7, 2021.
- 25. New York State Medicaid Update. June 2014. Volume 30. Number 6. Available: http://www.health.ny.gov/health_care/medicaid/program/update/2014/june14_mu.p df
- 26. Jamal MH, Corcelles R, Shimizu H, et al. Thromboemoblic events in bariatric surgery: a large multi-institutional referral center experience. Surgical Endoscopy. 2015; 29(2):376-380.
- 27. Brethauer SA, Kothari S, Sudan R, et al. Systematic review on reoperative bariatric surgery: American Society for Metabolic and Bariatric Surgery Revision Task Force. Surg Obes Relat Dis. 2014.

Bariatric Surgery Page 12 of 15

- 28. Buchwald H. 2004 ASBS Consensus Conference: Consensus Conference Statement Bariatric surgery for morbid obesity: Health implications for members, health professionals, and third-party payers. J Am Coll Surg 2005;200:593-604.
- 29. Roller JE, Provost DA. Revision of failed gastric restrictive operations to Roux-en-Y gastric bypass: impact of multiple prior bariatric operations on outcome. Obes Surg. 2006;16(7):865-869.
- 30. Colquitt JL, Picot J, Loveman E, et al. Surgery for obesity. Cochrane Database Syst Rev. 2009 Apr 15;(2):CD003641.
- 31. Endocrine Society. Clinical guideline. Pediatric obesity assessment, treatment, prevention. Jan 2017. Accessed May 12, 2020. Available: Pediatric Obesity—
 Assessment, Treatment, and Prevention: An Endocrine Society Clinical Practice
 Guideline | The Journal of Clinical Endocrinology & Metabolism | Oxford Academic (oup.com)
- 32. Bout-Tabaku S, Michalsky MP, Jenkins TM, et al. Musculoskeletal pain, self-reported physical function, and quality of life in the teen-longitudinal assessment of bariatric surgery (Teen-LABS) cohort. *JAMA Pediatr.* 2015;169(6):552-559.
- 33. Michalsky M, Reichard K, Inge T, Pratt J, Lenders C. ASMBS pediatric committee best practice guidelines. *Surg Obes Relat Dis.* 2012;8(1):1-7.
- 34. Michalsky MP, Inge TH, Jenkins TM, et al.; Teen-LABS Consortium. Cardiovascular risk factors after adolescent bariatric surgery. *Pediatrics*. 2018;141(2):e20172485.
- 35. Michalsky MP, Inge TH, Teich S, et al. Adolescent bariatric surgery program characteristics: the Teen Longitudinal Assessment of Bariatric Surgery (Teen-LABS) study experience. *Semin Pediatr Surg.* 2014;23(1):5-10.
- 36. Styne DM, Arslanian SA, Connor EL, et al. Pediatric obesity-assessment, treatment, and prevention: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab.* 2017;102(3):709-757.
- 37. Society of American Gastrointestinal and Endoscopic Surgeons (SAGES). Guidelines for clinical application of laparoscopic bariatric surgery. Jun 2008. Available: SAGES Clinical/Practice/Training Guidelines and other Publications
- 38. U.S Department of Health and Human Services. National Institutes of Health. National Heart, Lung, and Blood Institute. Prevention, detection, evaluation, and treatment of high blood pressure. Aug 2004. Available: Advancing Heart, Lung, Blood,, and Sleep Research & Innovation | NHLBI, NIH

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HMO	Prior Auth for COE
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MVP Premier Plus	Prior Auth for COE
MVP Premier Plus HDHP	Prior Auth for COE
MVP Secure	Prior Auth for COE
MVP EPO	Prior Auth for COE
MVP EPO HDHP	Prior Auth for COE
MVP PPO	Prior Auth for COE
MVP PPO HDHP	Prior Auth for COE
Student Health Plans	Prior Auth for COE
ASO	See SPD
Vermont Products	
POS in Plan	Prior Auth for COE
POS OOP	Prior Auth for COE
MVP Medicare Preferred Gold HMO POS	Prior Auth for COE
MVP Medicare Secure Plus PPO	Prior Auth for COE
MVP VT HMO	Prior Auth for COE
MVP VT HDHP HMO	Prior Auth for COE
MVP VT Plus HMO	Prior Auth for COE
MVP VT Plus HDHP HMO	Prior Auth for COE
MVP Secure	Prior Auth for COE
ASO	See SPD

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Revision History:

02/01/2022 - The requirement for a physician supervised weight loss program was removed and the participation in a pre-surgical multidisciplinary preparatory program was increased to six months. Under

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adult Roux-en-Y or sleeve gastrectomy, the upper age limit was removed, as well as the duration of morbid obesity diagnosis. Coverage was added for a customer with BMI of less than 35 with poorly controlled type II diabetes and a requirement for negative smoking test. Criteria was added for adolescent initial bariatric surgery and revisional bariatric surgery. Adolescents would be covered for either Roux-en-Y gastric bypass or sleeve gastrectomy, but only revisional surgery for technical failure or surgical complication. The Medicare variation was updated according to the Medicare NCD. Removed prior authorization for the initial bariatric surgery for Medicare and Medicaid plans. Prior authorization remains in place for revision surgical procedures for all lines of business.

04/01/2023 – Removed prior authorization medical necessity review off all bariatric surgery procedures.

08/01/2023 - Formal approval of 04/01/2023 changes completed.

06/01/2024 – Removed prior authorization from 43659, 43842, 43843, 43845 and added to be reviewed as experimental investigational procedures.

08/01/2024 - Endoscopic gastroplasty added to exclusions as experimental investigational.

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Benign Prostatic Hyperplasia (BPH) Treatments

Type of Policy: Surgical

Prior Approval Date: 03/06/2023

Approval Date: 03/28/2025

Effective Date: 06/01/2025

Related Polices: Prostate Cancer

Interventions

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

CPT Codes:

52441 - Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; single implant

52442- Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; each additional permanent adjustable transprostatic implant (List separately in addition to code for primary procedure)

53854 - Transurethral destruction of prostate tissue; by radiofrequency generated water vapor thermotherapy

HCPCS Codes:

C9739- Cystourethroscopy, with insertion of transprostatic implant; one to three implants

C9740 - Cystourethroscopy, with insertion of transprostatic implant; four or more implants

Requiring Retrospective Review

CPT Codes: N/A

Experimental/Investigational

CPT Codes:

C9769 - Cystourethroscopy, with insertion of temporary prostatic implant/stent with fixation/anchor and incisional struts

0421T- Transurethral waterjet ablation of prostate, including control of post-operative bleeding, including ultrasound guidance, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included when performed)

C2596 - Probe, image guided, robotic, waterjet ablation

51721 – Insertion of transurethral ablation transducer for delivery of thermal ultrasound for prostate tissue ablation, including suprapubic tube placement during the same session and placement of an endorectal cooling device, when performed

55881- Ablation of prostate tissue, transurethral, using thermal ultrasound, including magnetic resonance imaging guidance for, and monitoring of, tissue ablation

55882- Ablation of prostate tissue, transurethral, using thermal ultrasound, including magnetic resonance imaging guidance for, and monitoring of, tissue ablation; with insertion of transurethral ultrasound transducer for delivery of thermal ultrasound, including suprapubic tube placement and placement of an endorectal cooling device, when performed

Common Diagnosis Codes

ICD-10- CM Diagnosis Codes: N40.1

Common Procedure Codes

52450, 52601, 52630, 52647, 52648, 52649, 53850, 54520, 55801, 55821, 55831

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

Benign prostatic hyperplasia (BPH) is caused by the abnormal growth of benign (non-cancerous) prostate cells which enlarges the prostate gland. The gland may push against the bladder and urethra, causing lower urinary tract symptoms that include urinary outflow obstruction such as increased frequency of urination, hesitancy, nocturia (urinating at night), urgency and weak urinary stream. This policy will cover several surgical treatments designed to relieve obstruction.

Initial treatment for BPH is usually drug therapy (e.g. alpha blocker, PDE5 Inhibitor, finasteride/dutasteride) designed to relieve obstruction. There are several surgical

treatments for BPH that involve burning, cutting or removal of prostatic tissue.^[9] The most commonly performed minimally invasive treatments for BPH include transurethral resection of the prostate (TURP), vaporization, laser ablation, laser enucleation, open laparoscopic prostatectomy, transurethral microwave therapy (TUMT), transurethral needle ablation of the prostate (TUNA) and Urolift.

The Prostatic Urethral Lift procedure (eg. UroLift® System) is a minimally invasive approach to treating symptoms of urinary outflow obstruction secondary to benign prostatic hypertrophy (BPH). The Prostatic Urethral Lift (PUL) procedure lifts or holds the enlarged prostate tissue out of the way so it no longer blocks the urethra.

The PUL procedure consists of small permanent trans-prostatic implants, made with common implantable materials, (i.e., nitinol, stainless steel, and PET suture), placed cystoscopically to compress the prostate tissue, therefore increasing the urethral lumen and reducing obstruction to urine flow. In general, 4 or 5 implants are delivered into the prostatic urethral to maintain urethral patency.

Water Vapor Thermal Therapy (e.g., Rezum System) which uses convective radiofrequency (RF) water vapor energy to treat men with moderate-to-severe lower urinary tract symptoms.

Aquablation (AquaBeam by Procept BioRobotics) uses image guided waterjet ablation that is heat free and requires general anesthesia.

Transurethral Ultrasound Ablation (TULSA; TULSA-Pro) uses ultrasound to produce a high temperature to ablate the prostate via a catheter through the urethra. The TULSA-Pro also combines the use of Magnetic Resonance Imaging (MRI) to direct the robot driven ultrasound.

Indications/Criteria

MVP considers the following approaches to the treatment of benign prostatic hypertrophy (BPH) medically necessary for customers with benign prostatic hypertrophy:

- Transurethral resection of the prostate (TURP (52601, 52630))
- Laser prostatectomy (52647, 52648)
- Laser based procedures including contact laser ablation of the prostate (CLAP (52648))
- Holmium laser ablation, enucleation, resection (HoLAP, HoLEP, HoLRP (52649))
- Open laparoscopic prostatectomy (55801, 55821, 55831)
- Photoselective vaporization of the prostate (PVP (52648))
- Transurethral electrovaporization (TUVP, TVP, TUEP, TUVRP (52648))
- Transurethral microwave thermotherapy (TUMT (53850))

• Transurethral incision of the prostate (TUIP (54520))

Prostatic urethral lift (e.g., UroLift) is considered medically necessary for the treatment of symptomatic benign prostatic hyperplasia (BPH) when ALL of the following criteria are met:

- age 45 or above
- estimated prostate volume < 100 cc
- failure, contraindication, or intolerance to a trial of conventional medication therapy for BPH. (e.g., alpha blocker, PDE5 Inhibitor, finasteride/dutasteride)

The UroLift® System should not be used if the patient has:

- Prostate volume of > 100 cc
- A urinary tract infection
- Urethra conditions that may prevent insertion of delivery system into the bladder
- Urinary incontinence
- Current gross hernaturia
- A known allergy to nickel

Water vapor thermal therapy (Rezum System) is considered medically necessary for the treatment of symptomatic benign prostatic hyperplasia (BPH) when ALL of the following criteria are met:

- Age 50 or above
- Symptomatic despite maximal medical management including ALL of the following:
 - o International Prostate Symptom Score (IPSS) greater than or equal to 13
 - Maximum urinary flow rate (Qmax) or less than or equal to 15 ml/s (voided volume greater than 125ml)
 - Failure, contraindication, or intolerance to a trial of conventional medical therapy for BPH. (e.g., alpha blocker, PDE5 Inhibitor, finasteride/dutasteride)
- Prostate volume of 30-80 ml
- Poor candidate for other surgical interventions for BPH due to underlying disease or high risk of bleeding

Water Vapor Thermal Therapy is not medically necessary if there is any of the following:

- Known or suspected prostate cancer or prostate specific antigen (PSA) greater than 10ng/ml
- Active urinary tract infection

- History of bacterial prostatitis in the past three (3) months
- Prior prostate surgery
- Neurogenic bladder
- Active urethral stricture

Exclusions

Transurethral waterjet ablation (aquablation) proposed for the treatment of benign prostate hypertrophy is considered investigational because there is a low-quality body of evidence regarding the safety and effectiveness of the procedure compared with other treatments.

Transurethral Ultrasound Ablation (TULSA; TULSA-Pro) Procedure proposed for the treatment of benign prostate hypertrophy is considered investigational because there is a low-quality body of evidence regarding the safety and effectiveness of the procedure compared with other treatments.

Medicare Variation

Treatment for lower urinary tract symptoms using fluid jet system (aquablation) will be covered for Medicare customer ONCE when the following criteria is met:

- 1. Indications including **ALL** of the following:
 - a. Prostate volume of 30-150 cc by transrectal ultrasound (TRUS)
 - b. Persistent moderate to severe symptoms despite maximal medical management including **ALL** of the following:
 - i. International Prostate Symptom Score (IPSS) ≥12
 - ii. Maximum urinary flow rate (Qmax) of ≤15 mL/s (voided volume greater than 125 cc)
 - iii. Failure, contraindication or intolerance to at least three months of conventional medical therapy for LUTS/BPH (e.g., alpha blocker, PDE5 Inhibitor, finasteride/dutasteride)
- 2. Only treatment using an FDA approved/cleared device will be considered reasonable and necessary.

Limitations

The following are considered not reasonable and necessary:

- 1. Body mass index ≥ 42 kg/m²
- 2. Known or suspected prostate cancer (based on NCCN Prostate Cancer Early Detection guidelines) or a prostate specific antigen (PSA) > 10 ng/mL unless the patient has had a negative prostate biopsy within the last 6 months.

- 3. Bladder cancer, neurogenic bladder, bladder calculus or clinically significant bladder diverticulum
- 4. Active urinary tract or systemic infection
- 5. Treatment for chronic prostatitis
- 6. Diagnosis of urethral stricture, meatal stenosis, or bladder neck contracture
- 7. Damaged external urinary sphincter
- 8. Known allergy to device materials
- 9. Inability to safely stop anticoagulants or antiplatelet agents preoperatively.

For full Medicare coverage details refer to the following LCD for Medicare Customers: National Government Services, Inc. Local Coverage Determination (LCD) Fluid Jet System Treatment for LUTS/BPH (L38367). Revision effective date: 11/01/2020.

References (Updated 2025)

- American Urological Association Guideline: Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia: AUA Guideline. Published 2021. Amended 2023.. Available: <u>Non-Oncology Guidelines - American Urological</u> Association
- 2. American Urological Association (AUA). Transurethral destruction of prostate tissue; by radio-frequency generated water thermotherapy (Rezūm ®) appeal letter. Dec 5, 2019. Accessed Jul 23, 2020. Available Page 19 of 28 Medical Coverage Policy: 0159
- 3. Cantwell AL, Bogache WK, Richardson SF, et al. Multicentre prospective crossover study of the 'prostatic urethral lift' for the treatment of lower urinary tract symptoms secondary to benign prostatic hyperplasia. BJU Int. 2014;113(4):615-22. doi: 10.1111/bju.12540.
- 4. Chin PT, Bolton DM, Jack G, et al. Prostatic urethral lift: two-year results after treatment for lower urinary tract symptoms secondary to benign prostatic hyperplasia. Urology. 2012; 79(1):5-11.
- 5. Gupta S. L.I.F.T. study: Prostatic urethral lift for the treatment of LUTS associated with BPH. Indian J Urol. 2014;30(2):235–236.
- 6. Kaplan S. The prostate urethral lift: will it be uplifting or downgraded as a treatment strategy for benign prostatic hyperplasia? European Urol. 2015;67:714–715.
- 7. McNicholas TA, Woo HH, Chin PT, et al. Minimally invasive prostatic urethral lift: surgical technique and multinational experience. European Urology. 2013;64:292-299. www.sciencedirect.com.
- 8. McNicholas T. Editorial: Going with the flow! Relieving lower urinary tract symptoms and preserving ejaculation. BJUI. 2014:518-519.

- 9. McVary KT, Gange SN, Shore ND, et al.Treatment of LUTS secondary to BPH while preserving sexual function: randomized controlled study of prostatic urethral lift. J Sex Med. 2014;11(1):279-287
- 10. McVary KT, Roehrborn CG. Three-Year Outcomes of the Prospective, Randomized Controlled Rezūm System Study: Convective Radiofrequency Thermal Therapy for Treatment of Lower Urinary Tract Symptoms Due to Benign Prostatic Hyperplasia. Urology. 2018 Jan;111:1-9. doi: 10.1016/j.urology.2017.10.023. Epub 2017 Nov 6. PMID: 29122620.
- McVary KT, Rogers T, Roehrborn CG. Rezūm Water Vapor Thermal Therapy for Lower Urinary Tract Symptoms Associated With Benign Prostatic Hyperplasia: 4-Year Results From Randomized Controlled Study. Urology. 2019 Apr;126:171-179. doi: 10.1016/j.urology.2018.12.041. Epub 2019 Jan 21. PMID: 30677455.
- 12. Moul JW. Men's Health. Benign prostatic hyperplasia. In: Bope ET, Kellerman R, Rakel RE, editors. Conn's Current Therapy 2018, Philadelphia, PA: Saunders Elsevier; Ch 16. 1064-7.
- 13. National Institute for Health and Care Excellence (NICE). Insertion of prostatic urethral lift implants to treat lower urinary tract symptoms secondary to benign prostatic hyperplasia. 2014;475:1-7. www.guidance.nice.org.uk/ipg475.
- 14. National Institute for Health and Care Excellence (NICE). UroLift for treating lower urinary tract symptoms of benign prostatichyperplasia. September 2015.
- 15. Perera M, Roberts MJ, Doi SAR, Bolton D. Prostatic urethral lift improves urinary symptoms and flow while preserving sexual function for men with benign prostatic hyperplasia: a systematic review and meta-analysis. Eur Urol. 2015;67:704-713.
- 16. Rees J. Editorial: The prostatic urethral lift: a new treatment for LUTS. The Practitioner. 2014;258(1767):5.
- 17. Roehrborn CG, Gange SN, Shore ND, et al. The prostatic urethral lift for the treatment of lower urinary tract symptoms associated with prostate enlargement due to benign prostatic hyperplasia: the L.I.F.T. Study. J Urol. 2013;190(6):2161-2167.
- 18. Roehrborn CG, Gange SN, Shore ND, et al. Durability of the prostatic urethral Lift: 2-year results of the L.I.F.T. study. Urology Practice. 2015;2:1-7.
- 19. Roehrborn CG, Rukstalis DB, Barkin J, et al. Three year results of the prostatic urethral L.I.F.T. study. Canadian Journal of Urology. 2015;22(3):7772-7782.
- 20. Shore N, Freedman S, Gange S, et al. Prospective multi-center study elucidating patient experience after prostatic urethral lift. Canadian Journal of Urology. 2014;21(1):7094-7101.

- 21. Woo HH, Bolton DM, Laborde E, et al. Preservation of sexual function with the prostatic urethral lift: a novel treatment for lower urinary tract symptoms secondary to benign prostatic hyperplasia. J Sex Med. 2012;9:568–575.
- 22. Winters JC, Dmochowski RR, Goldman HB, Herndon CDA, Kobashi KC, Kraus SR, et al. Urodynamic Studies in Adults: AUA/SUFU Guideline. J Urol. 2012;188(6):2455-63.
- 23. Woo HH, Bolton DM, Laborde E, et al. Preservation of sexual function with the prostatic urethral lift: a novel treatment for lower urinary tract symptoms secondary to benign prostatic hyperplasia. J Sex Med. 2012;9:568–575.
- 24. UroLift® System. Available: http://urolift.com/urolift-system/
- 25. Hayes, Inc. Health Technology Brief. Rezūm System (NxThera Inc.) for Benign Prostatic Hyperplasia. Lansdale, PA: Hayes, Inc.: Feb 28, 2018 Annual Review: March 12, 2020
- 26. Dixon CM, Rijo Cedano E, Mynderse LA, Larson TR. Transurethral convective water vapor as a treatment for lower urinary tract symptomatology due to benign prostatic hyperplasia using the Rezūm® system: evaluation of acute ablative capabilities in the human prostate. Res Rep Urol. 2015a Jan 30;7:13-8.
- 27. McVary KT, Roehrborn CG. Three-Year Outcomes of the Prospective, Randomized Controlled Rezūm System Study: Convective Radiofrequency Thermal Therapy for Treatment of Lower Urinary Tract Symptoms Due to Benign Prostatic Hyperplasia. Urology. 2018 Jan;111:1-9.
- 28. Darson MF, Alexander EE, Schiffman ZJ, Lewitton M, Light RA, Sutton MA, Delgado-Rodriguez C, Gonzalez RR. Procedural techniques and multicenter postmarket experience using minimally invasive convective radiofrequency thermal therapy with Rezūm system for treatment of lower urinary tract symptoms due to benign prostatic hyperplasia. Res Rep Urol. 2017 Aug 21;9:159-168.
- 29. Hayes, Inc. Health Technology Assessment. High-Intensity Focused Ultrasound For Salvage Therapy Of Recurrent Prostate Cancer. Lansdale, PA: Hayes, Inc.: March 30, 2019; Annual Review: April 23, 2019
- 30. Medicare Local Coverage Decision: National Government Solutions (NGS), LLC. Local Coverage Decision, Water Vapor Thermal Therapy for LUTS/BPH (L37808) Original Effective date: 12/01/2018. Retired 02/15/2024
- 31. Medicare Local Coverage Determination: Palmetto GBA. Local Coverage Determination (LCD): Minimally Invasive Treatment for Benign Prostatic Hyperplasia Involving Prostatic Urethral Lift (Urolift®) (L36109) RETIRED 05/01/2020.
- 32. Centers for Medicare and Medicaid Services. National Government Services, Inc. Local Coverage Determination (LCD) for Fluid Jet System Treatment for LUTS/BPH (L38367) (Revision Effective Date 11/01/2020). Available: https://www.cms.gov/

- 33. Lerner LB, McVary, KT, Barry MJ et al: Management of lower urinary tract symptoms attributed to benign prostatic hyperplasia: AUA Guideline part I, initial work-up and medical management. J Urol 2021; 206: 806.
- 34. Hayes Health Technology Assessment. Aquablation for Treatment of Benign Prostatic Hyperplasia. HAYES, Inc.; © 2022 Hayes, a symplr company. March 30, 2021. Annual review March 21, 2022.

Customer Product	Medical Management Requirements*
New York Products	
HMO	Prior Auth
PPO in Plan	Prior Auth
PPO OOP	Prior Auth
POS in Plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Prior Auth
MVP Child Health Plus	Prior Auth
MVP Harmonious Health Care Plan	Prior Auth
MVP Medicare Complete Wellness	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP Medicare WellSelect PPO	Prior Auth
MVP Medicare WellSelect Plus PPO	Prior Auth
MVP Medicare Patriot Plan PPO	Prior Auth Prior Auth
MVP DualAccess D-SNP HMO	Prior Auth Prior Auth
MVP DualAccess Complete D-SNP HMO	Prior Auth
MVP DualAccess Plus D-SNP HMO	Prior Auth
UVM Health Advantage Select PPO	Prior Auth Prior Auth
USA Care PPO	Potential for Retrospective Review
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	
ASO	Prior Auth See SPD
Vermont Products	See SPD
POS in Plan	Dries Auth
	Prior Auth
POS OOP NAVD Madisara Professed Cold LIMO DOS	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP VT HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
ASO	See SPD

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Revision History:

02/01/2022 – Coverage added for water vapor thermal therapy (e.g., Rezum system) based on Medicare criteria and American Urological Association. Removed Medicare variation for water vapor thermal therapy. Criteria was removed requiring three months of two different combination of medication therapies. HIFU procedure (55880) was moved to the Investigational Procedures policy.

06/01/2023 -Added exclusion and Medicare variation for aquablation.

06/01/2025 – Annual review, TULSA (CPT Codes: 51721, 55881, 55882) added to exclusions, update to Medicare variation



Biofeedback Therapy

Type of Policy: Medical/Behavioral Health

Prior Approval Date: 04/03/2023

Approval Date: 02/17/2025

Effective Date: 06/01/2025

Related Polices: N/A

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

N/A

Codes Subject to Retrospective Review

N/A

Experimental/Investigational

N/A

Common Diagnosis Codes

ICD-10 Diagnosis Codes: G43.001, G43.009, G43.019, G43.101, G43.109, G43.111, G43.119, G44.209, G43.401, G43.409, G43.411, G43.419, G43.501, G43.509, G43.511, G43.519, G43.601, G43.609, G43.611, G43.619, G43.701, G43.709, G43.711, G43.719, G43.801, G43.809, G43.811, G43.819, G43.821, G43.829, G43.831, G43.839, G43.a0, G43.b0, G43.c0, G43.D0, G43.A1, G43.B1, G43.C1, G43.D1, K59.01, K59.02, N39.3, N39.41, N39.46, R15.0, R15.1, R15.2, R15.9, R35.0

Common Procedure Codes

CPT Codes:

Biofeedback Therapy Page 1 of 9

90875 - Individual psychophysiological therapy incorporating biofeedback training by any modality (face-to-face with the patient), with psychotherapy (eg, insight oriented, behavior modifying or supportive psychotherapy); 30 minutes

90876 - Individual psychophysiological therapy incorporating biofeedback training by any modality (face-to-face with the patient), with psychotherapy (eg, insight oriented, behavior modifying or supportive psychotherapy); 45 minutes

90901- Biofeedback training by any modality

90912 - Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry, when performed; initial 15 minutes of one-on-one physician or other qualified health care professional contact with the patient

90913 - Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry, when performed; each additional 15 minutes of one-on-one physician or other qualified health care professional contact with the patient

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy.

Overview

Biofeedback is a behavioral training technique that teaches a person how to control certain autonomic reactions such as heart rate, blood pressure, skin temperature, and muscular tension. Biofeedback therapy provides a visual or audio guide of the muscle contraction. It emphasizes relaxation, enhancement of muscle contraction and/or stress reduction. When used together, patients are taught to modify their physiologic response in an effort to gain muscle function thereby decreasing or eliminating incontinence, chronic constipation, migraine headaches, high blood pressure or chronic pain. Although there are numerous biofeedback devices available for home use, biofeedback should be performed in a clinical setting with the continuous presence of the physician or by a qualified non-physician practitioner.

Documentation Requirements

Documentation Requirements for urinary incontinence:

The medical record documentation must include:

- a complete history and physical examination;
- a genitourinary or gastrointestinal evaluation;
- evidence that the patient has failed a three-month trial of conservative interventions i.e., muscle exercises, habit training, or diet modification; and

Biofeedback Therapy Page 2 of 9

 evidence of failed medication therapy for urge incontinence unless medications are contraindicated.

For patients receiving continued biofeedback services, the medical record documentation must demonstrate continued improvement.

Treatment must be provided by a physician or by a qualified non-physician provider.

Indications/Criteria

Outpatient biofeedback therapy will be covered for the following:

- urinary incontinence (stress, urgency, mixed, or overflow); or
- fecal incontinence (adults only, 18 years of age and older); or
- constipation (adults only, 18 years of age and older); or
- anal spasms; or
- dysfunctional voiding in children; or
- migraine and tension-type headache; or
- muscle re-education of specific extremity muscle groups due to abnormal spasticity or weakness due to a stroke

Biofeedback therapy is covered when all the following criteria are met:

- the patient is motivated to actively participate in the treatment plan, including being responsive to the care plan requirements (e.g., practice and follow through at home); and
- the patient must be cognitively intact and capable of participating in the treatment plan (physically as well intellectually); and
- the patient's condition is appropriately treated with biofeedback (e.g., pathology does not exist to prevent success of the treatment).

Biofeedback in anorectal retraining (including Electromyography [EMG]) and/or manometry (which provides information on sphincter pressure):

 the use of biofeedback therapy for anorectal retraining may be utilized for anal abnormalities of spasticity, incapacitating muscle spasm, and/or muscle weakness.

Outpatient biofeedback will be covered up to a maximum of six sessions.

All referrals must be from colorectal, gastrointestinal, gynecologic-urology, neurologists; or obstetrical/gynecology practitioners.

Exclusions

Additional biofeedback sessions for periodic reinforcement are not covered.

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Biofeedback therapy is not covered for the treatment of ordinary muscle tension states, psychosomatic conditions, or any other condition not listed in the Indications/Criteria section.

Biofeedback is considered investigational for behavioral health disorders and does not currently meet the criteria standard for inclusion as an evidence-based treatment due to the low quality of published clinical evidence.

Biofeedback is considered investigational as a treatment for constipation or anal spasms in children as there is a lack of evidence in its effectiveness for these conditions.

Medicare Managed Care Variation

Medicare customers are covered according to the National Coverage Determination (NCD) for Biofeedback Therapy for the Treatment of Urinary Incontinence (30.1.1):

Biofeedback is covered for the treatment of stress and/or urge incontinence in customers who have failed a documented trial of pelvic muscle exercise training. A failed trial of pelvic muscle exercise training is defined as no clinically significant improvement in urinary incontinence after completing four weeks of an ordered plan of pelvic muscle exercises to increase periurethral muscle strength.

Medicare customers are covered according to the National Coverage Determination (NCD) for Biofeedback Therapy (30.1):

Outpatient biofeedback therapy is allowable only when it is reasonable and necessary for the individual patient for muscle re-education of specific muscle groups for:

- treating pathological muscle abnormalities of spasticity, incapacitating muscle spasm or weakness (muscle tension does not qualify) when conventional treatments (heat, cold, massage, exercise, and support) have not been successful.
- This therapy is not covered for treatment of ordinary muscle tension states or for psychosomatic conditions.
- Home use of biofeedback is not covered.

MVP Managed Medicaid, MVP Child Health Plus Variation

Biofeedback therapy, training, and devices are not covered for MVP Managed Medicaid and MVP Child Health Plus plans.

References (Reviewed 2023)

1. Agency for Healthcare Research and Quality (AHRQ). Comparative effectiveness review. Number 165. Treatments for fecal incontinence. Mar 2016. Retrieved on October 1, 2021. Available: <u>Treatments for Fecal Incontinence | Effective Health Care (EHC) Program (ahrq.qov).</u>

Biofeedback Therapy Page 4 of 9

- 2. American Society of Colon and Rectal Surgeons. Clinical practice guideline for the treatment of fecal incontinence. 2015. Available: https://www.fascrs.org/physicians/clinical-practice-guidelines.
- 3. American Society of Colon and Rectal Surgeons. Clinical practice guideline for the evaluation and management of constipation. 2016. Available: https://www.fascrs.org/physicians/clinical-practice-guidelines.
- 4. Centers for Medicare & Medicaid Services (CMS). Medicare Coverage Database. NCD for Biofeedback Therapy (30.1) Available: MCD Search (cms.gov).
- 5. Centers for Medicare & Medicaid Services (CMS). Medicare Coverage Database. NCD for Biofeedback Therapy for the Treatment of Urinary Incontinence (30.1.1) Effective Date Jul 1, 2001 Available: MCD Search (cms.gov).
- National Institute for Health and Clinical Excellence (NICE). Clinical guideline 49.
 Fecal incontinence. June 2007. Available: http://guidance.nice.org.uk/CG49/guidance/pdf/English.
- 7. National Institute for Health and Clinical Excellence (NICE). Clinical guideline 40. The management of urinary incontinence in women. June 2007. Available: http://www.nice.org.uk/quidance/ng123.
- 8. Burgio KL, Goode PS, Locher JL, Umlauf MG, Roth DL, Richter HE, Varner RE, Lloyd LK. Behavioral training with and without biofeedback in the treatment of urge incontinence in older women: a randomized controlled trial. JAMA. 2002 Nov 13; 288(18):2293-9.
- 9. Dannecker C, Wolf V, Raab R, Hepp H, Anthuber C. EMG-biofeedback assisted pelvic floor muscle training is an effective therapy of stress urinary or mixed incontinence: a 7-year experience with 390 patients. Arch Gynecol Obstet. 2005 Dec; 273(2):93-7.
- 10. Shamliyan, TA, et al. Systematic review; randomized, controlled trials of non-surgical treatments for urinary incontinence in women. Annals of Internal Medicine. 2008 Mar 18; 148(6):459-73.
- 11. Norton, C. Biofeedback and/or sphincter exercises for the treatment of fecal incontinence in adults. Cochrane Database Systematic Review. 2006 Jul 19; 3:CD002111.
- 12. Heymen S, Scarlett Y, Jones K, Ringel Y, Drossman D, Whitehead WE. Randomized, controlled trial shows biofeedback to be superior to alternative treatments for patients with pelvic floor dyssynergia-type constipation. Dis Colon Rectum. 2007 Apr; 50(4):428-41.
- 13. Grassi, L. et al. Electromyographic biofeedback-assisted relaxation training in juvenile episodic tension-type headache: clinical outcome at three year follow-up. Cephalalgia. 2001; 21(8); 798-803.

Biofeedback Therapy Page 5 of 9

- 14. Sartory, G. et al. A comparison of psychological and pharmacological treatment of pediatric migraine. Behavior, Research, and Therapy. 1998; 36(12): 1155-1170.
- 15. Nestoriuc, y., et al. Biofeedback treatment for headache disorders: A comprehensive efficacy review. Appl Psychophysiol Biofeedback. 2008; 33:125-140.
- 16. Nestoriuc, Y. and Martin, A. Efficacy of biofeedback for migraine: A meta-analysis. Pain. 2007; 128:111-127.Nestoriuc, Y., et al. Meta-analysis of biofeedback for tension-type headache: Efficacy, specificity, and treatment moderators. J Consult Clin Psychol. 2008; 76:379-396.
- 17. Fitz FF, Resende AP, Stüpp L, Sartori MG, Girão MJ, Castro RA. Biofeedback for the treatment of female pelvic floor muscle dysfunction: a systematic review and meta-analysis. Int Urogynecol J. 2012 Mar 17.
- 18. Herderschee R, Hay-Smith EJC. Herbison GP, Roovers JP, Heineman MJ. Feedback or biofeedback to augment pelvic floor muscle training for urinary incontinence in women. Cochrane Database of Systematic Reviews 2011, Issue 7. Art. No.: CD009252. DOI: 10.1002/14651858.CD009252.
- 19. Enck P, van der Voort IR, Klosterhalfen S. Biofeedback therapy in fecal incontinence and constipation. Neurogastroenterol Motil. 2009 Jun 30.
- 20. Drzewiecki BA1, Kelly PR, et al. Biofeedback training for lower urinary tractsymptoms: factors affecting efficacy. J Urol. 2009 Oct;182(4 Suppl):2050-5.
- 21. Kajbafzadeh AM1, Sharifi-Rad L, et al. Animated biofeedback: an ideal treatment for children with dysfunctional elimination syndrome. J Urol. 2011 Dec;186(6):2379-84.
- 22. Koenig JF1, McKenna PH. Biofeedback therapy for dysfunctional voiding in children. Curr Urol Rep. 2011 Apr;12(2):144-52.
- 23. Krzemiska K1, Maternik M1, et al. High efficacy of biofeedback therapy for treatment of dysfunctional voiding in children. Cent European J Urol. 2012;65(4):212-5.
- 24. Glombiewski JA, Bernardy K, Hauser W. Efficacy of EMG- and EEG-biofeedback in fibromyalgia syndrome: A meta-analysis and a systematic review of randomized controlled trials. Evid Based Complement Alternat Med. 2013;2013:962741.
- 25. Hayes Inc. Health Technology Assessment. Biofeedback for the treatment of dysfunctional voiding in children. March 4, 2009 Annual Review: March 10, 2011 ARCHIVED April 4, 2012
- 26. Hayes Inc. Health Technology Assessment. Electroencephalogram (EEG) Biofeedback Therapy. April 11, 2003. Annual Review March 13, 2008 ARCHIVED November 12, 2008.
- 27. North American Society for Pediatric Gastroenterology, Hepatology and nutrition (NASPGHAN). Clinical Guidelines. Evaluation and treatment of functional

Biofeedback Therapy Page 6 of 9

- constipation in infants and children: evidence-based recommendations for ESPGHAN and NASPGHAN.
- 28. Tabbers MM, DiLorenzo C, Berger MY, Faure C, Langendam MW, Nurko S, Staiano A, Vandenplas Y, Benninga MA; European Society for Pediatric Gastroenterology, Hepatology, and Nutrition; North American Society for Pediatric Gastroenterology. Evaluation and treatment of functional constipation in infants and children: evidence-based recommendations from ESPGHAN and NASPGHAN. J Pediatr Gastroenterol Nutr. 2014 Feb;58(2):258-74.

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Customer Product	Medical Management Requirements*
New York Products	
HMO	Potential for Retrospective Review
PPO in Plan	Potential for Retrospective Review
PPO OOP	Potential for Retrospective Review
POS in Plan	Potential for Retrospective Review
POS OOP	Potential for Retrospective Review
Essential Plan	Potential for Retrospective Review
MVP Medicaid Managed Care	Not Covered
MVP Child Health Plus	Not Covered
MVP Harmonious Health Care Plan	Not Covered
MVP Medicare Complete Wellness	Potential for Retrospective Review
MVP Medicare Preferred Gold HMO POS	Potential for Retrospective Review
MVP Medicare Secure HMO POS	Potential for Retrospective Review
MVP Medicare Secure Plus HMO POS	Potential for Retrospective Review
MVP Medicare WellSelect PPO	Potential for Retrospective Review
MVP Medicare WellSelect Plus PPO	Potential for Retrospective Review
MVP Medicare Patriot Plan PPO	Potential for Retrospective Review
MVP DualAccess D-SNP HMO	Potential for Retrospective Review
MVP DualAccess Complete D-SNP HMO	Potential for Retrospective Review
MVP DualAccess Plus D-SNP HMO	Potential for Retrospective Review
UVM Health Advantage Select PPO	Potential for Retrospective Review
USA Care PPO	Potential for Retrospective Review
Healthy NY	Potential for Retrospective Review
MVP Premier	Potential for Retrospective Review
MVP Premier Plus	Potential for Retrospective Review
MVP Premier Plus HDHP	Potential for Retrospective Review
MVP Secure	Potential for Retrospective Review
MVP EPO	Potential for Retrospective Review
MVP EPO HDHP	Potential for Retrospective Review
MVP PPO	Potential for Retrospective Review
MVP PPO HDHP	Potential for Retrospective Review
Student Health Plans	Potential for Retrospective Review
ASO	See SPD
Vermont Products	
POS in Plan	Potential for Retrospective Review
POS OOP	Potential for Retrospective Review
MVP Medicare Preferred Gold HMO POS	Potential for Retrospective Review
MVP Medicare Secure Plus HMO POS	Potential for Retrospective Review
MVP VT HMO	Potential for Retrospective Review
MVP VT HDHP HMO	Potential for Retrospective Review
MVP VT Plus HMO	Potential for Retrospective Review
MVP VT Plus HDHP HMO	Potential for Retrospective Review
MVP Secure	Potential for Retrospective Review
ASO	See SPD

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review.

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

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Revision History:

04/01/2022 – Annual review; added additional criteria for stroke indications, references and websites sections updated.

06/01/2023-Clarification added that biofeedback for fecal incontinence or constipation is covered for customers 18 years or older, only. Exclusion for biofeedback devices for home use was moved to the Electrical Stimulation Devices policy; coverage position is unchanged.

06/01/2025 - Annual review with no changes to coverage.

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Biventricular Pacing – Cardiac Resynchronization Therapy

Type of Policy: Surgical/Medical

Prior Approval Date: 08/02/2021

Approval Date: 09/11/2023

Effective Date: 12/01/2023

Related Polices: Implantable Cardioverter Defibrillators,

Implantable Dual Chamber Automatic

Defibrillators, Cardiac

Resynchronization Devices

Codes Requiring Prior Authorization

CPT/HCPCS Codes	Description
33213	Insertion of pacemaker pulse generator only; with existing dual leads
33214	Upgrade of implanted pacemaker system, conversion of single chamber system to dual chamber system (includes removal of previously placed pulse generator, testing of existing lead, insertion of new lead, insertion of new pulse generator)
33224	Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, with attachment to previously placed pacemaker or implantable defibrillator pulse generator (including revision of pocket, removal, insertion, and/or replacement of existing generator)

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

Codes Requiring Retrospective Review

Experimental/Investigational

CPT Code	Description

Insertion of wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming, and imaging supervision and interpretation, when performed; complete system
(includes electrode and generator [transmitter and battery])
Insertion of wireless cardiac stimulator for left ventricular pacing,
including device interrogation and programming, and imaging
supervision and interpretation, when performed; electrode only
Insertion of wireless cardiac stimulator for left ventricular pacing,
including device interrogation and programming, and imaging
supervision and interpretation, when performed; pulse generator
component(s) (battery and/or transmitter) only
Removal of only pulse generator component(s) (battery and/or
transmitter) of wireless cardiac stimulator for left ventricular pacing
Removal and replacement of wireless cardiac stimulator for left
ventricular pacing; pulse generator component(s) (battery and/or
transmitter)
Removal and replacement of wireless cardiac stimulator for left
ventricular pacing; pulse generator component(s) (battery and/or
transmitter), including placement of a new electrode

Common Diagnosis Codes

Common Diagnosis Codes associated with this policy have been provided for informational purposes only. The list of codes may not be all-inclusive and may be updated to reflect any applicable revisions to the ICD-10 code set and/or medical necessity guidelines applied in this policy.

ICD-10 Diagnosis Codes: I44.4, I44.5, I44.60, I44.69, I44.7, I45.0, I45.19, I44.30, I44.39, I45.4, I45.2, I46.2, I46.8, I46.9, I47.0, I47.2, I48.0, I48.2, I48.91, I49.01, I49.02, I50.20, I50.21, I50.23, I50.30, I50.31, I50.32, I50.33, I50.40, I50.41, I50.42, I50.43, I50.1, I50.9, Z86.79

Common Procedure Codes

CPT/HCPCS	Description
33208	Insertion of new or replacement of permanent pacemaker with transvenous electrode(s); atrial and ventricular
33225	Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, at time of insertion of implantable defibrillator or pacemaker pulse generator (eg, for upgrade to dual chamber system) (List separately in addition to code for primary procedure)
C1779	Lead, pacemaker, transvenous VDD single pass
C1785	Pacemaker, dual chamber, rate-responsive (implantable)
C1898	Lead, pacemaker, other than transvenous VDD single pass

C1900	Lead, left ventricular coronary venous system	
C2619	Pacemaker, dual chamber, nonrate-responsive (implantable)	
C2620	Pacemaker, single chamber, nonrate-responsive (implantable)	
C2621	Pacemaker, other than single or dual chamber (implantable)	
C7537	Insertion of new or replacement of permanent pacemaker with atrial transvenous electrode(s), with insertion of pacing electrode, cardiac venous system, for left ventricular pacing, at time of insertion of implantable defibrillator or pacemaker pulse generator (e.g., for upgrade to dual chamber system)	
C7538	Insertion of new or replacement of permanent pacemaker with ventricular transvenous electrode(s), with insertion of pacing electrode, cardiac venous system, for left ventricular pacing, at time of insertion of implantable defibrillator or pacemaker pulse generator (e.g., for upgrade to dual chamber system)	
C7539	Insertion of new or replacement of permanent pacemaker with atrial and ventricular transvenous electrode(s), with insertion of pacing electrode, cardiac venous system, for left ventricular pacing, at time of insertion of implantable defibrillator or pacemaker pulse generator (e.g., for upgrade to dual chamber system)	
C7540	Removal of permanent pacemaker pulse generator with replacement of pacemaker pulse generator, dual lead system, with insertion of pacing electrode, cardiac venous system, for left ventricular pacing, at time of insertion of implantable defibrillator or pacemaker pulse generator (e.g., for upgrade to dual chamber system)	

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

Biventricular pacing or Cardiac Resynchronization Therapy (CRT) [also called Cardiac Resynchronization Therapy Pacemaker (CRT-P)] has gained interest since its introduction in the early 1990's. CRT is the term applied to reestablishing synchronous contraction between the left ventricular free wall and the ventricular septum in an attempt to improve left ventricular efficiency and, subsequently, to improve functional class in patients with congestive heart failure, where it has been most extensively studied. However, additional studies have looked at patients with an indication for permanent

pacing due to bradycardia in the setting of AV block who will be pacing frequently through the ventricular lead. These studies have demonstrated that in patients with mildly reduced LV function, without heart failure, the use of CRT reduces the risk of further left ventricular dysfunction in those paced more than 40% of the time. Generally, CRT has been used to describe biventricular pacing, but cardiac resynchronization can be achieved by left ventricular pacing only in some patients. CRT is designed to help the right (RV) and left ventricle (LV) beat at the same time in a normal sequence treating ventricular desynchrony.

Indications/Criteria

Documentation Requirements:

Medical necessity must be documented in the medical record and available upon request, including diagnostic studies (EP studies), and either evidence of current ventricular pacing over 40% of the time or reason for anticipated ventricular pacing over 40% of the time (i.e., planned AV nodal ablation to create a complete heart block, etc). Documentation of a baseline LVEF between 35 and 50% by angiography, radionuclide scanning or echocardiography.

Policy Criteria

For customers with ejection fraction >35% and ≤50%:

• Customer expected to require ventricular pacing >40 % of the time.

Replacement of a biventricular pacemaker generator alone and/or leads is considered medically necessary.

Exclusions

- The use of a biventricular pacemaker alone for CRT for any other indication is considered experimental, investigational or unproven.
- His bundle pacing (HBP) for any indication is considered experimental, investigational, or unproven.
- Triple-site or triventricular pacing CRT for any indication is considered experimental, investigational, or unproven.
- Wireless pacing CRT for any indication is considered experimental, investigational, or unproven.

Medicare

Based on review there is no Medicare Local Coverage Determination (LCD) or Medicare National Coverage Determination (NCD).

References (2023)

- 1. Adabag S, Roukoz H, Anand IS, Moss AJ. Cardiac resynchronization therapy in patients with minimal heart failure: a systematic review and meta-analysis. J Am Coll Cardiol. 2011 Aug 23;58(9):935-41. doi: 10.1016/j.jacc.2011.05.022. PMID: 21851882.
- Bordachar P, Gras D, Clementy N, Defaye P, Mondoly P, Boveda S, Anselme F, Klug D, Piot O, Sadoul N, Babuty D, Leclercq C. Clinical impact of an additional left ventricular lead in cardiac resynchronization therapy nonresponders: The V3 trial. Heart Rhythm. 2018 Jun;15(6):870-876. doi: 10.1016/j.hrthm.2017.12.028. Epub 2017 Dec 26. PMID: 29288035.
- 3. Boston Scientific. Cardiac resynchronization (CRT) devices. Accessed November 9, 2020. Available at URL address: https://www.bostonscientific.com/en-US/patients/about-your-device/crt-devices.html
- 4. Centers for Medicare and Medicaid Services. Local Coverage Determination (LCD): Biventricular Pacing/Cardiac Resynchronization Therapy (L33271) Retired March 25, 2023.
- Cleland JG, Daubert JC, Erdmann E, Freemantle N, Gras D, Kappenberger L, Tavazzi L; Cardiac Resynchronization-Heart Failure (CARE-HF) Study Investigators. The effect of cardiac resynchronization on morbidity and mortality in heart failure. N Engl J Med. 2005 Apr 14;352(15):1539-49. doi: 10.1056/NEJMoa050496. Epub 2005 Mar 7. PMID: 15753115.
- 6. Cleland JG, Calvert MJ, Verboven Y, Freemantle N. Effects of cardiac resynchronization therapy on long-term quality of life: an analysis from the CArdiac Resynchronisation-Heart Failure (CARE-HF) study. Am Heart J. 2009 Mar;157(3):457-66. doi: 10.1016/j.ahj.2008.11.006. Epub 2009 Jan 20. PMID: 19249415.
- 7. Dupont M, Rickard J, Baranowski B, Varma N, Dresing T, Gabi A, Finucan M, Mullens W, Wilkoff BL, Tang WH. Differential response to cardiac resynchronization therapy and clinical outcomes according to QRS morphology and QRS duration. J Am Coll Cardiol. 2012 Aug 14;60(7):592-8. doi: 10.1016/j.jacc.2012.03.059. Epub 2012 Jul 11. PMID: 22796255.
- 8. ebrSystems. Inc©. WiSE System®. Accessed November 9, 2020. Available at URL address: http://ebrsystemsinc.com/
- 9. Gold MR, Thébault C, Linde C, Abraham WT, Gerritse B, Ghio S, St John Sutton M, Daubert JC. Effect of QRS duration and morphology on cardiac resynchronization therapy outcomes in mild heart failure: results from the Resynchronization Reverses Remodeling in Systolic Left Ventricular Dysfunction (REVERSE) study. Circulation. 2012 Aug 14;126(7):822-9. doi: 10.1161/CIRCULATIONAHA.112.097709. Epub 2012 Jul 10. PMID: 22781424.
- 10. Goldenberg I, Hall WJ, Beck CA, Moss AJ, Barsheshet A, McNitt S, Polonsky S, Brown MW, Zareba W. Reduction of the risk of recurring heart failure events with cardiac

- resynchronization therapy: MADIT-CRT (Multicenter Automatic Defibrillator Implantation Trial With Cardiac Resynchronization Therapy). J Am Coll Cardiol. 2011 Aug 9;58(7):729-37. doi: 10.1016/j.jacc.2011.04.024. PMID: 21816309.
- 11. Gorcsan J 3rd, Abraham T, Agler DA, Bax JJ, Derumeaux G, Grimm RA, Martin R, Steinberg JS, Sutton MS, Yu CM; American Society of Echocardiography Dyssynchrony Writing Group. Echocardiography for cardiac resynchronization therapy: recommendations for performance and reporting--a report from the American Society of Echocardiography Dyssynchrony Writing Group endorsed by the Heart Rhythm Society. J Am Soc Echocardiogr. 2008 Mar;21(3):191-213. doi: 10.1016/j.echo.2008.01.003. PMID: 18314047.
- 12. Hayes, Inc. Hayes Emerging Technology Report. WiSE Cardiac Resynchronization Therapy System. Hayes © 2021 Hayes, a symplr company. February 23, 2021.
- 13. Kusumoto FM, Schoenfeld MH, Barrett C, Edgerton JR, Ellenbogen KA, Gold MR, Goldschlager NF, Hamilton RM, Joglar JA, Kim RJ, Lee R, Marine JE, McLeod CJ, Oken KR, Patton KK, Pellegrini CN, Selzman KA, Thompson A, Varosy PD. 2018 ACC/AHA/HRS Guideline on the Evaluation and Management of Patients With Bradycardia and Cardiac Conduction Delay: Executive Summary: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines, and the Heart Rhythm Society. J Am Coll Cardiol. 2019 Aug 20;74(7):932-987. doi: 10.1016/j.jacc.2018.10.043. Epub 2018 Nov 6. Erratum in: J Am Coll Cardiol. 2019 Aug 20;74(7):1014-1016. PMID: 30412710.
- 14. Lenarczyk R, Kowalski O, Sredniawa B, Pruszkowska-Skrzep P, Mazurek M, Jędrzejczyk-Patej E, Woźniak A, Pluta S, Głowacki J, Kalarus Z. Implantation feasibility, procedure-related adverse events and lead performance during 1-year follow-up in patients undergoing triple-site cardiac resynchronization therapy: a substudy of TRUST CRT randomized trial. J Cardiovasc Electrophysiol. 2012 Nov;23(11):1228-36. doi: 10.1111/j.1540-8167.2012.02375.x. Epub 2012 May 31. PMID: 22651239.
- 15. Medtronic, Inc. Cardiac synchronization therapy (CRT) Therapy Systems. Last updated Oct 2020. Accessed November 9, 2020. Available at URL address: https://www.medtronic.com/us-en/healthcareprofessionals/products/cardiac-rhythm/crt-systems.html
- 16. Moss AJ, Hall WJ, Cannom DS, Klein H, Brown MW, Daubert JP, Estes NA 3rd, Foster E, Greenberg H, Higgins SL, Pfeffer MA, Solomon SD, Wilber D, Zareba W; MADIT-CRT Trial Investigators. Cardiac-resynchronization therapy for the prevention of heart-failure events. N Engl J Med. 2009 Oct 1;361(14):1329-38. doi: 10.1056/NEJMoa0906431. Epub 2009 Sep 1. PMID: 19723701.
- 17. Pouleur AC, Knappe D, Shah AM, Uno H, Bourgoun M, Foster E, McNitt S, Hall WJ, Zareba W, Goldenberg I, Moss AJ, Pfeffer MA, Solomon SD; MADIT-CRT Investigators. Relationship between improvement in left ventricular dyssynchrony

- and contractile function and clinical outcome with cardiac resynchronization therapy: the MADIT-CRT trial. Eur Heart J. 2011 Jul;32(14):1720-9. doi: 10.1093/eurheartj/ehr185. Epub 2011 May 24. PMID: 21609974.
- 18. Qian Z, Zou F, Wang Y, Qiu Y, Chen X, Jiang H, Hou X. Permanent His bundle pacing in heart failure patients: A systematic review and meta-analysis. Pacing Clin Electrophysiol. 2019 Feb;42(2):139-145. doi: 10.1111/pace.13565. Epub 2018 Dec 13. PMID: 30515877.
- 19. Reddy VY, Miller MA, Neuzil P, Søgaard P, Butter C, Seifert M, Delnoy PP, van Erven L, Schalji M, Boersma LVA, Riahi S. Cardiac Resynchronization Therapy With Wireless Left Ventricular Endocardial Pacing: The SELECT-LV Study. J Am Coll Cardiol. 2017 May 2;69(17):2119-2129. doi: 10.1016/j.jacc.2017.02.059. PMID: 28449772.
- 20. Russo AM, Stainback RF, Bailey SR, Epstein AE, Heidenreich PA, Jessup M, Kapa S, Kremers MS, Lindsay BD, Stevenson LW. ACCF/HRS/AHA/ASE/HFSA/SCAI/SCCT/SCMR 2013 appropriate use criteria for implantable cardioverter-defibrillators and cardiac resynchronization therapy: a report of the American College of Cardiology Foundation appropriate use criteria task force, Heart Rhythm Society, American Heart Association, American Society of Echocardiography, Heart Failure Society of America, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, and Society for Cardiovascular Magnetic Resonance. J Am Coll Cardiol. 2013 Mar 26;61(12):1318-68. doi: 10.1016/j.jacc.2012.12.017. Epub 2013 Mar 1. PMID: 23453819.

Customer Product	Medical Management Requirements*
New York Products	
HMO	Prior Authorization
PPO in Plan	Prior Authorization
PPO OOP	Prior Authorization
POS in Plan	Prior Authorization
POS OOP	Prior Authorization
Essential Plan	Prior Authorization
MVP Medicaid Managed Care	Prior Authorization
MVP Child Health Plus	Prior Authorization
MVP Harmonious Health Care Plan	Prior Authorization
MVP Medicare Complete Wellness	Prior Authorization
MVP Medicare Preferred Gold HMO POS	Prior Authorization
MVP Medicare Secure HMO POS	Prior Authorization
MVP Medicare Secure Plus HMO POS	Prior Authorization
MVP Medicare WellSelect PPO	Prior Authorization
MVP Medicare WellSelect Plus PPO	Prior Authorization
MVP Medicare Patriot Plan	Prior Authorization
MVP DualAccess D-SNP HMO	Prior Authorization
MVP DualAccess Complete D-SNP HMO	Prior Authorization
MVP DualAccess Plus D-SNP HMO	Prior Authorization
UVM Health Advantage Select PPO	Prior Authorization
USA Care PPO	Potential for Retrospective Review
Healthy NY	Prior Authorization
MVP Premier	Prior Authorization
MVP Premier Plus	Prior Authorization
MVP Premier Plus HDHP	Prior Authorization
MVP Secure	Prior Authorization
MVP EPO	Prior Authorization
MVP EPO HDHP	Prior Authorization
MVP PPO	Prior Authorization
MVP PPO HDHP	Prior Authorization
Student Health Plans	Prior Authorization
ASO	See SPD
Vermont Products	
POS in Plan	Prior Authorization
POS OOP	Prior Authorization
MVP Medicare Preferred Gold HMO	Prior Authorization
MVP Medicare Secure Plus HMO POS	Prior Authorization
MVP VT HMO	Prior Authorization
MVP VT HDHP HMO	Prior Authorization
MVP VT Plus HMO	Prior Authorization
MVP VT Plus HDHP HMO	Prior Authorization
MVP Secure	Prior Authorization
ASO	See SPD

[♦] Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review.

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Revision History:

12/01/2021 – New policy effective date.

MVP Health Care Medical Policy



Blepharoplasty, Brow Lift, and Ptosis Repair

Type of Policy: Surgical

Prior Approval Date: 05/05/2021

Approval Date: 06/05/2023

Effective Date: 08/01/2023

Related Polices: N/A

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

N/A

Codes Requiring Retrospective Review

N/A

Experimental/Investigational

N/A

Common Diagnosis Codes

ICD-10- CM Diagnosis Codes: G24.5, G51.0-G51.9, H02.30-H02.36, H02.401-H02.439, H02.511-H02.59, H02.831-H02.839, H02.511-H02.59, H02.831-H02.839, H02.841-H02.849, H02.851-H02-859, H02.861-H02.869, H02.871-H02.879, H02.89, H53.001-H53.039, H53.40-H53.489, Q10.0, Q10.3, Q11.1

Common Diagnosis Codes associated with this policy have been provided for informational purposes only. The list of codes may not be all-inclusive and may be updated to reflect any applicable revisions to the ICD-10 code set and/or medical necessity guidelines applied in this policy.

Common Procedure Codes

CPT Codes: 15820, 15821, 15822, 15823, 67900, 67901, 67902, 67903, 67904, 67906, 67908, 67909, 67911, 67914, 67915, 67916, 67917, 67921, 67922, 67923, 67924

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

Blepharoplasty refers to an operation in which redundant tissues (skin, muscle or fat) are excised from the eyelid. Ptosis repair refers to surgery that corrects a droop of the upper eyelid caused by an intrinsic disturbance of the eyelid structure ("true ptosis"). The procedure usually involves reattaching a loose muscle or tendon or using a graft material to reposition the lids. Since redundant upper eyelid tissue (dermatochalasis) and "true ptosis" often co-exist, a functional blepharoplasty may also be indicated at the time of the ptosis repair. Brow lift surgery is performed to correct brow ptosis secondary to laxity of the forehead muscles.

Indications/Criteria

Blepharoplasty or upper eyelid ptosis will be covered when performed as functional/reconstructive surgery when the following criteria are met:

- visual field testing demonstrate that there is an upper visual field loss of at least 20 degrees or 30% that is corrected when the upper lid margin is elevated by taping the eyelid and pre-operative frontal photographs demonstrate one or more of the following:
 - upper eyelid margin to within 2.5mm (1/4 of the diameter of the visible iris) of the corneal light reflex for both eyes;
 - o upper eyelid skin rests upon the eyelashes;
 - o upper eyelid demonstrates the presence of chronic dermatitis; or
 - o for browlift surgery, photographs should show the eyebrow below the supraorbital rim.
- visual fields are not required when the reason for the lid surgery is entropion or ectropion;
- photographs (slides or prints) and visual field studies must be submitted at the time the request is made and should be frontal, canthus-to-canthus, with the head perpendicular to the plane of the camera, not tilted;

- for blepharoplasty, the customer must have a documented diagnosis of blepharochalasis, dermatochalasis or pseudoptosis with visual field deficits as noted above; and
- if both blepharoplasty and ptosis repair are planned, both must be individually documented. This may require two (2) sets of photographs showing the effect of drooping of redundant skin (and its correction by taping) and the actual presence of blepharoptosis.

Blepharoplasty will be covered for conditions other than those listed above, for any of the following indications, regardless of visual field deficits:

- difficulty tolerating a prosthesis in an anophthalmic socket;
- epiphora (i.e., excessive tearing) due to ectropion and or punctal eversion;
- painful blepharospasm that is refractory to medical management; or
- upper eyelid defect caused by trauma, tumor or ablative surgery.

Lower lid blepharoplasty is considered part of a lid tightening or lid shortening procedure (i.e., tarsal strip/wedge resection, lateral canthal sling, suture) for the following indications:

- entropion (67921, 67922, 67923, 67924), where the lower lid is turned in causing the eyelashes to rub against the cornea causing severe irritation, excessive tearing, crusting of the eyelid, and mucous discharge and more conservative methods of treatment (lubrication, epilation, thermocauterization) are unsuccessful; or
- ectropion (67914, 67915, 67916, 67917), where the margin of the eyelid and the
 eyelashes turn out causing severe irritation, excessive tearing, crusting of the eyelid,
 and mucous discharge and more conservative methods of treatment (lubrication,
 taping) are unsuccessful. Most cases are the result of aging, but some cases result
 from scars from burns, trauma, and skin cancers.
- Blepharoplasty for children with congenital ptosis will be reviewed on a case-by-case basis.

Browlift surgery will be considered a covered benefit when performed as a functional/reconstructive surgery for the following conditions when functional impairment (e.g., interference with vision or visual field, difficulty reading due to upper eyelid drooping, head tilt or chin lift):

- permanent weakening or paralysis of the frontalis muscle is documented in the medical records;
- brow ptosis, causing the upper eyelid to interfere with vision; or

 documentation must clearly show that visual field impairment cannot be corrected by upper lid blepharoplasty alone as demonstrated by standard and taped visual field testing.

Exclusions

- Blepharoplasty, ptosis repair and browlift surgery, performed as cosmetic surgery in the absence of significant signs and symptoms of functional impairment (e.g., inability to perform fine manual work, interference with ability to read, driving and other activities of daily living (ADLs), are considered not medically necessary.
- Lacrimal gland drooping and prolapse are a normal part of the periorbital aging process and may be remedied by lacrimal gland suspension. This is therefore considered cosmetic and not a covered procedure.

Medicare Managed Care Variation

Any procedure(s) involving blepharoplasty must be supported by documented patient complaints which justify functional surgery. This documentation must address the signs and symptoms commonly found in association with ptosis, pseudoptosis, blepharochalasis and/or dermatochalasis. These include (but are not limited to):

- significant interference with vision or superior or lateral visual field, (e.g., difficulty seeing objects approaching from the periphery);
- difficulty reading due to superior visual field loss; or,
- looking through the eyelashes or seeing the upper eyelid skin.

The visual fields should demonstrate a significant loss of superior visual field and potential correction of the visual field by the proposed procedures. Visual fields must demonstrate a minimum 12 degrees or 30 percent loss of upper field vision with upper lid skin and/or upper lid margin in repose and elevated (by taping of the lid) to demonstrate potential correction by the proposed procedure(s). Photographs should also demonstrate the eyelid abnormality (ies) necessitating the procedures.

There is a National Government Services, Inc. Local Coverage Article (LCA) for Blepharoplasty. For full coverage details and exclusions refer to: National Government Services, Inc. Local Coverage Article (LCA) for Blepharoplasty (A523871525). Revision Effective Date 01/01/2018. Available: https://www.cms.gov/

Based on review, there is no Medicare/CMS National or Local Coverage Decision for Blepharoplasty.

References (Reviewed 2023)

1. National Government Services, Inc. Local Coverage Article (LCA) for Blepharoplasty (A52387). Article reviewed 5/28/2019. Available: https://www.cms.gov/

- 2. Riemann CD, Hanson S, Foster JA. A comparison of manual kinetic and automated static perimetry in obtaining ptosis fields. Arch Ophthalmol. 2000 Jan;118(1):65-9.
- 3. Purewal BK and Bosniak S. Theories of upper eyelid blepharoplasty. Theories of upper eyelid blepharoplasty. Ophthalmol Clin North Am. 2005 Jun;18(2):271-8.
- 4. Cahill KV, Bradley EA, Meyer DR, Custer PL, Holck DE, et al. Functional indications for upper eyelid ptosis and blepharoplasty surgery: a report by the American Academy of Ophthalmology. Ophthalmology. 2011 Dec;118(12):2510-7.
- 5. Faucett DC. Essential blepharospasm. In: Yanoff M, Duker JS, editors. Opthalmology. 4th ed. St Louis, MO: Elsevier Saunders: 2013: Ch 12.8.
- 6. Graham DW, Heller J, Kurkjian TJ, Schaub TS, Rohrich RJ. Brow lift in facial rejuvenation: a systematic literature review of open versus endoscopic techniques. Plast Reconstr Surg. 2011 Oct;128(4):335e-341e.
- 7. Hoenig JA. Comprehensive management of eyebrow and forehead ptosis. Otolaryngol Clin North Am. 2005 Oct;38(5):947-84.

Customer Product	Medical Management Requirements*
New York Products	
HMO	Potential for Retrospective Review
PPO in Plan	Potential for Retrospective Review
PPO OOP	Potential for Retrospective Review
POS in Plan	Potential for Retrospective Review
POS OOP	Potential for Retrospective Review
Essential Plan	Potential for Retrospective Review
MVP Medicaid Managed Care	Potential for Retrospective Review
MVP Child Health Plus	Potential for Retrospective Review
MVP Harmonious Health Care Plan	Potential for Retrospective Review
MVP Medicare Complete Wellness	Potential for Retrospective Review
MVP Medicare Preferred Gold HMO POS	Potential for Retrospective Review
MVP Medicare Secure HMO POS	Potential for Retrospective Review Potential for Retrospective Review
MVP Medicare Secure Plus HMO POS	Potential for Retrospective Review Potential for Retrospective Review
MVP Medicare WellSelect PPO	Potential for Retrospective Review Potential for Retrospective Review
MVP Medicare WellSelect Plus PPO	Potential for Retrospective Review
MVP Medicare Patriot Plan PPO	Potential for Retrospective Review Potential for Retrospective Review
MVP DualAccess D-SNP HMO	Potential for Retrospective Review Potential for Retrospective Review
MVP DualAccess Complete D-SNP HMO	Potential for Retrospective Review Potential for Retrospective Review
MVP DualAccess Complete D-SNP HMO MVP DualAccess Plus D-SNP HMO	·
	Potential for Retrospective Review
UVM Health Advantage Select PPO	Potential for Retrospective Review
USA Care PPO	Potential for Retrospective Review
Healthy NY	Potential for Retrospective Review
MVP Premier	Potential for Retrospective Review
MVP Premier Plus	Potential for Retrospective Review
MVP Premier Plus HDHP MVP Secure	Potential for Retrospective Review
	Potential for Retrospective Review
MVP EPO MVP EPO HDHP	Potential for Retrospective Review Potential for Retrospective Review
MVP PPO	Potential for Retrospective Review Potential for Retrospective Review
MVP PPO HDHP	Potential for Retrospective Review Potential for Retrospective Review
Student Health Plans	
ASO	Potential for Retrospective Review See SPD
	See SPD
Vermont Products	
POS in Plan	Potential for Retrospective Review
POS OOP	Potential for Retrospective Review
MVP Medicare Preferred Gold HMO POS	Potential for Retrospective Review
MVP Medicare Secure Plus HMO POS	Potential for Retrospective Review
MVP VT HMO	Potential for Retrospective Review
MVP VT HDHP HMO	Potential for Retrospective Review
MVP VT Plus HMO	Potential for Retrospective Review
MVP VT Plus HDHP HMO	Potential for Retrospective Review
MVP Secure	Potential for Retrospective Review
ASO	See SPD

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro ReviewRetrospective Review RequiredNot CoveredService is not a covered benefit.See SPDSee Specific Plan Design

Revision History:

8/1/2021 - Surgical correction of upper or lower eyelid retraction (CPT code 67909, 67911) is considered medically necessary when there is functional impairment or failure of medical management of symptoms. CPT 67909 and 67911 removed as experimental or investigational.

8/1/2023 – Annual review completed. No changes to criteria. Added language regarding lacrimal gland suspension exclusion.



Bone Density Study for Osteoporosis (DEXA)

Type of Policy: Medical

Prior Approval Date: 10/03/2022

Approval Date: 10/07/2024

Effective Date: 12/01/2024

Related Polices: N/A

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

N/A

Codes Subject to Retrospective Review

CPT Codes: 78350, 7835177086

Experimental/Investigational

CPT Codes: N/A

Common Diagnosis Codes

N/A

Common Procedure Codes

CPT Codes: 76977, 77078, 77080, 77081, 77085, 77089, 77090, 77091, 77092

HCPCS Code: G0130

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy.

Overview

Dual-energy X-ray absorptiometry is a radiological technique used to assess bone mass density and bone mineral content in certain individuals to determine the degree of osteoporosis and fracture risk.

Indications/Criteria

Bone mass measurement is covered when it is performed by a bone densitometer or a bone sonometer and is subject to the criteria listed below.

Documentation shall indicate the diagnosis and reason for request. DEXA may be indicated and recommended for any of the following:

- postmenopausal women age 65 and older and men age 70 and older;
- postmenopausal women and men age 50-69 with strong risk factors for osteoporosis, to screen for reduced bone mass, with willingness and intent to treat;
- patients who have had a fracture, to diagnose osteoporosis and assess its severity in the context of clinical management;
- estrogen-deficient women, to diagnose significantly low bone mass in order to make treatment decisions about drug therapy;
- patients with clinically suspected osteoporosis, to diagnose osteoporosis and assess its severity in the context of clinical management;
- patients with various metabolic diseases or secondary osteoporosis that adversely affect the skeleton, to diagnose clinically suspected osteoporosis;
- patients with vertebral abnormalities or roentgenographic osteopenia, to diagnose spinal osteopenia in order to make decisions about further diagnostic evaluation and therapy;
- patients with primary asymptomatic hyperparathyroidism, to diagnose low bone mass in order to identify those at-risk of severe skeletal disease who may be candidates for surgical intervention;
- patients receiving (or expecting to receive) glucocorticoid therapy ≥5 mg prednisone/day for more than three (3) consecutive months, to diagnose low bone mass in order to adjust therapy;
- patients on long-term therapy for osteoporosis, to monitor disease progression and response to treatment in order to help adjust therapy and identify non-responders;
- selected pre-menopausal women with evidence of partial ovarian dysfunction and very irregular menstrual cycles to help determine the need for earlier hormone intervention;

- post-menopausal women who are trying alternatives to estrogen replacement therapy, to document the adequacy of their programs and allow adjustments to be made; or
- patients with various osteodystrophies and osteomalacia, to monitor these conditions and make decisions regarding therapy.

Repeat bone mass measurements are not indicated more frequently than once every two years. For conditions specified, a bone mass measurement is covered for a customer more frequently than every two years, if medically necessary for the diagnosis or treatment of the patient and if related to the conditions listed. In these instances, payment may be made for tests performed after eleven months have elapsed since the previous bone mass measurement test. Such conditions are:

- monitoring patients on long-term glucocorticoid (steroid) therapy ≥ 5 mg prednisone/day for more than three months (customers must be on glucocorticoids for greater than three months, but bone mass measurement monitoring is at yearly intervals);
- monitoring patients on FDA-approved osteoporosis drug therapy, until test results have stabilized; or
- follow-up bone mineral density testing to assess response and efficacy of therapy, until a response to such therapy has been documented over time.

Vertebral fracture assessment from DXA (77085) is covered once every 2 years with T-score is less than -1.0 and when any of the following criteria are met:

- Females 70 years of age or older; or
- Males 80 years of age or older; or
- Historical height loss greater than 4 cm (greater than 1.5 inches); or
- Glucocorticoid therapy (e.g., 5 mg or greater of prednisone or equivalent per day for greater than or equal to 3 months)

Exclusions

- Routine bone mass screening of low-risk individuals is not medically indicated and is, therefore, not covered.
- Bone densitometry is not indicated for customers whose work-up or treatment will not be altered by bone densitometry results.
- Single photon absorptiometry (78350), dual photon absorptiometry (78351), and use of a bone scan to diagnose osteoporosis (78300, 78305, and 78306).
- Vertebral fracture via dual x-ray absorptiometry (DXA) (77086) is considered to represent vertebral fracture assessment only. It does not represent a bone density

study and, therefore, should not be used for screening. In addition, 77086 is not considered medically necessary for vertebral fracture assessment as there are alternative diagnostic imaging available.

Medicare Variation

Dual-energy X-ray absorptiometry (DXA), bone density study, 1 or more sites; axial skeleton (eg, hips, pelvis, spine), including vertebral fracture assessment (77085) is covered for Medicare products.

Vertebral fracture assessment via dual-energy X-ray absorptiometry (DXA) (77086) is covered for Medicare products.

References (Updated 2024)

- Centers for Medicare & Medicaid Services (CMS). Medicare Coverage Database.
 NCD for Bone (Mineral) Density Studies (150.3). Jul 2, 2007. Updated February 2019.
 Available: https://www.cms.gov/
- Centers for Medicare & Medicaid Services. MLN Matters Bone Mass Measurement (BMM). MLN Matters Number: MM5521. Updated June 15, 2013. Available: https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/mm5521.pdf
- 3. State of New York Insurance Law § 7657, Amendment 11723. Effective January 2003.
- 4. National Osteoporosis Foundation. Clinician's Guide to Prevention and Treatment of Osteoporosis. Updated November 2015. Available: https://my.nof.org/bone-source/education/clinicians-guide-to-the-prevention-and-treatment-of-osteoporosis
- 5. Allen, RS, et al. Institute for Clinical Systems Improvement (ICSI). Health Care Guideline: Diagnosis and Treatment of Osteoporosis. Eighth Edition. Updated July 2017. Available: https://www.icsi.org/guideline/osteoporosis/
- 6. United States Preventive Services Task Force. Screening for Osteoporosis to Prevent Fractures. Updated June 2018. Available: http://www.uspreventiveservicestaskforce.org/Page/Name/recommendations
- 7. Fuerst, T., et al. Evaluation of vertebral fracture assessment by dual X-ray Absorpitometry in a multicenter setting. Osteoporosis International. 2009 Jul; 20(7); 1199-205.
- 8. Bazzocchi A1, Spinnato P, Fuzzi F, Diano D, Morselli-Labate AM, Sassi C, et al. Vertebral fracture assessment by new dual-energy X-ray absorptiometry. Bone. 2012 Apr;50(4):836-41.

- 9. Aubry-Rozier B, Hans D, Krieg MA, et al. Morphometric vertebral assessments via the use of dual X-ray absorptiometry for the evaluation of radiographic damage in ankylosing spondylitis: A pilot study. J Clin Densitom. 2014;17(1):190-194.
- 10. BlueCross BlueShield Association (BCBSA), Technology Evaluation Center (TEC). Screening for vertebral fracture with dual X-ray absorptiometry. TEC Assessment Program. Chicago, IL: BCBSA; February 2006;20(14).
- 11. Committee on Practice Bulletins-Gynecology, The American College of Obstetricians and Gynecologists. ACOG Practice Bulletin N. 129. Osteoporosis. Obstet Gynecol. 2012 Sep; 120(3):718-34.
- 12. United States Food and Drug Administration (FDA). TBS iNsight®. Available at URL address: https://www.accessdata.fda.gov/cdrh_docs/pdf15/K152299.pdf
- 13. United States Food and Drug Administration (FDA). HealthVCF. Available at URL: https://www.accessdata.fda.gov/cdrh docs/pdf19/K192901.pdf
- 14. HAYES Evidence Analysis Research Brief: Trabecular Bone Score to Predict Fracture Risk in Postmenopausal Patients. HAYES, Inc.; © 2021 Hayes, a symplr company. January 25, 2022.

Customer Product	Medical Management Requirements*
New York Products	
НМО	Retrospective Review
PPO in Plan	Retrospective Review
PPO OOP	Retrospective Review
POS in Plan	Retrospective Review
POS OOP	Retrospective Review
Essential Plan	Retrospective Review
MVP Medicaid Managed Care	Retrospective Review
MVP Child Health Plus	Retrospective Review
MVP Harmonious Health Care Plan	Retrospective Review
MVP Medicare Complete Wellness	Retrospective Review
MVP Medicare Preferred Gold HMO POS	Retrospective Review
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MVP Medicare Secure Plus HMO POS	Retrospective Review
MVP Medicare WellSelect PPO	Retrospective Review
MVP Medicare WellSelect Plus PPO	Retrospective Review
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MVP Medicare Patriot Plan PPO	Retrospective Review
MVP DualAccess D-SNP HMO	Retrospective Review
MVP DualAccess Complete D-SNP HMO	Retrospective Review
MVP DualAccess Plus D-SNP HMO	Retrospective Review
UVM Health Advantage Select PPO	Retrospective Review
USA Care PPO	Potential for Retrospective Review
Healthy NY	Retrospective Review
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MVP Medicare Secure Plus HMO POS	Retrospective Review
MVP VT HMO	Retrospective Review
MVP VT HDHP HMO	Retrospective Review
MVP VT Plus HMO	Retrospective Review
MVP VT Plus HDHP HMO	Retrospective Review
MVP Secure	Retrospective Review
ASO	See SPD

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Revision History

12/01/2022 – Trabecular Bone Score (TBS) added to policy as investigational.

09/01/2023 – Trabecular Bone Score (TBS) removed as investigational and added to claims manual to no longer receive separate payment.

12/01/2024 – Added coverage to DXA +VFA (CPT 77085). Removed from medical review.



Bone Growth Stimulator

Page 1 of 8

Type of Policy: DME

Prior Approval Date: 02/07/2022

Approval Date: 02/04/2024

Effective Date: 04/01/2024

Related Polices: N/A

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

MVP Durable Medical Equipment (DME) Prior Authorization List Available:

Provider Reference Library Home (myphealthcare.com)

E0747 - Osteogenesis stimulator, electrical, noninvasive, other than spinal applications

E0748 - Osteogenesis stimulator, electrical, noninvasive, spinal applications

E0749 - Osteogenesis stimulator, electrical, surgically implanted

E0760 - Osteogenesis stimulator, low intensity ultrasound, noninvasive

Codes Requiring Retrospective Review:

N/A

Experimental/Investigational

N/A

Common Diagnosis Codes

Bone Growth Stimulator

ICD-10-CM Diagnosis Codes: M53.2x7, M53.2x8, M53.3, M53.85, M53.86, M53.87, M53.88, M80.00xS, M80.021A-M80.879A, M84.30xS, M84.38xS, M84.40xS, M84.421A-M84.673A, M84.68xS, Q68.8, Q71.61, Q71.63, Q74.0, Q74.1, Q74.2, Q74.3, Q74.8, Q74.9, S42.201A-S42.92B, S49.001A-S49.199A, S49.001A-S49.199A, S52.001A, S59.199A, S72.001A-S72.499C, S79.001A-S82.866C, S89.001A-S89.299A, S92.301A-S92.356B

Common Procedure Codes

20974, 20975

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

A bone growth stimulator is a device that is used to enhance the healing process of bones through the delivery of energy. Bone growth stimulators are commonly classified based on the type of energy delivered and how it is applied. The major subtypes include electric and ultrasonic bone growth stimulators.

Electric bone growth stimulators can administer electric current to the site in question in an attempt to stimulate bone growth and regeneration. Electric bone growth stimulators can be placed invasively (implanted) or non-invasively (external or non-implanted).

Ultrasound bone growth stimulators provide a non-thermal, low-intensity pulsed ultrasound to the fracture site in an attempt to stimulate bone growth and regeneration.

A long bone is limited to a clavicle, humerus, radius, ulna, femur, tibia, fibula, metacarpal, or metatarsal.

Indications/Criteria

Documentation Requirements

Non-union of a fracture must be documented by a minimum of two sets of radiographs obtained prior to starting treatment with the bone growth stimulator, separated by a minimum of 90 days, each including multiple views of the fracture site and with a written interpretation by a physician/podiatrist stating that there has been no clinically significant evidence of fracture healing between the two sets of radiographs. [1]

Non-invasive Electric Bone Growth Stimulator (E0747, E0748)

A non-invasive electric bone growth stimulator is covered when one of the following criteria is met: [1,2]

- non-union of a long bone fracture, defined as radiographic evidence that fracture healing has ceased for three (3) or more months prior to starting treatment with the bone growth stimulator; or
- failed fusion of a joint other than in the spine where a minimum of nine (9) months has elapsed since the last surgery; or
- there is a diagnosis of congenital pseudoarthrosis; or

- spinal fusion when one of the following is present:
 - failed spinal fusion where a minimum of nine (9) months has elapsed since the last surgery; or
 - o patients who are currently smokers; or
 - o patients who use corticosteroids; or
 - o use of any medications or substance that would negatively affect healing; or
 - o patients with Diabetes Mellitus and glycohemoglobin (HbA1c) > 7; or
 - o patients with renal disease; or patients with peripheral arterial disease.
 - o following a multilevel spinal fusion surgery involving three (3) or more vertebrae (e.g., C3-C5, L3-L5, L4-S1, etc.); or
 - o following spinal fusion surgery where there is a history of a previously failed spinal fusion at the same site.

Invasive Electric Bone Growth Stimulator (E0749)

An invasive electric bone growth stimulator is considered medically appropriate for the following

indications:

- when used as an adjunctive therapy with spinal surgery when one of the following is present:
 - for customers considered at high-risk for pseudoarthrosis due to previously failed spinal fusion at the same site; or
 - o for those undergoing multiple level fusion involving three (3) or more vertebrae (e.g., L3-L5, L4-S1, etc.); or
 - o patients who are currently smokers, ^[5, 6] who use corticosteroids, or any medications or substances that would negatively affect healing; or
 - o patients with Diabetes Mellitus and a glycohemoglobin (HbA1c) > 7; or
 - o patients with renal disease.
- non-union of a long bone fracture defined as radiographic evidence that fracture healing has ceased for three (3) or more months prior to starting treatment with the osteogenesis stimulator.

<u>Ultrasonic Bone Growth Stimulator (E0760)</u>

An ultrasonic bone growth stimulator is covered when all of the following criteria are met:

- non-union of a fracture documented by a minimum of two sets of radiographs obtained prior to starting treatment with the bone growth stimulator, separated by a minimum of 90 days. Each radiograph set must include multiple views of the fracture site accompanied by a written interpretation by a physician/podiatrist stating that there has been no clinically significant evidence of fracture healing between the two sets of radiographs; and
- the fracture is not of the skull or vertebrae; and
- the fracture is not tumor related.

Exclusions

- Bone growth stimulators are not covered for any reason other than those stated under Indications/Criteria of this policy.
- Bone growth stimulators are not indicated in customers with active implantable devices, such as cardiac pacemakers, without evaluation by the attending cardiologist or physician.
- Bone growth stimulators may not be used in pregnant or nursing women.
- Invasive and non-invasive electrical bone growth stimulation methods are not indicated in the following:
 - o fractures of children's epiphysis;
 - o severe osteoporosis; or
 - o systemic disorders (i.e., lupus, multiple sclerosis, etc.)
 - o sesamoid fracture
 - o phalange fracture
 - stress fractures
 - Small bones such as the scaphoid, carpal and tarsal bones
- Invasive electrical stimulation methods are not indicated in the presence of:
 - o pathological fracture due to malignant tumors, or
 - active osteomyelitis.
- Non-invasive electrical stimulation methods are not indicated in:
 - o non-union fractures when the fracture gap is > one (1) cm; or
 - customers who are uncooperative and/or have mental or physical conditions that preclude compliance.
- Ultrasonic bone growth stimulators:

- are not indicated in non-union fractures of the skull, vertebrae and those that are tumor related;
- o may not be used concurrently with non-invasive electric bone growth stimulators;
- use of an ultrasonic osteogenic bone growth stimulator for the treatment of a fresh fracture or delayed union will be denied as not medically necessary.
- Stress fractures
- Small bones such as the scaphoid, carpal and tarsal bones

Medicare Variation

For a complete description of the indications and limitations of coverage for osteogenesis stimulators for Medicare customers, please refer to the Local Coverage Determination (LCD) for Osteogenesis Stimulators (L33796) located at: MCD Search (cms.gov)

For a complete description of the indications and limitations of coverage for osteogenesis stimulators for Medicare customers, please refer to the NCD for Osteogenic Stimulators (150.2). Available: MCD Search (cms.gov)

References (Updated 2024)

- 1. Centers for Medicare & Medicaid Services, Noridian Healthcare Solutions, LLC Osteogenesis Stimulators (L33796). Revision Effective Date 01/01/2020. Available: MCD Search (cms.gov)
- Centers for Medicare & Medicaid Services (CMS). Medicare Coverage Database. NCD for Osteogenic Stimulators (150.2). Revision Effective Date Apr 27, 2005. Available: <u>MCD Search (cms.gov)</u>
- 3. Adie S, Harris IA, Naylor JM, et al. Pulsed electromagnetic field stimulation for acute tibial shaft fractures: a multicenter, double-blind, randomized trial. J Bone Joint Surg Am. 2011; 93(17):1569-1576.
- 4. Agency for Healthcare Research and Quality (AHRQ). The role of bone growth stimulating devices and orthobiologics in healing nonunion fractures. Health Technology Assessments. September 2005. Available at: http://www.cms.hhs.gov/determinationprocess/downloads/id29TA.pdf.
- 5. Akai M, et al. Effect of electrical stimulation on musculoskeletal systems; a metaanalysis of controlled clinical trials. Bioelectromagnetics 2002;23:132-43.
- 6. Busse JW, et al. The effect of low-intensity pulsed ultrasound therapy on time to fracture healing: a meta-analysis. CMAJ 2002 Feb 19;166(4):437-41.
- 7. Busse JW, et al. Low intensity pulsed ultrasonography for fractures: Systematic review of randomized controlled trials. Br Med J 2009;338:b351.

- 8. Davidson, MD. Larry. Cigarette Smoking and Its Impact on Spinal Fusions. Spineuniverse. Updated Mar.21, 2016.
- 9. Griffin XL, Costa ML, Parsons N, Smith N. Electromagnetic field stimulation for treating delayed union or non-union of long bone fractures in adults. Cochrane Database Syst Rev. 2011; (4):CD008471.
- 10. Hayes, Inc. Hayes Pocket Summary. Ultrasound Bone Growth Stimulation. Lansdale, PA: Hayes, Inc.; September 3, 2015.
- 11. Hayes, Inc. Directory Report. Electrical Bone Growth Stimulation, Invasive. Medical Technology Directory, Lansdale, PA: Hayes, Inc.; July 2016a, annual review 2020.
- 12. Hayes, Inc. Directory Report. Noninvasive Electrical Bone Growth Stimulators for Spinal Fusion or Foot and Ankle Indications. Medical Technology Directory, Lansdale, PA: Hayes, Inc.; September 2016b, updated 2021.
- 13. Hayes, Inc. Directory Report. Noninvasive electrical bone growth stimulators for acute, delayed union, and nonunion fractures. Medical Technology Directory, Lansdale, PA: Hayes, Inc.; June 2016, annual review October 2020.
- 14. Hayes, Inc. Directory Report. Ultrasound Bone Growth Stimulation. Medical Technology Directory, Lansdale, PA: Hayes, Inc.; September 2015; September 2016, Archived October 2020.
- 15. Leung KS, et al. Complex tibial fracture outcomes following treatment with low-intensity pulsed ultrasound. Ultrasound Med Biol 2004 Mar;30(3):389-95.
- 16. Linovitz RJ, et al. Combined magnetic fields accelerate and increase spine fusion: a double-blind, randomized, placebo controlled study. Spine 2002 Jun;27(13):1383-8.
- 17. Saxena A, DiDomenico L, Widfeldt A, et al. Implantable electrical bone stimulation for arthrodeses of the foot and ankle in high-risk patients: a multicenter study. J Foot Ankle Surg. 2005; 44(6):450-454.
- 18. Scolaro JA, Schenker ML, Yannascoli S, et al. Cigarette smoking increases complications following fracture: a systematic review. J Bone Joint Surg Am. 2014; 96(8):674-681.
- 19. Simonis RB, Parnell EJ, Ray PS, Peacock JL. Electrical treatment of tibial non-union: a prospective randomised, double-blind trial. Injury. 2003; 34(5):357-362.
- 20. Walker NA, Denegar CR, Preische J. Low-intensity pulsed ultrasound and pulsed electromagnetic field in the treatment of tibial fractures: a systematic review. J Athl Train. 2007; 42(4):530-535.

Customer Product	Medical Management Requirements*
New York Products	
НМО	Prior Auth
PPO in Plan	Prior Auth
PPO OOP	Prior Auth
POS in Plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Prior Auth
MVP Child Health Plus	Prior Auth
MVP Harmonious Health Care Plan	Prior Auth
MVP Medicare Complete Wellness	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP Medicare WellSelect PPO	Prior Auth
MVP Medicare WellSelect Plus PPO	Prior Auth
MVP Patriot Plan PPO	Prior Auth
MVP DualAccess D-SNP HMO	Prior Auth
MVP DualAccess Complete D-SNP HMO	Prior Auth
MVP DualAccess Plus D-SNP HMO	Prior Auth
UVM Health Advantage Select PPO	Prior Auth
USA Care PPO	Potential for Retrospective Review
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	
POS in Plan	Prior Auth
POS OOP	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP VT HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD

[♦] Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Revision History:

04/01/2022 – Annual review with no changes to the indications or criteria. References and websites sections updated.

04/01/2024 – Annual review; added clarifying exclusions of sesamoid, phalange, stress and small bone examples.



BRCA Testing (Genetic Testing for Susceptibility to Breast and Ovarian Cancer)

Type of Policy: Medical

Prior Approval Date: 10/03/2022

Approval Date: 10/07/2024

Effective Date: 12/01/2024

Related Polices: Oncotype DX and other

Cancer Gene Expression

Tests

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

N/A

Codes Subject to Retrospective Review

CPT Codes:

81432 - Hereditary breast cancer-related disorders (e.g., hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer); genomic sequence analysis panel

81433 - Hereditary breast cancer-related disorders (e.g., hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer); duplication/deletion analysis panel

84999 - Unlisted chemistry procedure

Experimental/Investigational

CPT Codes: 81432, 81433, 84999

Common Diagnosis Codes

ICD-10 Diagnosis Codes: Z80.3, Z80.41

BRCA Testing Page 1 of 10

Common Procedure Codes

CPT Codes: 81212, 81215, 81216, 81217, 81162, 81163, 81164, 81165, 81166, 81167

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy.

Overview

These genetic tests analyze the DNA extracted from blood or a buccal sample from an individual to determine if the individual has inherited a mutated version of the BRCA1 and BRCA2 genes associated with most cases of familial breast and ovarian cancer.

Genetic susceptibility testing for breast and ovarian cancer will be considered for highrisk women and men with a personal and/or family history of breast and/or ovarian cancer or known familial inherited susceptibility to breast and/or ovarian cancer and who plan to use the information in making treatment choices.

Indications/Criteria

Documentation Requirements

Medical necessity must be documented in the medical record and available upon request. Documentation must include third generation pedigree analysis for any genetic test and pre** and post-test counseling. Documentation must include, as part of the third-generation pedigree analysis, the results of BRCA testing of those individuals diagnosed with having cancer. Documentation of a pre-disposing condition for genetic counseling and testing should be submitted upon request.

**NY Ph-I 78-L requires informed consent

Genetic Counseling

A total of three visits (including pre-test counseling, informed consent counseling and post-test genetic counseling) will be allowed for BRCA testing. A laboratory visit may be done at the time of informed consent, but can be done independently, if the informed consent has been completed at an earlier visit.

Genetic Testing

Requests for laboratory work may be ordered when all the following criteria are met:

 The findings of BRCA1 testing, BRCA2 testing, or the study for 3 specific mutations in the BRCA1 and BRCA2 genes, primarily for individuals of Ashkenazi Jewish Ancestry (185delAG* and 5385insC* in BRCA1, and 6174delT in BRCA2, otherwise known as Multisite 3 BRAC Analysis) will have an impact on the types of therapies to treat the disorder.

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- 2. Genetic susceptibility testing for BRCA1 and BRCA 2 will be considered when one of the following categories of high-risk patients is met:
 - A. for an individual from a family with a known deleterious BRCA1/BRCA 2 gene mutation*; or
 - for a deleterious BRCA1/BRCA 2gene mutation known; NCCN recommend BRCA1/BRCA2 testing only for the specific familial mutation
 - B. an individual with a personal history of breast cancer and one or more of the following:
 - diagnosed at age ≤ 45;
 - diagnosed at age 46-50 with:
 - o an additional breast cancer primary at any age, or
 - o ≥ one close blood relative with breast cancer at any age, or
 - $\circ \ge$ one close blood relative with prostate cancer (Gleason score ≥ 7), or
 - An unknown or limited family history
 - Diagnosed ≤ 60 y with a:
 - o Triple negative (ER negative, PR negative, HER2 negative) breast cancer
 - Breast Cancer diagnosed at any age with:
 - $\circ \geq$ one close blood relative with breast cancer diagnosed ≤ 50 y, or
 - o ≥ one close blood relative with ovarian cancer at any age, or
 - o ≥ one close male blood relative with breast cancer
 - $\circ \geq$ one close blood relative with metastatic prostate cancer
 - $\circ \geq$ one close blood relative with pancreatic cancer at any age
 - ≥ two additional diagnosis of breast cancer at any age in customer and/or in close blood relatives
 - Ashkenazi Jewish ancestry
 - C. Personal history of ovarian cancer, including primary peritoneal or fallopian tube cancer
 - D. Personal history of male breast cancer
 - E. Personal history of metastatic prostate cancer at any age
 - F. Personal history of pancreatic cancer at any age
 - G. Personal history of high-grade prostate cancer (Gleason score > 7) at any age with

BRCA Testing Page 3 of 10

- ≥1 close blood relative with ovarian carcinoma, pancreatic cancer, or metastatic prostate cancer at any age or breast cancer <50; or
- ≥2 close blood relatives with breast or prostate cancer (any grade) at any age;
 or
- Ashkenazi Jewish ancestry
- H. Regardless of family history, BRCA testing is medically necessary in individuals with a BRCA-related cancer if the FDA labeling indicates that BRCA testing is necessary for the safe and effective use of the corresponding drug therapy, they meet criteria for use of the drug therapy, and the results of the testing will be used to determine if immediate treatment is needed.

For example:

- Lynparza (olaparib) and Talzenna (talazoparib) for metastatic HER2-negative breast cancer
- Lynparza (olaparib) and Zejula (niraparib) for ovarian cancer
- Platinum therapy for prostate cancer
- I. Family History Only (significant limitations of interpreting test results for an unaffected individual should be discussed)
 - First (1st) degree or second (2nd) degree blood relative meeting any of the above criteria
 - Third (3rd) degree blood relative who has breast cancer and/or invasive ovarian cancer and who has ≥ 2 close blood relatives with breast cancer (at least one with breast cancer ≤ 50 y) and/or ovarian cancer

Medical record documentation must include a discussion with the customer noting the following:

- most appropriate relatives for genetic testing;
- discussion encouraging the customer to discuss his/her genetic testing with such relatives; and
- review of the significant limitations of interpreting test results, in the absence of testing affected relatives first, and
- documentation must also include third generation pedigree analysis and pre** and post-test counseling.
- A three generation pedigree targeted to cancer family history must be completed. If the three-generation pedigree supports that the patient is not at risk then testing is not indicated (lack of BRCA mutation e.g. both parents have been testing and are negative for testing being requested).

BRCA Testing Page 4 of 10

- 3. Multisite 3 BRAC analysis (or equivalent) testing (CPT Code 81212) will be considered when the following criteria are met:
 - for an individual of Ashkenazi Jewish ancestry with a first or second degree relative with breast or ovarian cancer, or with a relative with a known mutation which is one of the three mutations known to occur more frequently in those of Ashkenazi ethnicity.

Note: For all above criteria, breast cancer includes ductal carcinoma in situ (DCIS) and invasive breast cancers. Qualifying cancers must be on the same side of the family.

Close blood relatives include first, second, and third-degree relatives on same side of family.

1st degree relatives include; parents, siblings and children.

2nd degree relatives include; grandparents, grandchildren, aunts, uncles, half-siblings, nieces and nephews.

3rd degree relatives include great grandmother, great grandfather, great granddaughter, great grandson, great aunt, great uncle, grand-niece, grand-nephew, first female cousin or first male cousin.

• Individuals with limited family history (e.g., fewer than two 1st or 2nd degree female relatives or female relatives surviving beyond 45 years in either lineage).

Exclusions

- Not meeting criteria under Indications/Criteria in this policy.
- BRCA testing is limited to once-in-a-lifetime.
- Testing of individuals with no personal or family history of breast, ovarian, fallopian tube, primary peritoneal, pancreatic, or prostate cancer. Such testing is considered screening and is excluded from coverage.
- BRCA screening for adult-onset conditions in children less than 18 years of age when results would not impact medical management.
- Prenatal testing.
- CHEK2 genetic testing has not been proven to impact health outcomes. It is considered experimental and investigation and, therefore, is not covered.
- Genetic tests for susceptibility to breast and ovarian cancer (e.g. candidate breast cancer susceptibility genes and single nucleotide polymorphisms [SNPs] testing).
- BREVAGenplus, single polymorphisms (SNPs), to predict and individual's risk for breast cancer, is considered investigational and not medically necessary as they have not been proven to improve health outcomes.

BRCA Testing Page 5 of 10

- BRCA testing (81432, 81433) as a component of multi-gene testing panels (e.g. myRisk™ (Myriad Genetics), BreastNext™, OvaNext™, PancNext™, Cancer Next™, Invitae Common Hereditary Cancer Panel, OncoGeneDx Comprehensive Cancer Panel (GeneDx)) using next-generation sequencing for cancer (e.g. hereditary breast, ovarian, and other cancers) are considered investigational as they have not been proven to improve health outcomes.
- Based upon our criteria and assessment of the peer-reviewed literature, including National Comprehensive Cancer Network (NCCN) clinical guidelines, testing for the identification of BRCA 1/2 pathogenic variant of unknown significance discovered in a family member, is considered investigational and should be performed in a research setting.

Medicare

This policy is consistent with Medicare requirements. For full Medicare coverage and limitation details refer to the following Medicare Local Coverage Determination (LCD): Molecular Pathology Procedures (L35000) and related Billing and Coding Article (A56199) Revision Effective Date: 08/01/2024.

References (Reviewed 2024)

- 1. American College of Obstetricians and Gynecologists (ACOG) Practice Bulletin No. 182: Hereditary breast and ovarian cancer syndrome. Obstetrics & Gynecology 2017; 130(3):e110-e126.
- 2. Armstrong J, Toscano M, Kotchko N, et al. American BRCA Outcomes and Utilization of Testing (ABOUT) Study: a pragmatic research model that incorporates personalized medicine/patient-centered outcomes in a real world setting. J Genet Couns. 2015; 24(1):18-28.
- 3. Cragun, D., et al. Panel based testing for inherited colorectal cancer: a descriptive study of clinical testing by a US laboratory. Clin Genet epub: 20 Mar 2014.
- 4. Domcheck, SM, et al. Mutiplex genetic testing for cancer susceptibility: out on the high wire without a net? J Clin Oncol 2013;31:1267-1270. Avail at: http://.ncbi.nlm.nih.gov/pubmed/23460708
- 5. Dite GS, Mahmoodi M, Bickerstaffe A et al. Using SNP genotypes to improve the discrimination of a simple breast cancer risk prediction model. Breast Cancer Res Treat 2013; 139(3):887-96.
- 6. John EM, Miron A, Gong G, at al. Prevalence of pathogenic BRCA1 mutation carriers in 5 US racial/ethnic groups. JAMA. 2007; 298(24):2869-2876.
- 7. Judkins T, Leclair B, Bowles K, et al. Development and analytical validation of a 25-gene next generation sequencing panel that includes the BRCA1 and BRCA2 genes to assess hereditary cancer risk. BMC Cancer. 2015; 15:215.

BRCA Testing Page 6 of 10

- 8. Manchanda R, Loggenberg K, Sanderson S, et al. Population testing for cancer predisposing BRCA1/BRCA2 mutations in the Ashkenazi-Jewish community: a randomized controlled trial. J Natl Cancer Inst. 2014; 30; 107(1):379.
- 9. National Cancer Institute (NCI) a. US National Institute of Health (NIH). Genetics of breast and gynecological cancers (PDQ® Health Professional Version). Updated: February 10. 2017. Available: https://www.cancer.gov/types/breast/hp/breast-ovarian-genetics-pdg#section/all
- 10. National Comprehensive Cancer Network (NCCN). Clinical Practice Guidelines in Oncology™. Genetic/familial high-risk assessment: breast, ovarian, and pancreatic. (V3.2021). © 2021 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website at: http://www.nccn.org/index.asp.
- 11. New York State Department of Health Medicaid Program. Medicaid Update. October 2015. Volume 31. Number 11. Available: http://www.health.ny.gov/health_care/medicaid/program/update/2015/oct15_mu.pdf
- 12. Palma, MD, et al. The relative contribution of point mutations and genomic rearrangements in BRCA1 and BRCA2 in high-risk breast cancer families. Cancer Research. 2008 Sep; 68(17):7006-14.
- 13. Rainville, IR., et al. Next-generation sequencing for inherited breast cancer risk: counseling through complexity. Curr Oncolo Rep 2014; 16:371.
- 14. Robson M; Im SA; Senkus E, et al. Olaparib for metastatic breast cancer in patients with a germline BRCA mutation. N Engl J Med. 2017; 377(6):523-533.
- 15. Ripperger T, Gadzicki D, Meindl A, Schlegelberger B. Breast cancer susceptibility: current knowledge and implications for genetic counseling. Eur J Hum Genet. 2009 Jun;17(6):722-31
- 16. Robson, E. et al. American Society of Clinical Oncology Policy Statement Update: Genetic and Genomic Testing for Cancer Susceptibility. Journal of Clinical Oncology. 28 (5): 893-901. Feb, 2010.
- 17. Smith LD, Tesoriero AA, Wong EM, et al. Contribution of large genomic BRCA1 alterations to early-onset breast cancer selected for family history and tumor morphology: a report from The Breast Cancer Family Registry. Breast Cancer Res. 2011; 13(1):R14.
- 18. Walsh, T. et al. Detection of inherited mutations for breast and ovarian cancer using genomic capture and massively parallel sequencing. Proc Natl Acad Sci. 2010; 107:12629-12633.
- 19. Walsh, T. et al. Spectrum of mutations in BRCA1, BRCA2, CHECK2, and TP53 in families at high risk for cancer. JAMA 2006; 295:1379-1388.

BRCA Testing Page 7 of 10

- 20. Walsh, T. et al. Mutations in 12 genes for inherited ovarian, fallopian tube, and peritoneal cancer identified by massively parallel sequencing. Proc Natl Acad Sci. 2011;108:18032-18037.
- 21. Weischer, M., et al. CHEK2*1100delC genotyping for clinical assessment of breast cancer risk: meta-analyses of 26,000 patient cases and 27,000 controls. Journal of Clinical Oncology. 2008 Feb 1; 26 (4):542-8.
- 22. US Preventive Services Task Force, Owens DK, Davidson KW, et al. Risk assessment, genetic counseling, and genetic testing for BRCA-related cancer: US Preventive Services Task Force Recommendation Statement. JAMA. 2019; 322(7):652-665.

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Customer Product	Medical Management Requirements*
New York Products	
HMO	Retrospective Review
PPO In Plan	Retrospective Review
PPO OOP	Retrospective Review
POS In Plan	Retrospective Review
POS OOP	Retrospective Review
Essential Plan	Retrospective Review
MVP Medicaid Managed Care	Retrospective Review
MVP Child Health Plus	Retrospective Review
Harmonious Health Care Plan	Retrospective Review
MVP Medicare Complete Wellness	Retrospective Review
MVP Medicare Preferred Gold HMO POS	Retrospective Review
MVP Medicare Secure HMO POS	Retrospective Review
MVP Medicare Secure Plus HMO POS	Retrospective Review
MVP Medicare WellSelect PPO	Retrospective Review
MVP Medicare WellSelect Plus PPO	Retrospective Review
MVP Medicare Patriot Plan PPO	Retrospective Review
MVP DualAccess D-SNP HMO	Retrospective Review
MVP DualAccess Complete D-SNP HMO	Retrospective Review
MVP DualAccess Plus D-SNP HMO	Retrospective Review
UVM Health Advantage Select PPO	Retrospective Review
USA Care PPO	Potential for Retrospective Review
Healthy NY	Retrospective Review
MVP Premier	Retrospective Review
MVP Premier Plus	Retrospective Review
MVP Premier Plus HDHP	Retrospective Review
MVP Secure	Retrospective Review
MVP EPO	Retrospective Review
MVP EPO HDHP	Retrospective Review
MVP PPO	Retrospective Review
MVP PPO HDHP	Retrospective Review
Student Health Plans	Retrospective Review
ASO	See SPD
Vermont Products	
POS In Plan	Retrospective Review
POS OOP	Retrospective Review
MVP Medicare Preferred Gold HMO POS	Retrospective Review
MVP Medicate Secure Plus HMO POS	Retrospective Review
MVP VT HMO	Retrospective Review
MVP VT HDHP HMO	Retrospective Review
MVP VT Plus HDHP HMO	Retrospective Review
MVP VT Plus HMO	Retrospective Review
MVP Secure	Retrospective Review
ASO	See SPD

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Revision History:

BRCA Testing Page 9 of 10

04/01/2022 – Annual review with no changes to the indications or criteria. Moved 0172U to the Genetic and Molecular Diagnostic Testing Medical Policy. References and websites updated.

12/01/2022 – added examples of other multi-gene testing panels and that use of these panels for all types of cancers is investigational.

12/01/2024 – Annual review with no changes to the indications or criteria.

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Breast Implantation and Removal

Type of Policy: Surgical

Prior Approval Date: 03/03/2023

Approval Date: 06/03/2024

Effective Date: 08/01/2024

Related Polices: Breast Reduction Surgery (Reduction Mammaplasty)

Breast Reconstruction Surgery Gender Affirming Treatment

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

CPT/HCPCS Codes:	Description:
19316	Mastopexy
19325	Mammaplasty, augmentation; with prosthetic implant
19328	Removal of intact mammary implant
19330	Removal of mammary implant material
19340	Immediate insertion of breast prosthesis following mastopexy, mastectomy or in reconstruction
19370	Revision of peri-implant capsule, breast, including capsulotomy, capsulorrhaphy, and/or partial capsulectomy
19371	Peri-implant capsulectomy, breast, complete, including removal of all intracapsular contents

Note: If there is a diagnosis of breast cancer indicated by one of the following ICD-10 Diagnosis Codes, prior authorization is not required:

Breast Implantation Page 1 of 6

C50.111, C50.112, C50.119, C50.211, C50.212, C50.219, C50.311, C50.312, C50.319, C50.411, C50.412, C50.419, C50.511, C50.512, C50.519, C50.611, C50.612, C50.619, C50.811, C50.812, C50.819, C50.911, C50.912, C50.919, D05.00, D05.01, D05.02, D05.10, D05.11, D05.12, D05.80, D05.81, D05.82, D05.90, D05.91, D05.92, Z172, Z1721, Z1722, Z173, Z1731, Z1732, Z174, Z17410, Z17411, Z1742, Z17420, Z17421, Z15.01, Z42.1, Z85.3

Codes Requiring Retrospective Review

n/a

Experimental/Investigational

N/A

Diagnosis Codes

ICD-10- CM Diagnosis Codes:

C50.011, C50.012, C50.019, C50.111, C50.112, C50.119, C50.211, C50.212, C50.219, C50.311, C50.312, C50.319, C50.411, C50.412, C50.419, C50.511, C50.512, C50.519, C50.611, C50.612, C50.619, C50.811, C50.812, C50.819, C50.911, C50.912, C50.919, D05.00, D05.01, D05.02, D05.1, D05.10, D05.11, D05.12, D05.80, D05.81, D05.82, D05.90, D05.91, D05.92, N64.89, N65.0, N65.1, T85.41xA, T85.42xA, T85.43xA, T85.44xA, T85.49xA, T85.79xA, T85.82, T85.83, T85.84, T85.86, T85.89, Z15.01, Z42.1, Z45.811, Z45.812, Z45.819, Z85.3, Z90.10, Z90.11, Z90.12, Z90.13

Common Diagnosis Codes associated with this policy have been provided for informational purposes only. The list of codes may not be all-inclusive and may be updated to reflect any applicable revisions to the ICD-10 code set and/or medical necessity quidelines applied in this policy.

Common Procedure Codes

19342, 19369, L8600

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

Breast implantation is performed for cosmetic breast augmentation, breast reconstruction following mastectomy, replacement of problem implants, implants to treat gender dysphoria or augmentation/reconstruction of congenital defects or anomalies. The implant is inserted beneath the pectoral muscles or breast tissue.

Indications/Criteria

Primary breast implantation, subject to the following criteria:

Breast Implantation Page 2 of 6

- post mastectomy, as part of a breast reconstruction procedure (Refer to the MVP Breast Reconstruction Policy).
- Implant to treat gender dysphoria (Refer to the MVP Gender Affirming Treatment Policy)

Medically necessary implant extraction (removal) and/or peri-implant capsulectomy, subject to the following criteria:

- capsular contracture (Baker grade III or IV) causing severe discomfort; or
- hematoma; or
- leakage or rupture of saline filled, silicone gel or alternative breast implant; or
- infection refractory to medical management (i.e. antibiotics); or
- ischemia; or
- skin loss or extrusion of the prosthesis through the muscle area; or
- breast implant-associated anaplastic large cell lymphoma; or
- Current implanted prosthesis has been recalled by the FDA or manufacturer.

Secondary/Subsequent breast implantation, subject to the following criteria:

- criteria for implant extraction has been met; and
- primary implantation was performed as part of a post mastectomy procedure.

Documentation should include:

- a complete history and physical, diagnosis and purpose of requested surgery;
- photographs (if requested by the Medical Director); and
- for implant extraction, the medical record documentation should present clear clinical evidence of the indication for the removal of the implants. Additionally, documentation such as radiology reports that will help support the medical necessity for the proposed procedure should be included.

Exclusions

Primary Breast Implantation

 Primary breast implantation for cosmetic reasons, such as breast augmentation to enlarge or reshape the breast is considered not medically necessary.

Extraction and/or Secondary Implantation

 Implant extraction is covered only when criteria in the indications/criteria section are met. The following do not qualify as medical complications for coverage of implant extractions:

Breast Implantation Page 3 of 6

- symptoms of, or a diagnosis of, an auto-immune disorder without documentation of a medical condition as stated under Indications/Criteria;
- anxiety over possible implant-associated disease;
- for cosmetic reasons such as shifting, incorrect implant size, visible scars, uneven appearance, and wrinkling;
- o removal of the implant in the opposite/contralateral breast; or
- o changes in breast and/or nipple sensation.
- Re-implantation of breast implants, except when related to a post mastectomy procedure, is considered cosmetic, and therefore, not medically necessary.
- Re-implantation of a breast implant is not medically necessary if previous implantation was for cosmetic purposes even if the removal was medically indicated.

References (Updated 2024)

- 1. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Breast cancer. Version 4.2020. Available: www.nccn.org/
- U.S. Food and Drug Administration. FDA breast implant consumer handbook 2006. Available: https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/Guidance/GuidanceDocuments/UCM071233.pdf
- 3. American Society of Plastic Surgeons (ASPS) Website. Evidence-Based Clinical Practice Guideline: Breast Reconstruction with Expanders and Implants. 2013. Available: http://www.plasticsurgery.org/Documents/Health-
 Policy/Guidelines/guideline-2013-breast-recon-expanders-implants.pdf
- American Society of Plastic Surgeons (ASPS). ASPS Recommended Insurance Coverage for Third Party Payers. Breast Implant Associated Anaplastic Large Cell Lymphoma. Approved Oct 2017; Reapproved Jun 2020. Accessed Nov 19, 2021. Available at URL address: https://www.plasticsurgery.org/documents/Health-Policy/Reimbursement/Insurance-2017-BIA-ALCL.pdf

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Customer Product	Medical Management Requirements*
New York Products	•
HMO	Prior Auth
PPO in Plan	Prior Auth
PPO OOP	Prior Auth
POS in Plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Prior Auth
MVP Child Health Plus	Prior Auth
MVP Harmonious Health Care Plan	Prior Auth
MVP Medicare Complete Wellness	Prior auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP Medicare WellSelect PPO	Prior Auth
MVP Medicare WellSelect Plus PPO	Prior Auth
MVP Medicare Patriot Plan PPO	Prior Auth
MVP DualAccess D-SNP HMO	Prior Auth
MVP DualAccess Complete D-SNP HMO	Prior Auth
MVP DualAccess Plus D-SNP HMO	Prior Auth
UVM Health Advantage Select PPO	Prior Auth
USA Care PPO	Potential for Retrospective Review
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	
ASO	Prior Auth See SPD
Vermont Products	See 25D
POS in Plan	Prior Auth
POS OOP	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth Prior Auth
MVP Medicare Secure Plus HMO POS MVP VT HMO	Prior Auth
	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT Plus HDHP HMO	Daina Austr
MVP Secure	Prior Auth
ASO	See SPD

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Breast Implantation Page 5 of 6

Revision History:

04/01/2021: Updated to new format, added examples of indications that may apply to each criteria point, added documentation requirements and added additional exclusion for cosmetic breast implants.

04/01/2023: Annual review; added indication for breast implant-associated anaplastic large cell lymphoma; removed prior authorization from 19342, 19369, L8600, updated references.

08/01/2024 – Add prior authorization to 19370, 19371 if being done without a diagnosis of breast cancer.

Breast Implantation Page 6 of 6



Breast Pumps

Type of Policy: DME

Prior Approval Date: 05/04/2020

Approval Date: 05/02/2022

Effective Date: 08/01/2022

Related Polices: N/A

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

N/A

Codes Requiring Retrospective Review

N/A

Experimental/Investigational

N/A

Common Diagnosis Codes

N/A

Common Procedure Codes

HCPCS Codes:

E0602 - Breast pump, manual, any type

E0603 - Breast pump, electric (AC and/or DC), any type

E0604 - Breast pump, hospital grade, electric (AC and/or DC), any type

A4281 - Tubing for breast pump, replacement

A4282 - Adapter for breast pump, replacement

- A4283 Cap for breast pump bottle, replacement
- A4284 Breast shield and splash protector for use with breast pump, replacement
- A4285 Polycarbonate bottle for use with breast pump, replacement
- A4286 Locking ring for breast pump, replacement
- A4287 Disposable collection and storage bag for breast milk, any size, any type, each
- S8265 Haberman feeder for cleft lip/palate

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

Breastfeeding has been proven to have numerous health benefits for both parent and child. Studies show that children who are breastfed have lower rates of mortality, meningitis, some types of cancers, asthma and other respiratory illnesses, bacterial and viral infections, ear infections, juvenile diabetes, some chronic liver diseases, allergies and obesity. The American Academy of Pediatrics recommends that parents breastfeed exclusively for the first six months but continue breastfeeding for at least the first year of a child's life. [1]

There are several varieties of breast pumps including manual, electric and hospital grade. A manual breast pump may be used by a lactating parent to ensure a milk supply if they are occasionally unable to breast feed or they are not at home for short periods of time. An electric breast pump provides speed and convenience for routine daily pumping for working parents who need to provide a milk supply while they are away from baby. Heavy duty or hospital grade breast pumps are used when baby is not able to nurse from the breast due to medical conditions.

Although breastfeeding is optimal for infants, there are a few conditions under which breastfeeding may not be in the best interest of the infant. Breastfeeding is contraindicated in infants with classic galactosemia (galactose 1-phosphate uridyltransferase deficiency); parents who have active untreated tuberculosis disease or are human T-cell lymphotropic virus type I— or II—positive; parents who are receiving diagnostic or therapeutic radioactive isotopes or have had exposure to radioactive materials (for as long as there is radioactivity in the milk); parents who are receiving antimetabolites or chemotherapeutic agents or a small number of other medications until they clear the milk; parents who are using drugs of abuse ("street drugs"); and parents who have herpes simplex lesions on a breast (infant may feed from other breast

if clear of lesions). In the United States, parents who are infected with human immunodeficiency virus (HIV) have been advised not to breastfeed their infants.

Indications/Criteria

Manual and Electric Breast Pump Coverage

- MVP will cover the purchase of one breast pump per live birth.
- Replacement supplies for the breast pump will be covered per live birth.
- Breastfeeding equipment and supplies include, but are not limited to, double electric breast pumps (including pump parts and maintenance) and breast milk storage supplies.
- Coverage of a double electric breast pump is not based on prior failure of a manual pump.

Hospital Grade Electric (AC or DC) Breast Pump Rental Only

Hospital Grade breast pump coverage is limited to the following:

- cases of prematurity (including multiple gestation);
- neurologic disorders;
- genetic abnormalities (e.g., Down's Syndrome);
- anatomic and mechanical malformations (e.g., cleft lip and palate);
- congenital malformations requiring surgery (e.g., respiratory, cardiac, gastrointestinal, CNS);
- prolonged infant hospitalization;
- conditions that prevent normal breastfeeding (e.g., respiratory compromise).

Tubing for breast pump, replacement (A4281): One additional replacement tubing for breast pump kit is covered per live birth.

For parents using a breast pump from a prior pregnancy, a new set of breast pump supplies is considered medically necessary with each subsequent pregnancy for initiation or continuation of breastfeeding during pregnancy or following delivery.

Exclusions

- Not meeting criteria listed under Indications/Criteria of this policy.
- The purchase of more than one breast pump per live birth is considered to be not medically necessary.
- Purchase of heavy duty electrical (hospital grade) breast pumps are not medically necessary.

Medicare

There are no National Coverage Determinations (NCD) or Local Coverage Determinations found for breast pump coverage.

References (Updated 2022)

- American Academy of Pediatrics. The Breastfeeding-Friendly Pediatric Office Practice].
 Pediatrics April 2017; Available:
 http://pediatrics.aappublications.org/content/early/2017/04/13/peds.2017-0647
- 2. American Academy of Family Physicians (AAFP). Breastfeeding (Policy Statement). 2017. Accessed April 12, 2021. Available: <u>Breastfeeding, Family Physicians Supporting (Position Paper) (aafp.org)</u>
- 3. Academy of Breastfeeding Medicine (ABM). ABM Clinical Protocol #7: Model Maternal Protocol Supportive of Breastfeeding (Revision 2018) Volume 13, Number 9, 2018. Available: https://www.bfmed.org/protocols
- 4. United States Patient Protection and Affordable Care Act. Part 590. August 1, 2011.
- 5. New York State Medicaid Program. Durable Medical Equipment, Orthotics, Prosthetics, and Supplies. Procedure codes and Coverage Guidelines. Version 2019-1 (08/01/2019). Available: https://www.emedny.org/providermanuals/dme/pdfs/dme_procedure_codes.pdf
- 6. U.S. Department of Health and Human Services. Health Resources and Services Administration. Women's Preventive Services Guidelines. Available: http://www.hrsa.gov/womensguidelines/
- 7. U.S. Preventive Services Task Force, Bibbins-Domingo K, Grossman DC, Curry SJ, Davidson KW, Epling JW Jr, et al. Primary Care Interventions to Support Breastfeeding: US Preventive Services Task Force Recommendation Statement. JAMA. 2016 Oct 25;316(16):1688-1693
- 8. New York State Department of Health. New York State Coverage of Breast Pumps.
 Available:
 https://www.health.ny.gov/community/pregnancy/breastfeeding/medicaid_coverage/breast_pump_coverage.htm
- World Health Organization (WHO). Guideline: protecting, promoting and supporting breastfeeding in facilities providing maternity and newborn services. 2017. Accessed April 12, 2021. Available at URL address: http://www.who.int/nutrition/publications/guidelines/breastfeeding-facilitiesmaternitynewborn/en/
- 10. Women's Preventive Services Initiative: Breastfeeding Services and Supplies. January 2022 © 2018 ACOG Foundation Available: Women's Breastfeeding Services, Products

<u>- Preventive Healthcare | Women's Preventive Services Initiative</u> (womenspreventivehealth.org)

Breast Pumps Page 5 of 7

Customer Product	Medical Management Requirements*
New York Products	
НМО	Potential for Retrospective Review
PPO in Plan	Potential for Retrospective Review
PPO OOP	Potential for Retrospective Review
POS In plan	Potential for Retrospective Review
POS OOP	Potential for Retrospective Review
Essential Plan	Potential for Retrospective Review
MVP Medicaid Managed Care	Potential for Retrospective Review
MVP Child Health Plus	Potential for Retrospective Review
MVP Harmonious Health Care Plan	Potential for Retrospective Review
MVP Medicare Complete Wellness	Potential for Retrospective Review
MVP Medicare Preferred Gold HMO POS	Potential for Retrospective Review
MVP Medicare Secure HMO POS	Potential for Retrospective Review
MVP Medicare Secure Plus HMO POS	Potential for Retrospective Review
MVP Medicare WellSelect PPO	Potential for Retrospective Review
MVP Medicare WellSelect Plus PPO	Potential for Retrospective Review
MVP Medicare Patriot Plan PPO	Potential for Retrospective Review
MVP DualAccess D-SNP HMO	Potential for Retrospective Review
MVP DualAccess Complete D-SNP HMO	Potential for Retrospective Review
MVP DualAccess Plus D-SNP HMO	Potential for Retrospective Review
UVM Health Advantage Select PPO	Potential for Retrospective Review
USA Care PPO	Potential for Retrospective Review
Healthy NY	Potential for Retrospective Review
MVP Premier	Potential for Retrospective Review
MVP Premier Plus	Potential for Retrospective Review
MVP Premier Plus HDHP	Potential for Retrospective Review
MVP Secure	Potential for Retrospective Review
MVP EPO	Potential for Retrospective Review
MVP EPO HDHP	Potential for Retrospective Review
MVP PPO	Potential for Retrospective Review
MVP PPO HDHP	Potential for Retrospective Review
Student Health Plans	Potential for Retrospective Review
ASO	See SPD
Vermont Products	
POS in Plan	Potential for Retrospective Review
POS OOP	Potential for Retrospective Review
MVP Medicare Preferred Gold HMO POS	Potential for Retrospective Review
MVP Medicare Secure Plus HMO POS	Potential for Retrospective Review
MVP VT HMO	Potential for Retrospective Review
MVP VT HDHP HMO	Potential for Retrospective Review
MVP VT Plus HMO	Potential for Retrospective Review
MVP VT Plus HDHP HMO	Potential for Retrospective Review
MVP Secure	Potential for Retrospective Review
ASO	See SPD

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review.

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Revision History:

08/01/2022 – Annual Review; adding coverage to K1005 - Disposable collection and storage bag for breast milk, any size, any type, each with no prior authorization or retrospective review.

Breast Pumps Page 7 of 7



Breast Reconstruction Surgery

Type of Policy: Surgical

Prior Approval Date: 01/09/2023

Approval Date: 10/02/2023

Effective Date: 12/01/2023

Related Polices:Breast Implantation

Breast Reduction Surgery (Reduction Mammaplasty) External Breast Prosthesis Gender Affirming Treatment

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

N/A

Codes Requiring Retrospective Review

N/A

Experimental/Investigational

N/A

Common Diagnosis Codes

ICD-10- CM Diagnosis Codes

C50.111, C50.112, C50.119, C50.211, C50.212, C50.219, C50.312, C50.319, C50.411, C50.412, C50.419, C50.511, C50.512, C50.519, C50.611, C50.612, C50.619, C50.811, C50.812, C50.819, C50.911, C50.912, C50.919, C79.81, D05.00, D05.01, D05.02, D05.10, D05.11, D05.12, D05.8, D05.80, D05.81, D05.82, D05.9, D05.91, D05.92, N65.0-N65.1, T85.41xA, T85.42xA, T85.43xA, T85.44xA, T85.49xA, T85.79xA, T85.82, T85.83, T85.84, T85.86, T85.89, Z42.1, Z45.811-Z45.819, Z85.3, Z90.10, Z90.11, Z90.12, Z90.13

Common Diagnosis Codes associated with this policy have been provided for informational purposes only. The list of codes may not be all-inclusive and may be updated to reflect any applicable revisions to the ICD-10 code set and/or medical necessity quidelines applied in this policy.

Common Procedure Codes

CPT Codes: 15777, 19350, 19357, 19361, 19364, 19367, 19368, 19369, 19380

The American Medical Association (AMA) has identified CPT code 19364 as the appropriate code for breast reconstruction with free flap procedures, regardless of the free flap technique used. MVP Health Care will no longer reimburse HCPCS codes S2066, S2067 and S2068 as all procedures reimbursable under each of those S codes are reimbursable under CPT code 19364.

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

Reconstructive surgery following breast surgery is performed to create a simulated breast, specifically attempting to match a normal breast. Surgery on the contralateral breast may be required to achieve bilateral symmetry. The reconstruction may be performed immediately following surgery or may be delayed until a later date. Breast reconstruction may involve a flap procedure. The flap procedure is an alternative approach to implant reconstruction involves creation of a skin flap using tissue taken from the back, abdomen, or buttocks and transplanted to the chest. Breast reconstruction surgery usually necessitates two stages; the first stage is for the reconstruction of the breast; the second stage is for reconstruction of the nipple and areola.

In an attempt to improve outcomes following breast reconstruction, researchers have used allogeneic skin grafts (biological implant) obtained from cadavers for providing additional coverage and support of implants and other tissues at the surgical site. Human acellular dermal matrices (HADM) [e.g. Alloderm®] provides a collagen-rich, immunologically nonresponsive, biological structural scaffold for tissue ingrowth, vascularization, and regeneration for use in breast reconstruction (BR) and other types of plastic surgery. In immediate postmastectomy breast reconstruction, HADM is used to create the implant pocket in 1-stage breast reconstruction and to help cover the tissue expander in 2-stage breast reconstruction.

Flap reconstructions are generally considered to give a more long-lasting and natural result than implants with fewer revision surgeries.

Physicians should discuss breast reconstruction options with customers.

Indications/Criteria

Documentation Requirements

- Documentation must include a complete history, physical examination and diagnosis. In addition, the documentation should specify if the proposed procedure will be immediate (done at the same time as the mastectomy or partial mastectomy) or delayed (done after the original mastectomy or partial mastectomy).
- Documentation should state whether the proposed reconstruction is for the affected breast or for symmetry of the contralateral non-affected breast.
- If the proposed procedure is for the second stage (nipple/areola reconstruction), the intention to utilize tattooing instead of skin grafting must be specifically noted.
 Include any other breast reconstructive surgical procedures performed with dates of surgery.
- Asymmetry must be documented by medical notes and photographs for revision of contralateral reconstructions.

The following breast reconstruction/construction procedures are covered after mastectomy, partial mastectomy, or to correct a congenital defect (i. e. Poland Syndrome):

- breast implantation; or (refer to MVP Breast Implantation policy);
- flap reconstruction procedures; or reconstruction of the contralateral breast for symmetry; or
- nipple/areola reconstruction and tattooing; or
- chest wall reconstruction.

Breast reconstruction in individuals with breast cancer who have not had a mastectomy or partial mastectomy will be considered by the Medical Director on a case-by-case basis.

There is no time limit specified for the reconstruction of the breast. In most cases, reconstruction is completed during the first year following mastectomy. Delays may occur due to complications of prior surgeries or other health issues which require higher priority.

Revision Criteria

Revision procedures are rarely required. Indications for such revisions of prior reconstructions include, but are not limited to:

 progression of disease or disfigurement in the breast for which mastectomy or partial mastectomy was performed; or

failure of the original surgery in the contra-lateral breast i.e., wound infection, contracted scars, rejected implant.

For customers that have undergone gender confirmation surgery, breast reconstruction surgery is covered under the parameters of the New York State Mandate. For additional information see: Criteria Standards for the Authorization and Utilization Management of Hormone Therapy and Surgery for the Treatment of Gender Dysphoria (ny.gov)

 Breast reconstruction related to treat gender dysphoria (Refer to the MVP Gender Affirming Treatment Policy)

Exclusions

- Requests not meeting criteria under Indications/Criteria of this policy.
- Bilateral augmentation solely to enlarge the breasts is cosmetic in nature and, therefore, is considered not medically necessary.
- Customers that do not have out-of-network benefits are required to utilize participating providers unless prior-authorized by MVP.
- An in-plan second opinion or consult may be required before coverage of out-ofnetwork care when a customer has no out-of-network benefit.

Medicare

There is a Medicare National Coverage Determination (NCD) for Breast Reconstruction Following Mastectomy. For full coverage and limitation details, refer to the Medicare link below:

Centers for Medicare and Medicaid Services (CMS) National Coverage Decision (NCD) 140.2, Breast Reconstruction following Mastectomy (140.2) Effective date 01/01/1997. Available: National Coverage Determination (NCD) for Breast Reconstruction Following Mastectomy (140.2) (cms.gov)

References (Reviewed 2023)

- 1. American Society of Plastic Surgeons. Evidence-Based Clinical Practice Guideline: Breast Reconstruction with Expanders and Implants. Published © March 2013. Available: www.plasticsurgery.org.
- 2. American Society of Plastic Surgeons, Breast Reconstruction following Breast Removal. Available: www.plasticsurgery.org.
- 3. United States. 105th Congress. H.R.616. Women's Health and Cancer Rights Act of 1997. Available: https://www.congress.gov/bill/105th-congress/house-bill/616.

- 4. Centers for Medicare and Medicaid Services (CMS) National Coverage Decision (NCD) 140.2, Breast Reconstruction following Mastectomy (140.2) Effective date 01/01/1997. Available: https://www.cms.gov/medicare-coverage-database.
- 5. Title IX Women's Health and Cancer Rights Act of 1998. H.R. 4328, the Omnibus Appropriations bill FY 99 Conference Report 105-825; Public Law: 105-277 (10/21/98). Available: https://www.congress.gov/bill/105th-congress/house-bill/4328.
- 6. New York State Insurance Law Amd SS3216, 3221 & 4303, Ins L. As passed in H.R. 4328, the Omnibus Appropriations bill FY 99 Conference Report 105-825; Public Law: 105-277 (10/21/98) TITLE IX--WOMEN'S HEALTH AND CANCER RIGHTS ACT 1998. SEC. 713. REQUIRED COVERAGE FOR RECONSTRUCTIVE SURGERY FOLLOWING MASTECTOMIES.
- 7. Hayes Medical Technology Directory. Human Acellular Dermal Matrix Grafts for Breast Reconstruction. Hayes, a TractManager Company; ©2020 TractManager. January 28, 2019. Annual Review: May 11, 2020. Available: www.hayesinc.com.
- 8. New York State Assembly Bill A8537 Chest Wall Reconstruction Commercial Coverage Mandate.

Customer Product	Medical Management Requirements*
New York Products	-
НМО	Potential for Retrospective Review
PPO In Plan	Potential for Retrospective Review
PPO OOP	Potential for Retrospective Review
POS In Plan	Potential for Retrospective Review
POS OOP	Potential for Retrospective Review
Essential Plan	Potential for Retrospective Review
MVP Medicaid Managed Care	Potential for Retrospective Review
MVP Child Health Plus	Potential for Retrospective Review
MVP Harmonious Health Care Plan	Potential for Retrospective Review
MVP Medicare Complete Wellness	
MVP Medicare Preferred Gold HMO POS	Potential for Retrospective Review
MVP Medicare Secure HMO POS	Potential for Retrospective Review
MVP Medicare Secure Plus HMO POS	Potential for Retrospective Review
MVP Medicare WellSelect PPO	Potential for Retrospective Review
MVP Medicare WellSelect Plus PPO	Potential for Retrospective Review
MVP Medicare Patriot Plan PPO	Potential for Retrospective Review
MVP DualAccess D-SNP HMO	Potential for Retrospective Review
MVP DualAccess Complete D-SNP HMO	Potential for Retrospective Review
MVP DualAccess Plus D-SNP HMO	Potential for Retrospective Review
UVM Health Advantage Select PPO	Potential for Retrospective Review
USA Care PPO	Potential for Retrospective Review
Healthy NY	Potential for Retrospective Review
MVP Premier	Potential for Retrospective Review
MVP Premier Plus	Potential for Retrospective Review
MVP Premier Plus HDHP	Potential for Retrospective Review
MVP Secure	Potential for Retrospective Review
MVP EPO	Potential for Retrospective Review
MVP EPO HDHP	Potential for Retrospective Review
MVP PPO	Potential for Retrospective Review
MVP PPO HDHP	Potential for Retrospective Review
Student Health Plans	Potential for Retrospective Review
ASO	See SPD
Vermont Products	
POS In Plan	Potential for Retrospective Review
POS OOP	Potential for Retrospective Review
MVP Medicare Preferred Gold HMO POS	Potential for Retrospective Review
MVP Medicare Secure Plus HMO POS	Potential for Retrospective Review
MVP VT HMO	Potential for Retrospective Review
MVP VT HDHP HMO	Potential for Retrospective Review
MVP VT Plus HMO	Potential for Retrospective Review
MVP VT Plus HDHP HOM	Potential for Retrospective Review
MVP Secure	Potential for Retrospective Review
ASO	See SPD

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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Prior Auth Potential for Retrospective Review Retro Review Not Covered See SPD Prior Authorization Required
No Prior Authorization Required. May be subject to Retrospective Review
Retrospective Review Required
Service is not a covered benefit.
See Specific Plan Design

Revision History:

06/01/2021 - Annual Review with no changes to the indications or criteria.

10/01/2022 – Added reimbursement rules for 19364, S2066, S2067, S2068 to the coding section.

04/01/2023 – Reviewed policy for compliance with Chest Wall Reconstruction Commercial Coverage Mandate in NY State, added reference.

12/01/2023 –Added coverage for breast construction/reconstruction to correct congenital deformities such as Poland Syndrome.



Breast Reduction Surgery (Reduction Mammaplasty)

Type of Policy: Surgical

Prior Approval Date: 10/03/2024

Approval Date: 12/02/2024 **Effective Date:** 04/01/2025

Related Polices: Breast Reconstruction Breast

Implantation and Removal

Breast Surgery for Gynecomastia

Gender Affirming Treatment

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

CPT/HCPCS Code:	Description:
19318	Reduction mammaplasty

Note: If there is a diagnosis of breast cancer indicated by one of the following ICD-10 Diagnosis Codes, prior authorization is not required:

C50.111, C50.112, C50.119, C50.211, C50.212, C50.219, C50.311, C50.312, C50.319, C50.411, C50.412, C50.419, C50.511, C50.512, C50.519, C50.611, C50.612, C50.619, C50.811, C50.812, C50.819, C50.911, C50.912, C50.919, D05.00, D05.01, D05.02, D05.10, D05.11, D05.12, D05.80, D05.81, D05.82, D05.90, D05.91, D05.92, Z172, Z1721, Z1722, Z173, Z1731, Z1732, Z174, Z17410, Z17411, Z1742, Z17420, Z17421, Z42.1, Z85.3

Experimental/Investigational Codes Requiring Retrospective Review

N/A

Diagnosis Codes

ICD-10-CM Diagnosis Codes: C50.011, C50.012, C50.019, C50.111, C50.112, C50.119, C50.211, C50.212, C50.219, C50.311, C50.312, C50.319, C50.411, C50.412, C50.419,

C50.511, C50.512, C50.519, C50.611, C50.612, C50.619, C50.811, C50.812, C50.819, C50.911, C50.912, C50.919, D05.00, D05.01, D05.02, D05.10, D05.11, D05.12, D05.80, D05.81, D05.82, D05.90, D05.91, D05.92, N64.89, N65.0, N65.1, T85.41xA, T85.42xA, T85.43xA, T85.44xA, T85.49xA, T85.79xA, T85.82, T85.83, T85.84, T85.86, T85.89, Z15.01, Z42.1, Z45.811, Z45.812, Z45.819, Z85.3, Z90.10, Z90.11, Z90.12, Z90.13

Common Diagnosis Codes associated with this policy have been provided for informational purposes only. The list of codes may not be all-inclusive and may be updated to reflect any applicable revisions to the ICD-10 code sets and/or medical necessity guidelines applied in this policy.

Common Procedure Codes

N/A

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

A breast reduction surgery or reduction mammaplasty is the surgical excision and removal of a substantial portion of the breast. The surgical removal of breast tissue, including the skin, reduces the weight and size of the breast. Normal breast development continues until an individual is in their early twenties, with the rate and development and the degree of asymmetry often varying. The goals of breast reduction surgery are for relief of pain in the back, neck and shoulders. Because breast reduction surgery may be used for both medically necessary and cosmetic reasons, this policy sets forth the objective criteria to distinguish medically necessary breast reduction surgery from cosmetic reduction procedures.

Indications/Criteria

Breast Reduction Surgery for Hypertrophy

Breast reduction surgery for hypertrophy will be considered medically necessary for individuals at least 18 years of age, or when growth that is complete (with breast size stable over one year) when documentation from a provider other than the surgeon requesting coverage is submitted that demonstrates that at least one of the following criteria have been tried and failed:

clavicular bra strap shoulder grooves causing severe pain or ulceration that interferes
with the customer's activities of daily living. The customer must have failed a six (6)
month trial of conservative therapy including analgesics and the use of supportive
and properly fitted garments; or

persistent pain in the back, neck, shoulders with documentation stating that other
musculoskeletal conditions have been ruled out (i.e., arthritis or spondylitis). The
customer must have failed a six (6) month trial of conservative therapy including
analgesics, non-steroidal anti-inflammatory drugs (NSAIDs) unless contraindicated,
physical therapy/chiropractic care, and the use of supportive and properly fitted
garments; or

chronic intertrigo, dermatitis, eczema or evidence of skin breakdown in the inframammary fold. The customer must have documentation of dermatologic consultation and must have failed dermatologic treatment (e.g., antibiotics or antifungal therapy) for a period of six (6) months or longer. In addition to the criteria listed above, it is required that the <u>minimum</u> amount of breast tissue (in grams) to be removed be determined by the customer's body surface area.

Formula for Calculation of Body Surface Area:

BSA (m^2) = 0.20247 x Height (m) $^{0.725}$ x Weight (kg) $^{0.425}$

You may also go to the following site for calculation of Body Surface Area: http://www.medcalc.com/body.html

Refer to Table 1 for the weight (in grams) of breast tissue removed per breast as a function of Body Surface Area.

Table 1: Weight of breast tissue removed, per breast, as a function of body surface area.

Body Surface Area	Threshold value for the <u>minimum</u> grams of tissue per breast to be removed	Threshold value for the <u>total</u> grams of breast tissue to be removed
1.35	199	398
1.40	218	436
1.45	238	476
1.50	260	520
1.55	284	568
1.60	310	620
1.65	338	676
1.70	370	740
1.75	404	808
1.80	441	882
1.85	482	964
1.90	527	1054
1.95	575	1150
2.00	628	1256
2.05	687	1374
2.10	750	1500
2.15	819	1638
2.20	895	1790
2.25	978	1956

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2.30	1068	2136
2.35	1167	2334
2.40	1275	2550
2.45	1393	2786
2.50	1522	3044
2.55	1662	3324

Schnur, Paul L, et al. "Reduction Mammaplasty: Cosmetic or Reconstructive Procedure?" Annals of Plastic Surgery. 232-237.

Photographs may be requested at the discretion of the Medical Director.

Other indications for Breast Reduction Surgery

The following indications are not subject to the above hypertrophy criteria.

Breast reduction surgery will be considered medically necessary when performed as part of a staged procedure prior to a prophylactic nipple-sparing mastectomy.

Breast reduction of a contralateral breast may be considered medically necessary following a mastectomy for breast cancer. Please refer to the MVP Breast Reconstruction Medical Policy.

Breast reduction related to the treatment of gender dysphoria, please refer to the MVP Gender Affirming Treatment medical policy.

Exclusions

- Requests not meeting Indication/Criteria stated in this policy.
- Requests for breast reduction surgery that is for cosmetic purposes.
- Breast augmentation is not covered as part of the breast reduction surgery.

Medicare Variation

Reduction mammaplasty is considered medically necessary:

When the patient has significant symptoms that have interfered with normal daily activities, despite conservative management, for at least 6 months, including at least one of the following criteria:

- History of back and/or shoulder pain which adversely affects activities of daily living (ADLs) unrelieved by, e.g.:
 - o conservative analgesia (e.g., such as NSAID, compresses, massage, etc.)
 - o supportive measures (e.g., such as garments, back brace, etc.),
 - physical therapy
 - correction of obesity

- History of significant arthritic changes in the cervical or upper thoracic spine, optimally managed with persistent symptoms and/or significant restriction of activity, e.g.:
 - Signs and symptoms of ulnar paresthesias
 - o Cervicalgia
 - Torticollis
 - Acquired kyphosis
- Signs and symptoms of:
 - intertriginous maceration or infection of the inframammary skin (e.g., hyperpigmentation, bleeding, chronic moisture, and evidence of skin breakdown), refractory to dermatologic measures, or
 - shoulder grooving with skin irritation (e.g., areas of excoriation and breakdown) by appropriate supporting garment

AND

Considerable attention has been given to the amount of breast tissue removed in differentiating between cosmetic and medically necessary reduction mammoplasty. To be considered a non-cosmetic procedure it is expected that at least a minimal amount of breast tissue will be removed. Yet, arbitrary minimum weight breast tissue removed criteria do not consistently reflect the consequences of mammary hypertrophy in individuals with a unique body habitus. There are wide variations in the range of height, weight, and associated breast size that cause symptoms. The amount of tissue that must be removed in order to relieve symptoms will vary and depend upon these variations.

The following are guidelines (not rules) that address the patient's body surface area (BSA) and the amount of breast tissue removed

BSA 1.35-1.45 199g-238g

BSA 1.46-1.55 239g-284g

BSA 1.56-1.69 285g-349g

Equal to or greater than 350g

Limitations of Coverage:

- 1. Cosmetic surgery to reshape the breasts to improve appearance is not a Medicare benefit.
- 2. Indications of Coverage must be met.

 Note: Reconstruction of the affected and the contralateral unaffected breast following a medically necessary mastectomy is considered a non-cosmetic procedure. National coverage provides for payment of breast reconstruction surgery following removal of a breast for any medical reason.

Centers for Medicare & Medicaid Services (CMS). Medicare Coverage Database. LCD for Reduction Mammaplasty (L35001) Feb 1, 2024. Available: https://www.cms.gov/

References (Updated 2024)

- American Society of Plastic Surgeons. Reduction Mammaplasty. Evidence-Based Practice Guidelines. May 2011. Available: https://www.plasticsurgery.org/Documents/Health-Policy/Guidelines/guidelines-2011-reduction-mammaplasty.pdf
- American Society of Plastic Surgeons (ASPS). Reduction Mammaplasty
 Recommended Insurance Coverage for Third-Party Payer Coverage. May 2011.
 Updated Reaffirmed: Mar 2021. Available at URL address:
 https://www.plasticsurgery.org/for-medical-professionals/healthpolicy/recommended-insurance-coverage-criteria
- 3. National Institute for Health (NIH). Breast reduction mammoplasty. February 8, 2011. Accessed June 28, 2012. Available: http://www.nih.gov/
- National Comprehensive Cancer Network® (NCCN). NCCN GUIDELINES™ Clinical Practice Guidelines in Oncology™. © Breast Cancer Risk Reduction. Version 1.2020-May 29, 2020. National Comprehensive Cancer Network, Inc . 2019 Available: www.nccn.org/
- 5. United States Department of Agriculture. Products & Services/BMI Tables Available: www.ars.usda.gov/Services/docs.htm?docid=11236
- 6. Medicare Local Coverage Decision: National Government Services, LLC. Local Coverage Decision, Reduction Mammaplasty (L35001) Original Effective Date: 10/01/2015 Revision Effective date: 02/01/2024. Available: https://www.cms.go
- 7. DeSilva NK, Brandt ML. Disorders of the breast in children and adolescents, Part 1: Disorders of growth and infections of the breast. J Pediatr Adolesc Gynecol. 2006 Oct;19(5):345-9.
- 8. Banikarim C, DeSilva N. Breast disorders in children and adolescents: An overview. Last updated Dec 21, 2017. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA
- 9. McGrath MH, Schooler WG. Elective plastic surgical procedures in adolescence. Adolesc Med Clin. 2004 Oct;15(3):487-502.
- 10. Regnault P. Breast ptosis. Definition and treatment. Clin Plast Surg. 1976 Apr;3(2):193-203. PMID: 1261176.

Customer Product	Medical Management Requirements*
New York Products	-
НМО	Prior Auth
PPO in Plan	Prior Auth
PPO OOP	Prior Auth
POS in Plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Prior Auth
MVP Child Health Plus	Prior Auth
MVP Harmonious Health Care Plan	Prior Auth
MVP Medicare Complete Wellness	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP Medicare WellSelect PPO	Prior Auth
MVP Medicare WellSelect Plus PPO	Prior Auth
MVP Patriot Plan PPO	Prior Auth
MVP DualAccess D-SNP HMO	Prior Auth
MVP DualAccess Complete D-SNP HMO	Prior Auth
MVP DualAccess Plus D-SNP HMO	Prior Auth
UVM Health Advantage Select PPO	Prior Auth
USA Care PPO	Potential for Retrospective Review
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	
POS in Plan	Prior Auth
POS OOP	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP VT HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD

[♦] Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Revision History:

04/01/2021 – updated to new format, added criteria for age of individuals, removed brachial plexus compression from the indications, added column with total grams of tissue.

04/01/2023 – Annual review; added exclusion that breast augmentation is not covered as part of the breast reduction surgery; references updated.

10/01/2024 – Annual review. Updated to include breast reduction as part of staged mastectomy. Updated to include Medicare variation.

04/01/2025 – Formal review of 10/01/24 updates completed.



Breast Surgery for Gynecomastia

Type of Policy: Surgical

Prior Approval Date: 10/03/2022

Approval Date: 10/07/2024

Effective Date: 12/01/2024

Related Polices: N/A

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

CPT Code:

19300 - Mastectomy for gynecomastia

Codes Requiring Retrospective Review:

N/A

Experimental/Investigational

N/A

Common Diagnosis Codes

ICD-10 Diagnosis Codes: C50.029

Common Procedure Codes

N/A

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

Breast Surgery for Gynecomastia

Gynecomastia is a proliferation of the glandular component of the male breast causing firm breast tissue to form.

Pseudogynecomastia is male breast enlargement due to fat accumulation.

Mixed gynecomastia is when both fat tissue and glandular tissue causes enlargement.

Gynecomastia is often the results of hormonal changes. Pubertal gynecomastia occurs in males between the age of 10 -16. Adult gynecomastia is associated with an increase in the estrogen/androgen ratio. Causes can be medications, diseases related to endocrine abnormalities, tumors, chronic disease, chromosomal abnormalities, and/or familial disorders.

Treatment for gynecomastia can include medical management and surgical.

Gynecomastia Scale per the American Society of Plastic Surgeons:

- Grade I Small breast enlargement with localized button of tissue that is concentrated around the areola.
- Grade II Moderate breast enlargement exceeding areola boundaries with edges that are indistinct from the chest.
- Grade III Moderate breast enlargement exceeding areola boundaries with edges that are distinct from the chest with skin redundancy present.
- Grade IV Marked breast enlargement with skin redundancy and feminization of the breast.

Indications/Criteria

Documentation must include a complete history and physical exam, appropriate diagnostic testing (hormone testing, liver enzymes, serum creatinine, thyroid function testing), and that any underlying causes have been evaluated and treated.

Adolescents (12-17yrs) and Adults

Mastectomy for the treatment of gynecomastia will be considered medical necessary when all of the following criteria are met:

- Unilateral or bilateral grade III or grade IV gynecomastia;
- Persisted for more than one year;
- Documented symptoms, including pain or tenderness directly related to the breast tissue, and which has a clinically significant impact upon normal activities of daily living despite non-narcotic analgesics and anti- inflammatory agents;
- Glandular breast tissue is documented by physical exam and ultrasound or mammography;
- 6 month failure of medical treatment for gynecomastia; and

• extra tissue is not the result of obesity, adolescence, or reversible effects of drug treatment or recreational drugs (including but limited to alcohol, and marijuana) that can be discontinued.

Breast surgery for a cancer diagnosis, including a mastectomy, is considered medically necessary.

Exclusions

- Mastectomy/breast reduction for gynecomastia when performed solely to improve the appearance of the male breast or to alter the contours of the chest wall is considered to be cosmetic.
 - Any service or surgery in connection with cosmetic care, which is primarily intended to improve appearance and self-esteem, will be denied as not medically necessary.
- Surgery performed for obesity.
- Mastectomy is not medically necessary when extra tissue is the result of obesity, adolescence, or reversible effects of drug treatment or recreational drugs that can be discontinued.
- Liposuction or ultrasonically-assisted liposuction (suction lipectomy) as a sole method of treatment for gynecomastia is considered experimental, investigational, or unproven.

Medicare Variation

Based on review there are no National or Local Determination Coverage for this region.

References (Reviewed 2024)

- American Association of Clinical Endocrinologists medical guidelines for clinical practice for the evaluation and treatment of hypogonadism in adult male patients. [2002 update]. Endocrine Pract. 2002; 8:439-456. Available: American Association of Clinical Endocrinologists Medical Guidelines for Clinical Practice for the Evaluation and Treatment of Hypogonadism in Adult Male Patients—2002 Update Endocrine Practice
- Weiss J.R., Moysich K.B., Swede H. (2005, January 14) Epidemiology of male breast cancer. Cancer epidemiol biomarkers prev. 14(1):20-26. Available: http://cebp.aacrjournals.org/content/14/1/20.long.
- 3. National Cancer Institute. Male breast cancer (PDQ®) treatment. General information. Modified February 2016. Available: http://www.cancer.gov/types/breast/hp/male-breast-treatment-pdg.

- 4. The National Comprehensive Cancer Network, Genetic/Familial High-Risk Assessment Breast, Ovarian, and Pancreatic Guidelines, Clinical Practice Guidelines in Oncology, Version 1.2020. Available: www.nccn.org.
- 5. American Society of Plastic Surgeons (ASPS). Health Policy. ASPS Recommended Insurance Coverage Criteria for Third-Party Payers. Gynecomastia. June 2015. Accessed August 2021. Available from URL address: Gynecomastia ICC.pdf (plasticsurgery.org)

Customer Product	Medical Management Requirements*
New York Products	
НМО	Prior Authorization
PPO in Plan	Prior Authorization
PPO OOP	Prior Authorization
POS in Plan	Prior Authorization
POS OOP	Prior Authorization
Essential Plan	Prior Authorization
MVP Medicaid Managed Care	Prior Authorization
MVP Child Health Plus	Prior Authorization
MVP Harmonious Health Care Plan	Prior Authorization
MVP Medicare Complete Wellness	Prior Authorization
MVP Medicare Preferred Gold HMO POS	Prior Authorization
MVP Medicare Secure HMO POS	Prior Authorization
MVP Medicare Secure Plus HMO POS	Prior Authorization
MVP Medicare WellSelect PPO	Prior Authorization
MVP Medicare WellSelect Plus PPO	Prior Authorization
MVP Medicare Patriot Plan PPO	Prior Authorization
MVP DualAccess D-SNP HMO	Prior Authorization
MVP DualAccess Complete D-SNP HMO	Prior Authorization
MVP DualAccess Plus D-SNP HMO	Prior Authorization
UVM Health Advantage Select PPO	Prior Authorization
USA Care PPO	Potential for Retrospective Review
Healthy NY	Prior Authorization
MVP Premier	Prior Authorization
MVP Premier Plus	Prior Authorization
MVP Premier Plus HDHP	Prior Authorization
MVP Secure	Prior Authorization
MVP EPO	Prior Authorization
MVP EPO HDHP	Prior Authorization
MVP PPO	Prior Authorization
MVP PPO HDHP	Prior Authorization
Student Health Plans	Prior Authorization
ASO	See SPD
Vermont Products	
POS in Plan	Prior Authorization
POS OOP	Prior Authorization
MVP Medicare Preferred Gold HMO POS	Prior Authorization
MVP Medicare Secure Plus HMO POS	Prior Authorization
MVP VT HMO	Prior Authorization
MVP VT HDHP HMO	Prior Authorization
MVP VT Plus HMO	Prior Authorization
MVP VT Plus HDHP HMO	Prior Authorization
MVP Secure	Prior Authorization
ASO	See SPD

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

*Medical Management Requirements

Prior Auth
Potential for Retrospective Review
Retro Review
Retro Review
Not Covered
See SPD
Prior Authorization Required
Not Prior Authorization Required. May be subject to Retrospective Review.
Retrospective Review Required
Service is not a covered benefit.
See Specific Plan Design

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Revision History

12/01/2022 – added coverage criteria and exclusions to coverage for adolescents and adults for treatment of gynecomastia.

12/1/2024 – annual review of criteria, no changes, updated links in references.



Bronchial Thermoplasty

Type of Policy: Medical

Prior Approval Date: 09/13/2022

Approval Date: 10/07/2024

Effective Date: 12/01/2024

Related Polices:

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

N/A

Codes Requiring Retrospective Review

CPT Codes:

31660 - Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 1 lobe

31661 - Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 2 or more lobes

Experimental/Investigational

CPT Codes:

31660 - Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 1 lobe

31661 - Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 2 or more lobes

Common Diagnosis Codes

N/A

Common Diagnosis Codes associated with this policy have been provided for informational purposes only. The list of codes may not be all-inclusive and may be updated to reflect any applicable revisions to the ICD-10 code set and/or medical necessity quidelines applied in this policy.

Common Procedure Codes

N/A

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

Bronchial thermoplasty is a bronchoscopic procedure that uses radiofrequency ablation to reduce, debulk, or partially eliminate excess smooth muscle tissue in the patient's distal airways. Bronchial thermoplasty has been proposed to treat patients 18 years and older whose asthma is not well controlled with standard therapy. It is intended to decrease the number of severe asthma attacks and improve asthma control on a long-term basis.

Indications/Criteria

Due to the lack of long-term outcome data in the published medical literature indicating safety and effectiveness, bronchial thermoplasty for the treatment of asthma or any other indication is considered investigational.

Exclusions

N/A

Medicare Variation

Based on review there are no National or Local Determination Coverage for this region.

References (Reviewed 2024)

- 1. Cox PG, Miller J, Mitzner W, Leff AR. Radiofrequency ablation of airway smooth muscle for sustained treatment of asthma: Preliminary investigations. Eur Respir J. 2004; 24(4):659-663.
- 2. Cox G, Miller JD, McWilliams A, et al. Bronchial thermoplasty for asthma. Am J Respir Crit Care Med. 2006; 173(9):965-969.
- 3. Cox G, Thomson NC, Rubin AS, et al; AIR Trial Study Group. Asthma control during the year after bronchial thermoplasty. N Engl J Med. 2007; 356(13):1327-1337.

- 4. Thomson NC, Rubin AS, Niven RM, et al.; AIR Trial Study Group. Long-term (5 year) safety of bronchial thermoplasty: Asthma Intervention Research (AIR) trial. BMC Pulm Med. 2011; 11:8.
- 5. Castro M, Rubin AS, Laviolette M, et al. Effectiveness and safety of bronchial thermoplasty in the treatment of severe asthma: A multicenter, randomized, double-blind, sham-controlled clinical trial. Am J Respir Crit Care Med. 2010; 181(2):116-124.
- 6. Castro M, Rubin A, Laviolette M, Hanania NA, Armstrong B, Cox G. Persistence of effectiveness of bronchial thermoplasty in patients with severe asthma. Ann Allergy Asthma Immunol. 2011; 107(1):65-70.
- 7. Pavord ID, Cox G, Thomson NC, et al. Safety and efficacy of bronchial thermoplasty in symptomatic, severe asthma. Am J Respir Crit Care Med. 2007; 176(12):1185-1191.
- 8. Torrego Fernández A. Bronchial thermoplasty in the treatment of asthma. Arch Bronconeumol. 2010; 46(2):85-91.
- 9. Global Initiative for Asthma (GINA). Global strategy for asthma management and prevention. Bethesda, MD: Global Initiative for Asthma (GINA); December 2011.
- 10. National Institute for Health and Clinical Excellence (NICE). Bronchial Thermoplasty for severe asthma. Interventional Procedure Guidance 419. London, UK: NICE; January 2012.
- 11. Chung KF, Wenzel SE, Brozek JL, et al. International ERS/ATS guidelines on definition, evaluation and treatment of severe asthma. Eur Respir J. 2014; 43(2):343-373.
- 12. Torrego A, Solà I, Munoz AM, et al. Bronchial thermoplasty for moderate or severe persistent asthma in adults. Cochrane Database Syst Rev. 2014; 3:CD009910.
- 13. Wechsler ME, Laviolette M, Rubin AS, et al.; Asthma Intervention Research 2 Trial Study Group. Bronchial thermoplasty: long-term safety and effectiveness in patients with severe persistent asthma. J Allergy Clin Immunol. 2013; 132(6):1295-1302.
- 14. HAYES Health Technology Assessment™. Bronchial Thermoplasty for Treatment of Asthma in Adults. Hayes, a sympir company © 2022 July 5, 2022 Available: www.hayesinc.com/.
- 15. Boston Scientific Corporation. Bronchial Thermoplasty™. © 2014 Boston Scientific Corporation. Available: http://btforasthma.com/.
- 16. Federal Drug Administration. Alair Bronchial Thermoplasty System-P080032. Summary of safety and effectiveness data. Updated 2010 May 19. Available: http://www.accessdata.fda.gov/cdrh_docs/pdf8/P080032c.pdf.
- 17. California Technology Assessment Forum. Bronchial thermoplasty for the treatment of severe asthma. Published 2011 Oct 19.

Customer Product	Medical Management Requirements*
New York Products	
НМО	Retrospective Review E&I
PPO in Plan	Retrospective Review E&I
PPO OOP	Retrospective Review E&I
POS in Plan	Retrospective Review E&I
POS OOP	Retrospective Review E&I
Essential Plan	Retrospective Review E&I
MVP Medicaid Managed Care	Retrospective Review E&I
MVP Child Health Plus	Retrospective Review E&I
MVP Harmonious Health Care Plan	Retrospective Review E&I
MVP Medicare Complete Wellness	Retrospective Review E&I
MVP Medicare Preferred Gold HMO POS	Retrospective Review E&I
MVP Medicare Secure HMO POS	Retrospective Review E&I
MVP Medicare Secure Plus HMO POS	Retrospective Review E&I
MVP Medicare WellSelect PPO	Retrospective Review E&I
MVP Medicare WellSelect Plus PPO	Retrospective Review E&I
MVP Medicare Patriot Plan PPO	Retrospective Review E&I
MVP DualAccess D-SNP HMO	Retrospective Review E&I
MVP DualAccess Complete D-SNP HMO	Retrospective Review E&I
MVP DualAccess Plus D-SNP HMO	Retrospective Review E&I
UVM Health Advantage Select PPO	Retrospective Review E&I
USA Care PPO	
Healthy NY	Potential for Retrospective Review
	Retrospective Review E&I
MVP Premier MVP Premier Plus	Retrospective Review E&I
	Retrospective Review E&I
MVP Premier Plus HDHP	Retrospective Review E&I
MVP Secure	Retrospective Review E&I
MVP EPO	Retrospective Review E&I
MVP EPO HDHP	Retrospective Review E&I
MVP PPO	Retrospective Review E&I
MVP PPO HDHP	Retrospective Review E&I
Student Health Plans	Retrospective Review E&I
ASO	See SPD
Vermont Products	
POS in Plan	Retrospective Review E&I
POS OOP	Retrospective Review E&I
MVP Medicare Preferred Gold HMO POS	Retrospective Review E&I
MVP Medicare Secure Plus HMO POS	Retrospective Review E&I
MVP VT HMO	Retrospective Review E&I
MVP VT HDHP HMO	Retrospective Review E&I
MVP VT Plus HMO	Retrospective Review E&I
MVP VT Plus HDHP HMO	Retrospective Review E&I
MVP Secure	Retrospective Review E&I
ASO	See SPD

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Authorization Required

Potential for Petrocopostive Poview

No Prior Authorization Required

Potential for Retrospective Review
Retro Review
Retro Review
Retrospective Review Retrospective Review Required
Retrospective Review Required

Retrospective Review Required Service is not a covered benefit. See Specific Plan Design

Revision History:

Not Covered

See SPD

12/01/2022 – Annual review with no changes.

12/01/2024 – Annual review with no changes.



Cardiac Output Monitoring by Thoracic Electrical Bioimpedance

Type of Policy: Medical

Prior Approval Date: 02/07/2022

Approval Date: 02/04/2024

Effective Date: 04/01/2024

Related Polices: Implantable Cardioverter Defibrillators,

Implantable Dual Chamber Automatic

Defibrillators,

Cardiac Resynchronization Devices

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

N/A

Codes Subject to Retrospective Review

N/A

Experimental/Investigational

N/A

Common Diagnosis Codes

N/A

Common Procedure Codes

N/A

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive.

Overview

A thoracic electrical bioimpedance (TEB) device, a form of plethysmography, has been proposed as a means to monitor cardiac output by non-invasively measuring hemodynamic parameters including stroke volume, systemic vascular resistance, and thoracic fluid status. Hemodynamic measurements of cardiac output (CO) using thoracic electrical bioimpedance (TEB) devices relates change in thoracic electrical conductivity to changes in thoracic aortic blood volume and blood flow.

Indications/Criteria

Thoracic electrical bioimpedance (TEB) has not been proven to improve clinical outcomes and, therefore, is considered experimental and investigational.

Exclusions

N/A

Medicare and Medicaid Managed Care Variation

There currently is a National Coverage Determination (NDC) for Cardiac Output Monitoring by Thoracic Electrical Bioimpedance (TEB) (20.16). For full Medicare coverage details please refer to the following NCD website: https://www.cms.gov/

Thoracic electrical bioimpedance is covered for the following uses:

- differentiation of cardiogenic from pulmonary causes of acute dyspnea when medical history, physical examination, and standard assessment tools provide insufficient information, and the treating physician has determined that thoracic electrical bioimpedance hemodynamic data are necessary for appropriate management of the patient;
- optimization of atrioventricular (A/V) interval for patients with A/V sequential cardiac pacemakers when medical history, physical examination, and standard assessment tools provide insufficient information, and the treating physician has determined that thoracic electrical bioimpedance hemodynamic data are necessary for appropriate management of the patient;
- monitoring of continuous inotropic therapy for patients with terminal congestive heart failure, when those patients have chosen to die with comfort at home, or for patients waiting at home for a heart transplant;
- evaluation for rejection in patients with a heart transplant as a pre-determined alternative to a myocardial biopsy. Medical necessity must be documented should a biopsy be performed after thoracic electrical bioimpedance; and
- optimization of fluid management in patients with congestive heart failure when medical history, physical examination, and standard assessment tools provide insufficient information, and the treating physician has determined that thoracic electrical bioimpedance hemodynamic data are necessary for appropriate management of the patient.

Cardiac output monitoring using electrical bioimpedance is not covered for the following uses:

- the management of all forms of hypertension;
- customers with proven or suspected disease involving regurgitation of the aorta;
- customers with minute ventilation (MV) sensor function pacemakers since the device may adversely affect the functioning of that type of pacemaker; or
- during cardiac bypass surgery.

References (Updated 2024)

- 1. Centers for Medicare & Medicaid Services, CMS, National Determination for Thoracic Electrical Bioimpedance (TEB) (20.16). Pub. 100-3, Effective date: 11/24/2006.
- 2. Belott, P. (1999). Bioimpedance in the pacemaker clinic. <u>AACN Clinical Issues</u>, 10 (3). [On-Line]. 2001. Available: https://aacnjournals.org/aacnacconline/article-abstract/10/3/414/13724/Bioimpedance-in-the-Pacemaker-Clinic
- 3. Pranulis, M. (2000). Impedance cardiology non-invasive hemodynamic monitoring provides an opportunity to deliver cost effective, quality care for patients with cardiovascular disorders. The Journal of Cardiovascular Management, 11 (3).
- 4. Hunt SA, Abraham WT, Chin MH, Feldman AM, Francis GS, Ganiats TG, et al.; American College of Cardiology Foundation; American Heart Association. 2009 Focused update incorporated into the ACC/AHA 2005 Guidelines for the Diagnosis and Management of Heart Failure in Adults a Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines Developed in Collaboration With the International Society for Heart and Lung Transplantation. J Am Coll Cardiol. 2009 Apr 14; 53(15):e1-e90.
- 5. Jessup M, Abraham WT, Casey DE, Feldman AM, Francis GS, Ganiats TG, et al. 2009 focused update: ACCF/AHA Guidelines for the Diagnosis and Management of Heart Failure in Adults: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines: developed in collaboration with the International Society for Heart and Lung Transplantation. Circulation. 2009 Apr 14; 119(14):1977-2016. Epub 2009 Mar 26.
- 6. Handelsman H. Measuring cardiac output by electrical bioimpedance. Agency for Health Care Policy and Research (AHCPR) Report No. 6. Pub. No. 92-0073. Rockville, MD: September 1992. Available at: www.ahrq.gov/clinic/techarch.htm#techreviews
- 7. Jordan HS, Ioannidis JPA, Goudas LC, Chung M, Kupelnick B, Miller K, et al. Thoracic electrical bioimpedance. Contract No. 290-97-0019, Task Order #10. Rockville, MD: Agency for Healthcare Research and Quality (AHRQ); November 27, 2002. Available at: http://www.cms.gov/mcd/viewtechassess.asp?id=23

- 8. Wang DJ, Gottlieb SS. Impedance cardiography: more questions than answers. Curr Cardiol Rep. 2006 May; 8(3):180-6.
- 9. Smith RD, Levy P, Ferrario CM; Consideration of Noninvasive Hemodynamic Monitoring to Target Reduction of Blood Pressure Levels Study Group. Value of noninvasive hemodynamics to achieve blood pressure control in hypertensive subjects. Hypertension. 2006 Apr; 47(4):771-7.
- 10. Lo HY, Liao SC, Ng CJ, Kuan JT, Chen JC, Chiu TF. Utility of impedance cardiography for dyspneic patients in the ED. Am J Emerg Med. 2007 May; 25(4):437-41.
- 11. Kamath SA, Drazner MH, Tasissa G, Rogers JG, Stevenson LW, Yancy CW. Correlation of impedance cardiography with invasive hemodynamic measurements in patients with advanced heart failure: the Bioimpedance Cardiography (BIG) substudy of the Evaluation Study of Congestive Heart Failure and Pulmonary Artery Catheterization Effectiveness (ESCAPE) Trial. Am Heart J. 2009 Aug; 158(2):217-23.
- 12. Malfatto G, Blengino S, Perego GB, Branzi G, Villani A, Facchini M, Parati G. Transthoracic impedance accurately estimates pulmonary wedge pressure in patients with decompensated chronic heart failure. Congest Heart Fail. 2012 Jan-Feb; 18(1):25-31. doi: 10.1111/j.1751-7133.2011.00248.x. Epub 2011 Sep 14.
- 13. McMurray JJ, Adamopoulos S, Anker SD, Auricchio A, Böhm M, Dickstein K, et al.; Task Force for the Diagnosis and Treatment of Acute and Chronic Heart Failure 2012 of the European Society of Cardiology, Bax JJ, Baumgartner H, Ceconi C, Dean V, Deaton C, Fagard R, et al.; ESC Committee for Practice Guidelines. ESC guidelines for the diagnosis and treatment of acute and chronic heart failure 2012: The Task Force for the Diagnosis and Treatment of Acute and Chronic Heart Failure 2012 of the European Society of Cardiology. Developed in collaboration with the Heart Failure Association (HFA) of the ESC. Eur J Heart Fail. 2012 Aug; 14(8):803-69.
- 14. Krzesiński P, Gielerak GG, Kowal JJ. A "patient-tailored" treatment of hypertension with use of impedance cardiography: a randomized, prospective and controlled trial. Med Sci Monit. 2013 Apr 5; 19:242-50.

Customer Product	Medical Management Requirements*
New York Products	
HMO	Potential for Retrospective Review
PPO in Plan	Potential for Retrospective Review
PPO OOP	Potential for Retrospective Review
POS in Plan	Potential for Retrospective Review
POS OOP	Potential for Retrospective Review
Essential Plan	Potential for Retrospective Review
MVP Medicaid Managed Care	Potential for Retrospective Review
MVP Child Health Plus	Potential for Retrospective Review
MVP Harmonious Health Care Plan	Potential for Retrospective Review
MVP Medicare Complete Wellness	Potential for Retrospective Review
MVP Medicare Preferred Gold HMO POS	Potential for Retrospective Review
MVP Medicare Secure HMO POS	Potential for Retrospective Review
MVP Medicare WellSelect PPO	Potential for Retrospective Review
MVP Medicare WellSelect Plus PPO	Potential for Retrospective Review
MVP Medicare Patriot Plan PPO	Potential for Retrospective Review
MVP DualAccess D-SNP HMO	Potential for Retrospective Review
MVP DualAccess Complete D-SNP HMO	Potential for Retrospective Review
MVP DualAccess Plus D-SNP HMO	Potential for Retrospective Review
UVM Health Advantage Select PPO	Potential for Retrospective Review
USA Care	Potential for Retrospective Review
Healthy NY	Potential for Retrospective Review
MVP Premier	Potential for Retrospective Review
MVP Premier Plus	Potential for Retrospective Review
MVP Premier Plus HDHP	Potential for Retrospective Review
MVP Premier	Potential for Retrospective Review
MVP Premier Plus	Potential for Retrospective Review
MVP Premier Plus HDHP	Potential for Retrospective Review
MVP Secure	Potential for Retrospective Review
MVP EPO	Potential for Retrospective Review
MVP EPO HDHP	Potential for Retrospective Review
MVP PPO	Potential for Retrospective Review
MVP PPO HDHP	Potential for Retrospective Review
Student Health Plans	Potential for Retrospective Review
ASO	See SPD
Vermont Products	
POS in Plan	Potential for Retrospective Review
POS OOP	Potential for Retrospective Review
MVP Medicare Preferred Gold HMO POS	Potential for Retrospective Review
MVP Medicare Secure Plus HMO POS	Potential for Retrospective Review
MVP VT HMO	Potential for Retrospective Review
MVP VT HDHP HMO	Potential for Retrospective Review
MVP VT Plus HMO	Potential for Retrospective Review
MVP VT Plus HDHP HMO	Potential for Retrospective Review
MVP Secure	Potential for Retrospective Review
ASO	See SPD
_ 	300 31 2

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

*Medical Management Requirements

Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review.

Retro Review Required
Not Covered Service is not a covered benefit
See SPD See Specific Plan Design

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Revision History:

04/01/2022 – Annual review with no changes to the indications or criteria.

04/01/2024 – Remove Bioimpedance derived physiologic cardiovascular analysis (CPT code 93701) from prior authorization.



Cardiac Procedures

Type of Policy: Medical

Prior Approval Date: 04/01/2024

Approval Date: 03/28/2025

Effective Date: 06/01/2025

Related Polices: Percutaneous Left Atrial

Appendage (LAA) Closure Devices

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

33418 – Transcatheter mitral valve repair, percutaneous approach, including transseptal puncture when performed; initial prosthesis

33419- Transcatheter mitral valve repair, percutaneous approach, including transseptal puncture when performed; additional prosthesis(es) during same session (List separately in addition to code for primary procedure)

33477 - Transcatheter pulmonary valve implantation, percutaneous approach, including pre-stenting of the valve delivery site, when performed

Experimental/Investigational Codes Subject to Retrospective Review

0569T – Transcatheter tricuspid valve repair, percutaneous approach; initial prosthesis

0570T - Transcatheter tricuspid valve repair, percutaneous approach; each additional

0613T Percutaneous transcatheter implantation of interatrial septal shunt device, including right and left heart catheterization, intracardiac echocardiography, and imaging guidance by the proceduralist, when performed

33542 (noncovered if used to report partial left ventriculectomy/Batista procedure)

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33548 - Surgical ventricular restoration procedure, includes prosthetic patch, when performed (e.g., ventricular remodeling, SVR, SAVER, Dor procedures)

33999 Unlisted procedure, cardiac surgery

92972 - Percutaneous transluminal coronary lithotripsy

93799 Unlisted cardiovascular service or procedure

Common Diagnosis Codes

N/A

Common Procedure Codes

CPT Codes: 33140, 33141, 33510 33511, 33512, 33513, 33514, 33516, 33517, 33518, 33519, 33521, 33522, 33523, 33530, 33533, 33534, 33535, 33536, 33545, 77262, 77280, 77285, 77300, 77470, 92920, 92921, 92924, 92933, 92934, 92937, 92941, 92943, 92973, 92974, 92975, 92978, 92979, 93451, 93452, 93453, 93454, 93455, 93456, 93457, 93458, 93459, 93460, 93461, 93462, 93580, 93581, 93582

HCPCS Codes: G0166, C9600, C9601, C9602, C9603, C9604, C9605, C9606, C9607, C9608

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy.

Overview

Catheter-based Intracoronary Brachytherapy has been approved by the FDA as a technique to reduce re-stenosis following transluminal intracoronary angioplasty (PTCA), primarily in those procedures with a stenosis occurring at the site of a prior stent placement (i.e., "in-stent re-stenosis"). The FDA has approved a number of intracoronary brachytherapy devices. This approval, however, limits the use of these devices to the treatment of in-stent re-stenosis in native coronary arteries and vein grafts. Intravascular brachytherapy requires the expertise of a multidisciplinary team that includes an in-plan interventional cardiologist, an in-plan radiation oncologist, and an in-plan radiation physicist.

External Counterpulsation (ECP) is a non-invasive outpatient procedure intended to relieve angina pectoris by improving perfusion of areas of the heart deprived of adequate blood supply. ECP involves sequential pneumatic compression of the legs that is coordinated with cardiac contractions and is designed to increase aortic blood pressure, improve venous blood return, and decrease after load on the left ventricle.

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The goal of ECP is to reduce the severity and frequency of angina pectoris. Customers receive external counterpulsation for one or two 60-minute treatment sessions each day (usually five days per week) for a total of 35 hours. Treatment should be completed within two months of initiation of therapy.

Transmyocardial Laser Revascularization (TMLR) is a surgical technique which employs a laser to bore holes through the myocardium in an attempt to restore perfusion to areas of the heart not being adequately perfused by diseased or clogged coronaries for palliation of intractable angina.

A transcatheter patent foramen ovale (PFO) occluder (e.g., Amplatzer™ PFO Occluder) is a permanently implanted device designed to provide a non-surgical method for PFO closure, blocking clots from passing from the right atrium to the left atrium. The Amplatzer PFO Occluder is inserted through a catheter that is placed in a leg vein and advanced to the heart. It is then implanted close to the hole in the heart between the top right chamber (right atrium) and the top left chamber (left atrium). The PFO Occluder is intended to reduce the risk of a stroke in patients who previously had a stroke thought to be caused by a blood clot passing through a patent foramen ovale and then traveled to the brain.

Angioplasty plus stent implantation is a common treatment for angina. Angioplasty opens the partially blocked artery and the implanted stent keeps it open. Twenty percent of treated patients have growth of tissue within the stent causing re-stenosis of the artery.

Individuals with co-morbid conditions, such as diabetes, have a higher risk of in-stent re-stenosis. After implantation, drug eluting stents allow a slow release of drug over a period of 15-45 days that prevents proliferation of tissue within the stent and prevents in-stent re-stenosis.

Transcatheter mitral valve repair using the MitraClip Mitral Valve Repair System (Abbott Vascular Inc.) is for the repair of a damaged or leaking mitral valve (MV) in the heart.

Ventricular reduction surgery and surgical ventricular restoration are proposed procedures to treat end-stage heart failure. Ventricular reduction surgery has also been referred to as partial left ventriculectomy or the Batista procedure. Surgical ventricular restoration (SVR) may also be referred to as ventricular remodeling, surgical anterior ventricular endocardial restoration (SAVER), endoventricular circular patchplasty or the Dor procedure. The efficacy of these procedures have not been established to prove more beneficial than medical therapy or cardiac transplantation.

Transcatheter Tricuspid Valve Repair (TTVR) is a proposed method for repairing the tricuspid valve using a less invasive method.

Documentation Requirements

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Documentation of the clinical severity of the customer's coronary artery disease must be submitted upon request. Documentation, as appropriate, should include but is not limited to the following:

- clinical history of heart disease;
- medical therapies attempted and therapeutic results of such therapies;
- PTCA and/or drug eluting stents procedure indication/contraindications and clinical pertinent documentation;
- exercise testing results;
- imaging study results; and
- general medical condition and life expectancy.

In the case of ECP, the medical record must document the customer's inability to undergo more traditional re-vascularization techniques (CABG, PTCA). External cardiac assist, electronic electrocardiography (EECG), pulse oximetry, and plethymography would be considered part of ECP.

Indications/Criteria

<u>Indications for Catheter-based Intracoronary Brachytherapy</u>

• Intracoronary vascular brachytherapy is indicated for the management of the status post coronary stent placement patient who presents with symptoms of chest pains attributable to in-stent restenosis.

Indications for External Counter Pulsation (ECP)

- Customers who have been diagnosed with disabling angina (Canadian Cardiovascular Society Class III or IV who, in the opinion of a cardiologist or cardiothoracic surgeon, are not readily amenable to surgical intervention, such as PTCA or cardiac bypass due to one of the following:
 - their condition is inoperable, or they are at high-risk of operative complications or post-operative failure;
 - their coronary anatomy is not readily amenable to such procedures; or
 - o they have co-morbid states that create excessive risk.

Indications for Transmyocardial Laser Revascularization (TMLR)

 Customers who have been diagnosed with disabling intractable, (Canadian Cardiovascular Society Class III or IV) stable or unstable angina which has been found refractory to standard medical therapy, including drug therapy at the maximum tolerated or maximum safe dosages in a hospital inpatient setting. In addition, the angina syndrome must be caused by areas of the heart not amenable to surgical therapies such as PTCA, stenting, coronary atherectomy, or coronary bypass.

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- Coverage is further limited to those uses of the laser used in performing the procedure which have been approved by the FDA for the purpose for which they are being used.
- Customers must meet additional selection guidelines such as:
 - ejection fraction > 25%;
 - o viable ischemic heart tissue as established by (unspecified) diagnostic study that cannot be re-vascularized by direct coronary vascularization; and
 - stable cardiovascular status with regard to severe ventricular arrhythmias;
 decompensate congestive heart failure or acute myocardial infarction.

Indications for Drug Eluting Stents

Drug-eluting stents are indicated to improve luminal diameter in vessels and lesions in accordance with the FDA approved package labeling instructions.

<u>Indications for a Transcatheter Patent Ovale (PFO) Occluder (e.g., Amplatzer PFO</u> Occluder)

- is covered when all the following criteria are met:
 - Customer is 18 to 60 years of age; and
 - Customer has a patent foramen ovale (PFO); and
 - Customer has had a cryptogenic stroke due to a presumed paradoxical embolism, as determined by a neurologist and cardiologist following an evaluation to exclude know causes of ischemic stroke.

Percutaneous transcatheter mitral valve repair (CPT: 33418, 33419) using an FDA approved device (MitraClip) is considered medically necessary when:

- Symptomatic mitral regurgitation with both:
 - Mitral regurgitation is 3+ or 4+ due to abnormality of the mitral apparatus;
 and
 - Not an operable candidate for open surgery, as judged by a heart team that includes a cardiac surgeon experienced with mitral valve surgeries, and a cardiologist that is experienced in mitral valve disease.

Transcatheter Pulmonary Valve (TPV)

TPV implantation with an FDA approved device (e.g., Harmony Transcatheter Pulmonary Valve (TPV) System, Melody Transcatheter Pulmonary Valve, and Sapien S3 Valve) is considered medically necessary when the following criteria are met:

 Dysfunctional right ventricular outflow tract (RVOT) tract (native, patched or implanted conduit) with one of the following clinical indications for intervention:

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- o Moderate or greater pulmonary regurgitation; or
- pulmonary stenosis with a mean RVOT gradient greater than or equal to 35 mm Hg.

Transcatheter valve replacement for other indications (e.g., degenerated bioprosthetic valve [valve-in-valve implantation]) is considered experimental and investigational because the effectiveness of this approach for these indications has not been established.

Exclusions

Not meeting criteria under Indications/Criteria in this policy.

Catheter-based Intracoronary Brachytherapy

- Applications other than those listed in the indications/criteria section for intracoronary brachytherapy are considered investigational, including, but not limited to, the treatment of coronary stenoses unrelated to prior stent placement and the treatment of stenoses of non-native coronary vessels and, as such, are considered not medically necessary.
- Recent evidence of a myocardial infarction within three (3) days prior to brachytherapy.
- History of prior radiotherapy to same arterial segment.
- Evidence of severe peripheral vascular disease.
- Child bearing potential.
- Left main coronary artery disease.
- Intraprocedural angiography shows evidence of thrombus, spasm or dissection;
- Use of radioactive stent for prevention of re-stenosis and treatment of de novo lesions.
- Inability to maintain customer on antiplatelet and/or anticoagulant therapy.

External Counter Pulsation (ECP)

- Customer is a candidate for interventional procedures.
- Left main coronary artery disease.
- Cardiac catheterization within one to two weeks.
- Arrhythmia (e.g., atrial fibrillation, atrial flutter, ventricular tachycardia).
- Aortic insufficiency.
- Evidence of an abdominal aortic aneurysm or severe ileofemoral occlusive disease.
- Limiting peripheral vascular disease (PVD) and/or phlebitis.

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- Severe hypertension > 180/110 mm Hg.
- Bleeding diathesis or Coumadin therapy with an INR > 1.8.
- Pregnancy or possible pregnancy.
- There is insufficient evidence that customer will benefit from a second or subsequent ECP procedure; therefore, the benefit is restricted to a single course of treatment.
- Canadian Cardiovascular Society Classification II angina.
- Heart failure:
 - NYHA Class II/III stable heart failure symptoms with an ejection fraction of ≤ 30%; or
 - NYHA Class IV.
- Cardiogenic shock.
- Acute myocardial infarction.

<u>Transmyocardial Laser Revascularization (TMLR)</u>

- Unstable angina.
- Recent myocardial infarct.
- Depressed left ventricular ejection fraction (<25%).
- Pre-existing arrhythmias, CHF, bleeding tendencies.

Drug Eluting Stents are not covered for the following:

- any indication not listed in the FDA approved package labeling instructions;
- use of multiple stents in quantities greater than that listed in the FDA approved package labeling instructions, have not been evaluated clinically and therefore, are considered not medically necessary; or
- the use of different types of stents in combination has not been clinically evaluated and; therefore, are considered not medically necessary.

Intravascular Lithotripsy (IVL)

Intravascular Lithotripsy (IVL) System using the Coronary IVL Catheter (e.g., Shockwave Medical) (CPT Code: 92972, C1761) for the treatment of coronary artery plaques is considered experimental and investigational.

Ventricular Reduction Surgery

 Due to lack of efficacy in the peer reviewed literature, partial ventriculectomy, also known as ventricular reduction, ventricular remodeling, heart volume reduction surgery, or the Batista procedure (33542, 33999) is considered investigational.

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 Due to lack of efficacy in the peer-reviewed literature, surgical ventricular restoration (33548), also known as the Dor procedure, is considered investigational for the treatment of ischemic dilated cardiomyopathy or post infarction left ventricular aneurysm

Transcatheter Tricuspid Valve Procedures (0569T, 0570T)

Transcatheter Tricuspid Valve Procedures are considered experimental/investigational because there is insufficient evidence is peer-reviewed medical literature regarding their safety and effectiveness.

Medicare Variation

Transcatheter Tricuspid Valve Repair is covered for Medicare plans according to the National Coverage Analysis Transcatheter Tricuspid Valve Replacement (TTVR) CAG-00467N when performed under a CMS-approved Coverage with Evidence Development (CED) study for the treatment of symptomatic tricuspid regurgitation meeting the following criteria:

- Documented symptomatic tricuspid regurgitation that is graded severe; and
- Transcatheter tricuspid valve repair system is FDA-approved, and
- Customer remains symptomatic despite optimal medical therapy; and
- Customer is under the care of a heart team that has experience in the care and treatment of tricuspid regurgitation, which at a minimum, includes the following providers:
 - o a Cardiac Surgeon, and
 - o Interventional Cardiologist, and
 - o Heart failure cardiologist, and
 - o Electrophysiologist, and
 - o Multi-modality imaging specialist, and
 - o interventional echocardiographer.

References (Updated 2025)

- 1. Smith, SC, et al. ACC/AHA/SCAI 2011 guideline update for percutaneous coronary intervention; a report of the American College of Cardiology/American Heart Association Task Force on Guidelines (ACC/AHA/SCAI Writing Committee to Update the 2001 Guidelines for Percutaneous Coronary Intervention). Available: https://www.ahajournals.org/lookup/doi/10.1161/CIR.0b013e31823ba622.
- 2. Oliver, LN., et al. A meta-analysis of randomized controlled trials assessing drugeluting stents and vascular brachytherapy in the treatment of coronary artery in-stent restenosis. International Journal of cardiology. 2008. May 23; 126(2):216-23.

Cardiac Procedures Page 8 of 15

- 3. Wakesman, R, et al. Five-year follow-up after intracoronary gamma radiation for instent re-stenosis. Circulation. 2004 Jan; 109:240-344.
- 4. Ajani, A.E., et al. Three year follow-up after intracoronary gamma radiation therapy for in-stent re-stenosis. Original WRIST. Washington Radiation for In-Stent Re-stenosis trial. Cardiovascular Radiation medicine. 2001 Oct-Dec; 2(4):200-4.
- 5. Lu YG, Chen YM, Li L, Zhao RZ, Fu CH, Yan H. Drug-eluting stents vs. intracoronary brachytherapy for in-stent restenosis: a meta-analysis. Clin Cardiol. 2011 Jun; 34(6):344-51.
- 6. Silber S, Albertsson P, Aviles FF, Carmici PG Colombo A, Hamm C, et al. Guidelines for percutaneous coronary interventions. The Task Force for Percutaneous Coronary Interventions of the European Society of Cardiology. Eur Heart J. 2005 Apr; 26(8):804-47.
- 7. Centers for Medicare & Medicaid Services (CMS) National Coverage Determination (NCD) for External Counterpulsation (ECP) Therapy for Severe Angina (20.20). Effective Date: 3/20/2006.
- 8. Snow, V., et al. American College of Physicians; American College of Cardiology Chronic Stable Angina Panel. Primary care management of chronic stable angina and asymptomatic suspected or know coronary artery disease: a clinical practice guideline from the American College of Physicians. Annals of Internal Medicine. 2004 October 5; 141 (7):562-7.
- 9. Brosche. TA., et al. Enhanced external counterpulsation. Dimensions of Critical Care Nursing. 2004; 23(5):208-14.
- 10. Feldman AM, et al. Treating heart failure with enhanced external counterpulsation (EECP): design of the Prospective Evaluation of EECP in Heart Failure (PEECH) trial. J Card Fail 2005 Apr;11(3):240-5.
- 11. Vasomedical, Inc. EECP [corporate website]. Available: www.eecp.com/.
- 12. McKenna C, McDaid C, Suekarran S, et al. Enhanced external counterpulsation for the treatment of stable angina and heart failure: A systematic review and economic analysis. Health Technol Assess. 2009; 13(24): iii-iv, ix-xi, 1-90.
- 13. Amin F, Al Hajeri A, Civelek B, et al. Enhanced external counterpulsation for chronic angina pectoris. Cochrane Database Syst Rev. 2010 ;(2):CD007219.
- 14. Lin S, Liu M, Wu B, et al. External counterpulsation for acute ischaemic stroke. Cochrane Database Syst Rev. 2012;1:CD009264.
- 15. Centers for Medicare & Medicaid Services (CMS) National Coverage Determination (NCD) for Transmyocardial Revascularization (TMR) (20.6). Effective Date: 07/01/1999. Available: https://www.cms.gov/.

Cardiac Procedures Page 9 of 15

- 16. Eagle, KA, et al. ACC/AHA 2004 guideline updates for coronary artery bypass graft surgery: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee to Update the 1999 Guidelines for Coronary Artery Bypass graft Surgery). Circulation 2004; 110; 1168-1176.
- 17. Gibbons, RJ, et al. American College of Cardiology; American Heart Association Task Force on practice guidelines (Committee on the Management of Patients with Chronic Stable Angina). ACC/AHA 2002 guideline update for the management of patients with chronic stable angina—summary article: a report of the American College of Cardiology/American Heart Association Task Force on practice guidelines (Committee on the Management of Patients with Chronic Stable Angina). Journal American College Cardiology. 2003 Jan 1; 41(1):159-68.
- 18. Briones, E et al. Transmyocardial laser revascularization versus medical therapy for refractory angina. Cochrane Database of Systematic Reviews 1990, Issue I, Art No.:1002/14651858.CDC003712.pub2.
- 19. Liao L, Sarria-Santamera A, Matchar DB, et al. Meta-analysis of survival and relief of angina pectoris after transmyocardial revascularization. Am J Cardiol. 2005; 95(10):1243-1245.
- 20. Bridges C, Horvath K, Nugent W, et al. The Society of Thoracic Surgeons practice guideline series: transmyocardial laser revascularization. Ann Thorac Surg. 2004; 77(4):1494-1502. Available: https://www.annalsthoracicsurgery.org/article/S0003-4975(04)00205-X/pdf.
- 21. Hillis LD, Smith PK, Anderson JL, et al. 2011 ACCF/AHA guideline for coronary artery bypass graft surgery. A report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. Developed in collaboration with the American Association for Thoracic Surgery, Society of Cardiovascular Anesthesiologists, and Society of Thoracic Surgeons. Circulation. 2011; 124(23):2610-2642. Available:
 - https://www.ahajournals.org/doi/10.1161/CIR.0b013e31823c074e.
- 22. Jneid H, Anderson JL, Wright RS, et al. AACF/AHA Task Force. 2012 AACF/AHA focused update of the guideline for the management of patients with unstable angina/non-ST-elevation myocardial infarction (updating the 2007 guideline and replacing the 2011 focused update): a report of the American College of Cardiology foundation/American Heart Association Task Force on Practice Guidelines. Circulation. 2012. July 16, 2012. Available:
 - https://www.ahajournals.org/doi/10.1161/CIR.0b013e318256f1e0.
- 23. Campbell F, Messina J, FitzGerald P, et al. C. Systematic review of the efficacy and safety of transmyocardial and percutaneous laser revascularization for refractory angina pectoris. 2009 Jan 26, updated May 2010.

Cardiac Procedures Page 10 of 15

- 24. Cryolife, Inc. Cardiogenesis. Available: https://www.cryolife.com/products/cardiogenesis/
- 25. HAYES Directory™. Paclitaxel-Eluting Stents for Treatment of Coronary Artery Disease. Lansdale, PA: HAYES, Inc.; ©2010 Winifred S. Hayes, Inc. Dec. 14, 2010.
- 26. HAYES Directory™. Sirolimus-Eluting Stents for Treatment of Coronary Artery Disease. Lansdale, PA: HAYES, Inc.; ©2010 Winifred S. Hayes, Inc. Dec. 14, 2010.
- 27. Greenhalgh, J., et al. Drug-eluting stents versus bare metal stents for angina or acute coronary syndromes. Cochrane Database Systematic Review. 2010 May 12;(5):CD004587.
- 28. King, SB, et al. 2007 focused update of the ACC/AHA/SCAI 2005 Guideline Update for Percutaneous Coronary Intervention: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines: (2007 Writing Group to Review Evidence and Update the 2005 ACC/AHA/SCAI Guideline Update for Percutaneous Coronary Intervention). Journal American College of Cardiology. 2008. Jan 15; 172-209.
- 29. Lemos, P, Saia, F, Hofman, SH, et.al., Short- and Long-Term Clinical Benefits of Sirolimus-Eluting Stents Compared to Conventional Bare Metal For Patients With Acute Myocardial Infarction, Journal of The American College of Cardiology. March 2004, Available: www.medscape.com.
- 30. Boston Scientific, Directions for use, TAXUS™ Express^{2TM}, Paclitaxel-Eluting Coronary Stent System, Monorail® and Over the wire Coronary Stent Delivery System (2007). Available:
- $http://www.bostonscientific.com/templatedata/imports/collateral/Coronary/taxexp_dfu_01_us.pdf$
- 31. Cordis®, Instructions for use. CYPHER® Sirolimus-eluting Coronary Stent on Raptor™ Over the Wire System and CYPHER® Sirolimus-eluting Coronary Stent on Raptorial™ Rapid Exchange Delivery System (2011). Available: http://www.cordislabeling.com/pdf/IFU_Approved_10056733r13.pdf
- 32. Endeavor® Zotarolimus-Eluting Coronary Stent on the Over-the-Wire (OTW), Rapid Exchange (RX), or Multi Exchange II (MX2) stent Delivery Systems., Driver MXII, Driver Over-the Wire, Driver RX Coronary Stent System, Instructions for use. Medtronic, Inc. (2012).
- 33. Xience™ V, Xience nano™, XIENCE PRIME™, XIENCE PRIME™ LL, XIENCE Xpedition™, XIENCE Xpedition™ SV and XIENCE Xpedition™ LL (XIENCE Family) of Everolimus Eluting Coronary Stents on the MULTI-LINK VISION® or MULTI-LINKMINI VISION® Delivery Systems Everolimus Eluting Stent System. Indications and Important Safety Information. Abbott Vascular. 2012. Available: http://www.abbottvascular.com/us/xience-v.html.

Cardiac Procedures Page 11 of 15

- 34. Onorato E, Melzi G, Casilli F, et al. Patent foramen ovale with paradoxical embolism: mid-term results of transcatheter closure in 256 patients. J Interv Cardiol. 2003; 16(1):43-50.
- 35. Windecker S, Wahl A, Chatterjee T, et al. Percutaneous closure of patent foramen ovale in patients with paradoxical embolism: long term risk of recurrent thromboembolic events. Circulation. 2000; 101(8):893-898.
- 36. U.S. Food and Drug Administration (FDA). Premarket Approval (PMA). AMPLATZER PFO Occluder. No. P120021. Rockville, MD: FDA. November 1, 2016. Available: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm?id=P120021.
- 37. Carroll JD, Saver JL, Thaler DE, et al.; RESPECT Investigators. Closure of patent foramen ovale versus medical therapy after cryptogenic stroke. N Engl J Med. 2013;368(12):1092-1100. Available: http://www.nejm.org/doi/full/10.1056/NEJMoa1301440#t=article.
- 38. AGA Medical Corporation. Respect PFO Clinical Trial. NCT00465270. Last updated February 18, 2019. Available: http://www.clinicaltrials.gov/ct2/show/study/NCT00465270?term=respect+and+pfo&rank=1.
- 39. Ntaios G, Papavasileiou V, Makaritsis K, Michel P. PFO closure vs. medical therapy in cryptogenic stroke or transient ischemic attack: A systematic review and meta-analysis. Int J Cardiol. 2013;169(2):101-105. Available: https://www.ncbi.nlm.nih.gov/pubmed/24041984.
- 40. Meerkin D, Butnaru A, Dratva D, Bertrand OF, Tzivoni D. Early safety of the Amplatzer Cardiac PlugTM for left atrial appendage occlusion. Int J Cardiol. 2013;168(4):3920-3925. Available: http://europepmc.org/abstract/med/23890886.
- 41. Gloekler S, Shakir S, Doblies J, et al. Early results of first versus second generation Amplatzer occluders for left atrial appendage closure in patients with atrial fibrillation. *Clin Res Cardiol*. 2015. Epub ahead of print. March 4, 2015. Available: http://link.springer.com/article/10.1007%2Fs00392-015-0828-1.
- 42. Nietlispach F, Gloekler S, Krause R, et al. Amplatzer left atrial appendage occlusion: single center 10-year experience. Catheter Cardiovasc Interv. 2013;82(2):283-289. Available: https://www.ncbi.nlm.nih.gov/pubmed/23412815.
- 43. Park JW, Bethencourt A, Sievert H, et al. Left atrial appendage closure with Amplatzer cardiac plug inatrial fibrillation: initial European experience. Catheter Cardiovasc Interv. 2011;77(5):700-706. Available: https://www.ncbi.nlm.nih.gov/pubmed/20824765.
- 44. Danna P, Proietti R, Sagone A, et al. Does left atrial appendage closure with a cardiac plug system reduce the stroke risk in nonvalvular atrial fibrillation patients? A single-

Cardiac Procedures Page 12 of 15

- center case series. Pacing Clin Electrophysiol. 2013;36(3):347-353. Available: http://europepmc.org/abstract/med/23252940.
- 45. Santoro G, Meucci F, Stolcova M, et al. Percutaneous left atrial appendage occlusion in patients with non-valvular atrial fibrillation: implantation and up to four years follow-up of the AMPLATZER Cardiac Plug. EuroIntervention. 2014. Epub ahead of print. October 30, 2014. Available: https://www.ncbi.nlm.nih.gov/pubmed/25354761.
- 46. American Heart Association (AHA). Classes of Heart Failure. 2017. Available: http://www.heart.org/HEARTORG/Conditions/HeartFailure/AboutHeartFailure/Classes-of-Heart-Failure_UCM_306328_Article.jsp#.WUgyO_NK0jY.
- 47. Hayes Medical Technology Directory. HAYES Medical Technology Directory™. Transcatheter Closure of Prosthetic Aortic or Mitral Paravalvular Leaks. Lansdale, PA: HAYES, s symplr company. September 14, 2017. Available: www.hayesinc.com.
- 48. Health Technology Assessment Percutaneous Mitral Valve Repair for Secondary (Functional) Mitral Valve Regurgitation in High-Risk Adults. HAYES, Inc.; © 2021 Hayes, a symplr company. December 10, 2020. Annual review January 30, 2022.
- 49. Centers for Medicare & Medicaid Services (CMS). Medicare Coverage Database. NCD for Partial Ventriculectomy (20.26). April 15, 1997. Available: https://www.cms.gov/
- 50. Hayes Evolving Evidence Review. Intravascular Lithotripsy for Calcified Peripheral Arterial Lesions. ©2024 Hayes, a sympir company. November 19, 2021. Annual review July 21, 2023.
- 51. Hayes Evolving Evidence Review. Intravascular Lithotripsy (IVL) System with C2 Coronary IVL Catheter (Shockwave Medical Inc.) for Calcified Coronary Lesions. ©2024 Hayes, a sympir company. August 31, 2021. July 20, 2023
- 52. HAYES Evidence Analysis Research Brief: Transcatheter Tricuspid Valve Replacement for Tricuspid Valve Disease. HAYES, Inc. June 7, 2023.
- 53. Hayes Evolving Evidence Review. Evoque Tricuspid Valve Replacement System (Edwards Lifesciences Corp.) for Tricuspid Regurgitation. HAYES, Inc. August 20, 2024.
- 54. Centers for Medicare and Medicaid Services (CMS) National Coverage Analysis (NCA) for Transcatheter Tricuspid Valve Replacement (TTVR) CAG-00467N, January 13, 2025. Available: MCD Search

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Customer Product	Medical Management Requirements*
New York Products	
HMO	Prior Auth
PPO in Plan	Prior Auth
PPO OOP	Prior Auth
POS in Plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Prior Auth
MVP Child Health Plus	Prior Auth
MVP Harmonious Health Care Plan	Prior Auth
MVP Medicare Complete Wellness	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Complete Wellness	Prior Auth
MVP Medicare Secure HMO POS	Prior Auth
MVP Medicare WellSelect PPO	Prior Auth
MVP Medicare WellSelect Plus PPO	Prior Auth
MVP Medicare Patriot Plan PPO	Prior Auth
MVP DualAccess D-SNP HMO	Prior Auth
MVP DualAccess Complete D-SNP HMO	Prior Auth
MVP DualAccess Plus D-SNP HMO	Prior Auth
UVM Health Advantage Select PPO	Prior Auth
USA Care	Potential for Retrospective Review
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	
POS in Plan	Prior Auth
POS OOP	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP VT HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure ASO	Prior Auth See SPD
ASU	See Shn

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Auth
Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Revision History

06/01/2021 – format updated; indications for the percutaneous LAA closure devices were moved into a new medical policy call Percutaneous LAA closure devices.

12/01/2022 – added coverage for Percutaneous transcatheter mitral valve repair (CPT: 33418, 33419) using an FDA approved device (MitraClip).

02/01/2024 – added coverage for Transcatheter Pulmonary Valve (TPV) (CPT 33477).

06/01/2024 – Moved exclusion for ventricular reduction surgery from archived policy into this policy and added Intravascular Lithotripsy to exclusions as experimental and investigational.

06/01/2025 – Moved Transcatheter Tricuspid Valve Repair (TTVR 0569T, 0570T) moved from Investigational BIM and moved to Cardiac Procedure due to Medicare opening coverage to CMS approved studies. E&I for all other lines of business.

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MVP

Health Care Medical Policy

Cell-Free Fetal DNA-Based Prenatal Screening for Fetal Aneuploidy

Type of Policy: Medical

Prior Approval Date: 08/01/2022

Approval Date: 08/05/2024

Effective Date: 10/01/2024

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

N/A

Codes Requiring Retrospective Review

81422 - Fetal chromosomal microdeletion(s) genomic sequence analysis (eg, DiGeorge syndrome, Cri-du-chat syndrome), circulating cell-free fetal DNA in maternal blood

81599- Unlisted multianalyte assay with algorithmic analysis

0060U - Twin zygosity, genomic targeted sequence analysis of chromosome 2, using circulating cell-free fetal DNA in maternal blood

0327U - Fetal aneuploidy (trisomy 13, 18, and 21), DNA sequence analysis of selected regions using maternal plasma, algorithm reported as a risk score for each trisomy, includes sex reporting, if performed

Experimental/Investigational Review

Codes: 81422, 81599, 0060U, 0327U

Common Diagnosis Codes

N/A

Common Procedure Codes

81420, 81507

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

Non-invasive prenatal testing involves analyzing cell-free DNA circulating in maternal blood. It has been proposed to be an option for prenatal screening testing for trisomy 21 and a few other fetal chromosomal aneuploidies or abnormalities.

Sequencing-based trisomy tests are available but not limited to the following: MaterniT21Plus[™], MaterniT®, Harmony[™], Panorama[™], and Prequel[™].

There are multiple options for non-invasive prenatal screening for fetal chromosomal abnormalities. The non-invasive tests usually include measurement of maternal serum markers, and many include fetal nuchal translucency. First-trimester screening involves testing with both an ultrasound measuring fetal nuchal translucency and serum tests performed on maternal blood. Second trimester screening includes serum screening using triple or quadruple bio-marker screening and ultrasonography.

The current standard of care for the prenatal diagnosis of chromosomal abnormalities is chorionic villus sampling or amniocentesis.

Indications/Criteria

Non-invasive prenatal testing using cell-free DNA circulating in maternal blood ((e.g., MaterniT21 PLUS, Harmony Prenatal Test, Panorama Prenatal Test) medically necessary for testing for fetal aneuploidy (trisomy 13, 18 and 21) for pregnant customers of any age with single or twin pregnancies but not higher multi-gestational pregnancies.

Exclusions

Cell-Free Fetal DNA testing to determine the sex of the baby or multiple gestation testing is considered not to be a medically necessary service.

Non-invasive pre-natal testing using cell-free DNA circulating in maternal blood is not indicated for persons seeking a definitive diagnosis.

Non-invasive pre-natal testing using cell-free DNA circulating in maternal blood is not indicated for screening or detection of microdeletions or other chromosomal disorders (e.g., other trisomy). Non-invasive pre-natal testing using cell-free DNA is considered investigational because the safety and/or effectiveness cannot be established based on review of available peer reviewed medical literature. (CPT code 81422)

Non-invasive pre-natal testing using cell-free DNA circulating in maternal blood for screening or detection of fetal sex chromosome aneuploidies is considered

Cell-Free Fetal DNA-Based Prenatal Screening for Fetal Aneuploidy

investigational because the safety and/or effectiveness cannot be established based on review of available peer reviewed medical literature.

Single-gene disorder screening (e.g., Vistara (Natera)(PLU Code 0327U) is considered investigational because the safety and/or effectiveness cannot be established based on review of available peer reviewed medical literature.

Screening for twin zygosity (PLU Code 0060U) is considered investigational because the safety and/or effectiveness cannot be established based on review of available peer reviewed medical literature.

References (Reviewed 2024)

- 1. Audibert F, De Bie I, Johnson JA, et al. No. 348-joint SOGC-CCMG guideline: update on prenatal screening for fetal aneuploidy, fetal anomalies, and adverse pregnancy outcomes [published correction appears in *J Obstet Gynaecol Can*. August 2018;40(8):1109]. *J Obstet Gynaecol Can*. 2017;39(9):805-817.
- 2. Wapner, RJ. et al. Chromosomal microarray versus karotyping for prenatal diagnosis. N Engl J Med 2012; 367:2175-2184.
- 3. American College of Obstetricians and Gynecologists (ACOG), Committee Opinion No. 545. Noninvasive prenatal testing for fetal aneuploidy. Obstet Gynecol. 2012 Dec; 120(6): 1532-4.
- 4. Ashoor, G. et al. Chromosomal-selective sequencing of maternal cell-free DNA for first-trimester detection of trisomy 21 and trisomy 18. Am J Obstet Gynecol 2012; 206:322.e1-5.
- 5. Malone, F., et al. First and second-trimester evaluation of risk (faster) trial: principle results of the NICHD multicenter down syndrome screening study. American Journal of Obstetrics and Gynecology. 189(6): S56. December 2003.
- American College of Medical Genetics (ACMG), ACMG Policy Statement. ACMG statement on noninvasive prenatal screening for fetal aneuploidy. Genetics in Medicine. March 2013.
- 7. Driscoll, DA., et al. First trimester diagnosis and screening for fetal aneuploidy. Genetics in Medicine. 2008. 10. 73-75.
- 8. Bianchi DW, Platt LD, Goldberg JD, Abuhamad AZ, Sehnert AJ, Rava RP; MatErnal BLood IS Source to Accurately diagnose fetal aneuploidy (MELISSA) Study Group. Genome-wide fetal aneuploidy detection by maternal plasma DNA sequencing. Obstet Gynecol. 2012 May; 119(5):890-901.
- 9. Palomaki GE, Deciu C, Kloza EM, Lambert-Messerlian GM, Haddow JE, Neveux LM, et al. DNA sequencing of maternal plasma reliably identifies trisomy 18 and trisomy 13 as well as Down syndrome: an international collaborative study. Genet Med. 2012 Mar; 14(3):296-305.

Cell-Free Fetal DNA-Based Prenatal Screening for Fetal Aneuploidy

- 10. Palomaki GE, Kloza EM, Lambert-Messerlian GM, Haddow JE, Neveux LM, Ehrich M, et al. DNA sequencing of maternal plasma to detect Down syndrome: an international clinical validation study. Genet Med. 2011 Nov; 13(11):913-20.
- 11. Chiu RW, Akolekar R, Zheng YW, Leung TY, Sun H, Chan KC, et al. Non-invasive prenatal assessment of trisomy 21 by multiplexed maternal plasma DNA sequencing: large scale validity study. BMJ. 2011 Jan 11;342:c7401.
- 12. California Technology Assessment Forum (2012). Fetal aneuploidy detection by maternal plasma DNA sequencing. Available: Fetal aneuploidy detection by maternal plasma DNA sequencing: a technology assessment PubMed (nih.gov).
- 13. National Society of Genetic Counselors. (2012). Noninvasive prenatal testing/noninvasive prenatal diagnosis: the position of the National Society of Genetic Counselors.
- 14. Norton, ME., et al. Non-Invasive Chromosomal Evaluation (NICE) Study: results of a multicenter prospective cohort study for detection of fetal trisomy 21 and trisomy 18. Am J Obstet Gynecol 2012; 207:137, e1-8.
- 15. Wright CF, Burton H. The use of cell-free fetal nucleic acids in maternal blood for non-invasive prenatal diagnosis. Hum Reprod Update. 2009; 15(1):139-151.
- 16. Integrated Genetics MaterniT21 PLUS[©]. 2009-2012. Available: <u>451927 MaterniT 21 PLUS Core (chr21,18,13,sex) | Integrated Genetics.</u>
- 17. Ariosa Diagnostics. Integrated Genetics, a division of LabCorp. Harmony™ Prenatal Test. Available at: http://www.ariosadx.com/.
- 18. Natera. Panorama™ Prenatal Test. © 2014 Panorama™ Prenatal Test. Available: Panorama Overview | Natera.
- 19. Morain, S., et al. A new era in noninvasive prenatal testing. The New England Journal of Medicine. 2013; 369:499-501.
- 20. Bianchi DW, Parker RL, Wentworth J, Madankumar R, Saffer C, Das AF, et al. DNA sequencing versus standard prenatal aneuploidy screening. N Engl J Med. 2014 Feb 27;370(9):799-808.
- 21. Gregg AR, Gross SJ, Best RG, Monaghan KG, Bajaj K, Skotko BG, et al. ACMG statement on noninvasive prenatal screening for fetal aneuploidy. Genet Med. 2013 May;15(5):395-8.
- 22. Society for Maternal-Fetal Medicine (SMFM). SMFM Statement: Maternal serum cell-free DNA screening in low risk women. Accessed June 12, 2014. Available: https://www.smfm.org/publications/157-smfm-statement-maternal-serum-cell-free-dna-screening-in-low-risk-women.

- 23. HAYES Precision Medicine Research Brief. VisibiliT (Sequenom) Hayes, a TractManager Company © 2020 TractManager August 11, 2016. Available: www.hayesinc.com/.
- 24. American College of Obstetricians and Gynecologists (ACOG), Society for Maternal Fetal Medicine (SMFM). Committee Opinion No. 640. September 2015 (Reaffirmed 2017) Cell-free DNA screening For fetal aneuploidy. Obstet Gynecol. 2015;126(3):e31-e37. (This Committee Opinion Replaces Committee Opinion Number 545). Committee on Genetics Society for Maternal-Fetal Medicine.
- 25. American College of Obstetricians and Gynecologists (ACOG). Multifetal gestations: twin, triplet, and higher-order multifetal pregnancies: ACOG practice bulletin summary, number 231. *Obstetrics & Gynecology*. 2021;137(6):1140-1143.
- 26. American College of Obstetricians and Gynecologists (ACOG). Screening for Fetal Chromosomal Abnormalities: ACOG practice bulletin summary, number 226. October 2020.
- 27. Yaron Y, Jani J, Schmid M, Oepkes D. Current status of testing for microdeletion syndromes and rare autosomal trisomies using cell-free DNA technology. Obstet Gynecol. 2015;126(5):1095-1099.
- 28. Raniga S, Desai PD, Parikh H. Ultrasonographic soft markers of aneuploidy in second trimester: Are we lost? MedGenMed. 2006; 8(1):9.
- 29. Trivedi DK, Iles RK. Shotgun metabolomic profiles in maternal urine identify potential mass spectral markers of abnormal fetal biochemistry dihydrouracil and progesterone in the metabolism of Down syndrome. Biomed Chromatogr. 2015;29(8):1173-1183.
- 30. HAYES Clinical Utility Evaluation: Cell-Free DNA (cfDNA) [Formerly NIPS, NIPT]
 Screening for Fetal Sex Chromosome Aneuploidy. Hayes, a TractManager Company
 © 2020 TractManager October 26, 2017. Annual Review: October 21, 2020.
- 31. Hayes Clinical Utility Evaluation: Cell-Free DNA (CfDNA) [Formerly NIPS, NIPT] Screening For Fetal Trisomy 21, 18, And 13 In Low-Risk Women with Singleton Pregnancy. ©2021 Hayes, a sympir Company. April 19, 2021.
- 32. Hayes Clinical Utility Evaluation. Cell-Free DNA (cfDNA) [Formerly NIPS, NIPT] Screening for Fetal Trisomy 21, 18, and 13 in Women with Twin Pregnancies. ©2021 Hayes, a sympir Company. July 7, 2021.
- 33. New York State Medicaid Update. New York State Medicaid Expansion of Non-Invasive Prenatal Trisomy Screening Policy. August 2021, Volume 37, Number 10 Available: New York State Medicaid Update August 2021 Volume 37 Number 10 (ny.gov).

- 34. New York State Medicaid Update. New York State Medicaid Expansion of Non-Invasive Prenatal Trisomy Screening Policy. April 2022, Volume 38, Number 4 Available: New York State Medicaid Update April 2022 Volume 38 Number 4 (ny.gov).
- 35. U.S. Food & Drug Administration (FDA): Genetic Non-Invasive Prenatal Screening Tests May Have False Results: FDA Safety Communication, April 19, 2022. Available: Genetic Non-Invasive Prenatal Screening Tests May Have False Results: FDA Safety Communication | FDA.
- 36. Hoskovec J, et al. Maternal carrier screening with single-gene NIPS provides accurate fetal risk assessments for recessive conditions. Genet Med Feb 2023; 25(2): 100334.
- 37. Mohen, P, et al. Clinical experience with non-invasive prenatal screening for single-gene disorders. Ultrasound Obstet Gynecol 2022 Jan;59(1):33-39
- 38. Zhang, J and Saucier JB. Non-invasive prenatal sequencing for multiple Mendelian monogenic disorders using circulating cell-free fetal DNA. Nat Med 2019 Mar;25(3):439-447.

Customer Product	Medical Management Requirements*		
New York Products	•		
НМО	Potential for Retrospective Review		
PPO in Plan	Potential for Retrospective Review		
PPO OOP	Potential for Retrospective Review		
POS in Plan	Potential for Retrospective Review		
POS OOP	Potential for Retrospective Review		
Essential Plan	Potential for Retrospective Review		
MVP Medicaid Managed Care	Potential for Retrospective Review		
MVP Child Health Plus	Potential for Retrospective Review		
MVP Harmonious Health Care Plan	Potential for Retrospective Review		
MVP Medicare Complete Wellness	Potential for Retrospective Review		
MVP Medicare Preferred Gold HMO POS	Potential for Retrospective Review		
MVP Medicare Secure HMO POS	Potential for Retrospective Review		
MVP Medicare Secure Plus HMO POS	Potential for Retrospective Review		
MVP Medicare WellSelect PPO	Potential for Retrospective Review		
MVP Medicare WellSelect Plus PPO	Potential for Retrospective Review		
MVP Medicare Patriot Plan PPO	Potential for Retrospective Review		
MVP DualAccess D-SNP HMO	Potential for Retrospective Review		
MVP DualAccess Complete D-SNP HMO	Potential for Retrospective Review		
MVP DualAccess Plus D-SNP HMO	Potential for Retrospective Review		
UVM Health Advantage Select PPO	Potential for Retrospective Review		
USA Care PPO	Potential for Retrospective Review		
Healthy NY	Potential for Retrospective Review		
MVP Premier	Potential for Retrospective Review		
MVP Premier Plus	Potential for Retrospective Review		
MVP Premier Plus HDHP	Potential for Retrospective Review		
MVP Secure	Potential for Retrospective Review		
MVP EPO	Potential for Retrospective Review		
MVP EPO HDHP	Potential for Retrospective Review		
MVP PPO	Potential for Retrospective Review		
MVP PPO HDHP	Potential for Retrospective Review		
Student Health Plans	Potential for Retrospective Review		
ASO	See SPD		
Vermont Products	3cc 3i b		
POS in Plan	Potential for Retrospective Review		
POS OOP	Potential for Retrospective Review Potential for Retrospective Review		
MVP Medicare Preferred Gold HMO POS	Potential for Retrospective Review Potential for Retrospective Review		
MVP Medicare Preferred Gold HMO POS MVP Medicare Secure Plus HMO POS	Potential for Retrospective Review Potential for Retrospective Review		
MVP SmartFund MSA	·		
MVP VT HMO	Potential for Retrospective Review		
	Potential for Retrospective Review		
MVP VT HDHP HMO	Potential for Retrospective Review		
MVP VT Plus HMO	Potential for Retrospective Review		
MVP VT Plus HDHP HMO	Potential for Retrospective Review		
MVP Secure	Potential for Retrospective Review		
ASO	See SPD		

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

MVP Health Care Medical Policy

Revision History

06/01/2021 – Annual review with no changes to the indications or criteria. Added to the exclusions use of testing for gender determination.

11/01/2021 – Updated coverage criteria for Medicaid Managed Care Plans which was expanded to include pregnant customers aged 30 and older including twin pregnancies.

07/01/2022 – Updated coverage criteria for Medicaid Managed Care Plans (including HARP) to remove the age requirement and risk criteria.

08/01/2024 – Removed 81420 and 81507 from prior authorization or retrospective review. Added coverage to cell free DNA based prenatal screening for fetal aneuploidy. Added exclusions for screening single gene disorders and twin zygosity. References reviewed and updated.

10/01/2024 -completed formal review of fast-tracked changes effective 08/01/24



MVP Health Care Behavioral Health Medical Necessity Criteria

Children's Family Treatment and Support Services (CFTSS)

Type of Policy: Behavioral Health

Prior Approval Date: 10/06/2022

Approval Date: 11/04/2024

Effective Date: 02/01/2025

Related Polices: Home and Community Based Services – Pediatric

Home and Community Based Services - Adult

Personalized Recovery Oriented Services (PROS)

Assertive Community Treatment (ACT)

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

N/A

Codes Requiring Retrospective Review

N/A

Experimental/Investigational

N/A

Common Procedure Codes

Service	Rate Code	Procedure Code / Modifier
Other Licensed Practitioner (OLP)	7900	90791 EP
	7901	H0004 EP
		H0004 HR
		H0004 HS
	7981	H0004 U1 UA
	7982	H0004 U1 UB

	7902	H2011 EP ET
	7903	H2011 EP GT
	7904	90882 EP TS
	7905	H0004 HQ EP
	7920	90791 EO SC
	1320	H0004 SC
		H0004 SC
		H0004 HS SC
	7927	H0004 EQ HQ SC
Community Psychiatric Support and Treatment (CPST)	7911	H0036 EP
community regionalities cappeare and recommend (er or,	7912	H0036 EP HQ
	7921	H0036 EP SC
	7928	H0036 EP HQ SC
Psychosocial Rehabilitation (PSR)	7913	H2017 EP
,	7914	H2017 EP HQ
	7922	H2017 EP SC
	7929	H2017 EP HQ SC
Family Peer Supports (FPS)	7915	H0038 EP UK
, ,	7916	H0038 EP UK HQ
	7923	H0038 EP UK SC
	7930	H0038 EP HQ SC
		UK
Your Peer Supports (FPS)	7917	H0038 EP
	7918	H0038 EP HQ
	7923	H0038 EP SC
	7930	H0038 EP HQ SC
Crisis Intervention (CI)	7906	H2011 EP HO
 Mobile Crisis 	7907	H2011 EP HT
 Mobile Follow-up Services 	7908	H2011 EP
 Telephonic Follow-up Services 	7909	S9484 EP
	7910	S9485 EP
	7936	S9484 EP HO
	7937	S9485 EP HO
	7938	H2011 TS HO
	7939	H2011 TS HM HA
	7940	H2011 TS HT
	7941	H2011 TS HO GT
	7942	H2011 TS HM GT

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are

subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview:

Children and Family Treatment and Support Services (CFTSS) are behavioral health services that provide kids and teens with mental health and/or substance use resources. Services are provided at home and in the community, based on where children and families are most comfortable. CFTSS empower children, teens, and their families to improve their overall quality of life by focusing on their mental health and well-being. These services help guide families to make informed decisions about their care. CFTSS are also intended to prevent the need for emergency room visits, hospital stays, or out of home placements.

MVP provides coverage of CFTSS to kids and teens under the age of twenty-one (21) who are enrolled in an MVP Medicaid Managed Care Plan. Services are covered with any designated CFTSS provider regardless of their participation in the MVP Network. These services include Other Licensed Practitioner (OLP), Crisis Intervention (CI), Community Psychiatric Supports and Treatment (CPST), Psychosocial Rehabilitation (PSR), Family Peer Support (FPS), and Youth Peer Support (YSP).

Other Licensed Practitioner (OLP): OLP service is delivered by a Non-physician licensed behavioral health practitioner (NP-LBHP) who is licensed in the state of New York operating within the scope of practice defined in State law and in any setting permissible under State practice law. OLP does not require a DSM diagnosis in order for the service to be delivered. NP-LBHPs include individuals licensed and able to practice independently as a:

- Licensed Psychoanalyst;
- Licensed Clinical Social Worker (LCSW);
- Licensed Marriage & Family Therapist (LMFT);
- Licensed Mental Health Counselor (LMHC); or
- Licensed Creative Arts Therapist (LCAT)

An NP-LBHP also includes the following individuals who are licensed under supervision or direction of a licensed Clinical Social Worker (LCSW), a Licensed Psychologist, or a Psychiatrist (MD/DO):

Licensed Master Social Worker (LMSW)

In addition to licensure, service providers that offer addiction services must demonstrate competency as defined by state law and regulations. Any practitioner above must operate within a child serving agency that is licensed, certified, designated and/or approved by OCFS, OMH, OASAS OR DOH or its designee, in settings permissible by that designation.

Please refer to the "Children's Health and Behavioral Health Services Transformation-Medicaid State Plan Provider Manual for Children's BH Early and Periodic Screening and Diagnostic Treatment (EPSDT) Services" for additional information regarding this service. This service is available for children from birth to 21 years of age.

Admission to OLP:

Criteria 1 or 2 must be met:

The child/youth is being assessed by the NP-LBHP to determine the need for treatment. The NP-LBHP develops a treatment plan for goals and activities necessary to correct or ameliorate conditions discovered during the initial assessment visits that:

- Corrects or ameliorates conditions that are found through an EPSDT screening;
 OR
- 2. Addresses the prevention, diagnosis, and/or treatment of health impairments; the ability to achieve age-appropriate growth and development, and the ability to attain, maintain, or regain functional capacity.

Continued Stay:

Criteria 1 OR 2 and 3, 4, 5, 6:

- The child/youth is making some progress but has not fully reached established service goals and there is expectation that if the child/youth continues to improve, then the service continues OR
- Continuation of the service is needed to prevent the loss of functional skills already achieved AND
- 3. The child/youth continues to meet admission criteria AND
- 4. The child/youth and/or family/caregiver(s) continue to be engaged in services AND
- 5. An alternative service(s) would not meet the child/youth needs AND
- 6. The treatment plan has been appropriately updated to establish or modify ongoing goals.

Discharge:

Any one of criteria 1-6 must be met:

- 1. The child/youth no longer meets continued stay criteria OR
- 2. The child/youth has successfully reached individual/family established service goals for discharge; OR
- 3. The child/youth or parent/caregiver(s) withdraws consent for services; OR

- 4. The child/youth is not making progress on established service goals, nor is there expectation of any progress with continued provision of services; OR
- 5. The child/youth is no longer engaged in the service, despite multiple attempts on the part of the provider to apply reasonable engagement strategies; OR
- 6. The child/youth and/or family/caregiver(s) no longer needs OLP as he/she is obtaining a comparable benefit through other services and resources.

OLP Limits/Exclusions:

- Group limit refers to number of child/youth participants, regardless of payor. Groups should not exceed 8 children/youth.
- Consideration may be given to smaller limit of customers if participants are younger than 8 years of age. Consideration should be given to group size when collaterals are included.
- Consideration for group limits, or, the inclusion of an additional group clinician/facilitator, should be based on, but not limited to: the purpose/nature of the group, the clinical characteristics of the participants, age of participants, developmental level and severity of needs of the participants, inclusion of collaterals in group; as well as the experience and skill of the group clinician/facilitator
- Inpatient hospital facilities are allowed for licensed professional other than social workers if a Preadmission Screening and Resident Review (PASRR) indicate it is medically necessary treatment. Social worker visits are included in the Nursing Facility Visit and may not be billed separately.
- Visits to Intermediate Care Facilities for individuals with Mental Retardation (ICF-MR) are not covered as they are under the scope of the Office for People With Developmental Disabilities OPWDD
- All NP-LBHP services provided while the person is a resident of an institution for Mental Disease, such a free-standing psychiatric hospital or psychiatric residential treatment facility, are part of the institutional service and not otherwise reimbursable by Medicaid.
- If a child requires medically necessary services that are best delivered in the school setting by a community provider the service needs to be detailed on the treatment plan.
- If a child needs assistance in the schools (educationally necessary) and a school employee will be providing the service, the service must be on the child's Individualized Education Plan (IEP) (504 plan services are not reimbursable by Medicaid).
- Evidence based practices (EBP) require approval, designations, and fidelity reviews on an ongoing basis as determined necessary by New York State. Treatment services must be a part of a treatment plan including goals and activities necessary to correct or ameliorate conditions discovered during the initial assessment visits.

Crisis Intervention (CI):

Crisis Intervention (CI) Services are provided to children/youth who are identified as experiencing an acute psychological/emotional change which results in a marked increase in personal distress, and which exceeds the abilities and the resources of those involved (e.g. collateral, provider, community member) to effectively resolve any imminent concern. A child/youth in crisis may be referred by a family member or other collateral contact who has knowledge of the child/youth's capabilities and functioning.

The goals of CI are engagement, symptom reduction, stabilization, and restoring individuals to a previous level of functioning or developing the coping mechanisms to minimize or prevent the crisis in the future.

Please refer to "Medicaid State Plan Children and Family Support and Treatment Services Provider Manual for Children's BH Early and Periodic Screening and Diagnostic Treatment (EPSDT) Services" for additional information regarding this service. This service is available for children from birth to 21 years of age.

As of May 1, 2024, Crisis Intervention rates and billing guidance has been consolidated with Mobile Crisis to further support greater flexibility and access across the lifespan. For rates and billing for Crisis Intervention, visit Medicaid Managed Care (ny.gov). For information specific to this change see Mobile Crisis and Crisis Residence Authority and Reimbursement Changes memo, State Plan Amendment Updates to Mobile Crisis Services memo and State Plan Amendment Updates for Crisis Residence Reimbursement Standards memo.

Admission to Crisis Intervention

All criteria must be met:

- 1. The child/youth experiencing acute psychological/emotional change which results in a marked increase in personal distress, and which exceeds the abilities and the resources of those involved (e.g. collateral, provider, community member) to effectively resolve it; AND
- 2. The child/youth demonstrates at least one of the following:
 - a. Suicidal/assaultive/destructive ideas, threats, plans or actions that represent a risk to self or others; or
 - b. Impairment in mood/thought/behavior disruptive to home, school, or the community or
 - c. Behavior escalating to the extent that a higher intensity of services will likely be required; AND
- 3. The intervention is necessary to further evaluate, resolve, and/or stabilize the child/youth; AND

- 4. The services are recommended by the following Licensed practitioners of the Healing Arts operating within the scope of their practice under State License:
 - a. Psychiatrist
 - b. Other treating Physician
 - c. Licensed Psychoanalyst
 - d. Registered Professional Nurse
 - e. Nurse Practitioner
 - f. Clinical Nurse Specialist
 - g. Licensed Clinical Social Worker
 - h. Licensed Marriage and Family Therapist
 - i. Addictionologist/Addiction Specialist
 - j. Physician Assistant
 - k. Licensed Master Social Worker (LMSW)
 - I. Licensed Mental Health Counselor or
 - m. Licensed Psychologist

Discharge

Any one of criteria 1-or 2 must be met:

- n. The child/youth no longer meets admission criteria (demonstrates symptom reduction, stabilization, and restoration, or developing the coping mechanisms to pre-crisis levels of functioning) and/or meets criteria for another level of care, either more or less intensive; OR
- o. The child/youth or parent/caregiver(s) withdraws consent for services

Limits/Exclusions:

- Within the 72-hour timeframe of a crisis, de-escalation techniques are utilized in an attempt to calm the child; information is gathered from the child, family, and/or other collateral supports on what may have triggered the crisis; information is gathered on the child's history; review of medications occurs, as appropriate, and a crisis plan is developed with the child/family. Warm handoff to providers of needed services should also be occurring following these expectations.
- The following activities are excluded: financial management, supportive housing, supportive employment services, and basic skill acquisition services that are habilitative in nature.

- Services may not be primarily educational, vocational, recreational, or custodial (i.e., for the purpose of assisting in the activities of daily living such as bathing, dressing, eating, and maintaining personal hygiene and safety; for maintaining the recipient's or anyone else's safety, and could be provided by persons without professional skills or training). Services also do not include services, supplies or procedures performed in a nonconventional setting including: resorts, spas, therapeutic programs, and camps. Once the current crisis episode and follow up exceeds 72 hours, then it shall be considered a new crisis intervention episode or will be transferred to a longer-term service for rehabilitation skill building such as CPST. An episode is defined as starting with the initial face to face contact with the child.
- The child/youth's chart must reflect resolution of the crisis which marks the end of the episode. Warm handoff to follow up services with a developed plan should follow. Substance Use should be recognized and addressed in an integrated fashion as it may add to the risk and increase the need for engagement in care. Crisis services cannot be denied based upon substance use. Crisis Team members should be trained on screening for substance use disorders.

Community Psychiatric Supports and Treatment (CPST):

CPST services are goal-directed supports and solution-focused interventions intended to address challenges associated with a behavioral health need and to achieve identified goals or objectives as set forth in the child/youth's treatment plan. This includes the implementation of interventions using evidenced-based techniques, drawn from cognitive-behavioral therapy and/or other evidenced-based psychotherapeutic interventions approved by New York State. CPST includes the following components: Rehabilitative Psychoeducation, Intensive Interventions, Strengths Based Treatment Planning, Rehabilitative Supports, Crisis Avoidance, and Intermediate Term Crisis Management.

CPST is designed to provide community-based services to children and families who may have difficulty engaging in formal office settings but can benefit from community based rehabilitative services. CPST allows for delivery of services within a variety of permissible settings including community locations where the customer lives, works, attends school, engages in services (e.g. provider office sites), and/or socializes.

Please refer to "Medicaid State Plan Children and Family Support and Treatment Services Provider Manual for Children's BH Early and Periodic Screening and Diagnostic Treatment (EPSDT) Services" for additional information regarding this service. This service is available for children from birth to 21 years of age.

Admission to Community Psychiatric Supports and Treatment

All criteria must be met:

- 1. The child/youth has a behavioral health diagnosis that demonstrates symptoms consistent or corresponding with the DSM OR the child/youth is at risk of development of a behavioral health diagnosis; AND
- 2. The child/youth is expected to achieve skill restoration in one of the following areas:
 - a. participation in community activities and/or positive peer support networks
 - b. personal relationships;
 - c. personal safety and/or self-regulation
 - d. independence/productivity;
 - e. daily living skills
 - f. symptom management
 - g. coping strategies and effective functioning in the home, school, social or work environment; AND
- 3. The child/youth is likely to benefit from and respond to the service to prevent the onset or the worsening of symptoms, AND
- 4. The services are recommended by the following Licensed Practitioners of the Healing Arts operating within the scope of their practice under State License:
 - a. Licensed Master Social Worker
 - b. Licensed Clinical Social Worker
 - c. Licensed Mental Health Counselor
 - d. Licensed Creative Arts Therapist
 - e. Licensed Marriage and Family Therapist
 - f. Licensed Psychoanalyst
 - g. Licensed Psychologist
 - h. Physician Assistant
 - i. Psychiatrist
 - j. Another treating Physician
 - k. Registered Professional Nurse or
 - I. Nurse Practitioner

Continued Stay

All criteria must be met:

1. The child/youth continues to meet admission criteria; AND

- 2. The child/youth shows evidence of engagement toward resolution of symptoms but has not fully reached established service goals and there is expectation that if the service continues, the child/youth will continue to improve; AND
- 3. The child/youth does not require an alternative and/or higher, more intensive level of care or treatment; AND
- 4. The child/youth is at risk of losing skills gained if the service is not continued; AND
- 5. Treatment planning includes family/caregiver(s) and/or other support systems, unless not clinically indicated or relevant

Discharge

Any one of criteria 1-6 must be met:

- The child/youth no longer meets admission criteria and/or meets criteria for another level of care, either more or less intensive; OR
- The child/youth has successfully met the specific goals outlined in the treatment plan for discharge; OR
- 3. The child/youth or parent/caregiver(s) withdraws consent for services; OR
- 4. The child/youth is not making progress on established service goals, nor is there expectation of any progress with continued provision of services; OR
- 5. The child/youth is no longer engaged in the service, despite multiple attempts on the part of the provider to apply reasonable engagement strategies; OR

Limits/Exclusions:

The provider agency will assess the child prior to developing a treatment plan for the child.

- Treatment services must be part of the treatment plan including goals and activities necessary to correct or ameliorate conditions discovered during the initial assessment visits.
- A child with a developmental disability diagnosis without a co-occurring behavioral health condition is ineligible to receive this rehabilitative service.
- Group face-to-face may be delivered under Rehabilitative Supports and Rehabilitative Psychoeducation
- Group limit refers to number of child/youth participants, regardless of payor. Groups cannot exceed 8 children/youth.
- Consideration should be given to smaller limit of customers if participants are younger than 8 years of age. Consideration should be given to group size when family/collaterals are included.

- Consideration for group limits, or, the inclusion of an additional group clinician/facilitator, should be based on, but not limited to: the purpose/nature of the group, the clinical characteristics of the participants, age of participants, developmental level and severity of needs of the participants, inclusion of family/collaterals in group; as well as the experience and skill of the group clinician/facilitator
- Evidence-Based Practices (EBP) require prior approval, designations, and fidelity reviews on an ongoing basis as determined necessary by New York State. The Institute of Medicine (IOM) defines "evidence-based practice" as a combination of the following three factors: (1) best research evidence, (2) best clinical experience, and (3) consistent with patient values (IOM, 2001).1 o Implemented interventions using evidence-based techniques may ameliorate targeted symptoms and/or recover the person's capacity to cope with or prevent symptom manifestation.

Psychosocial Rehabilitation (PSR):

Psychosocial Rehabilitation Services (PSR) are designed for children/youth and their families/caregivers to assist with implementing interventions outlined in the treatment plan to compensate for or eliminate functional deficits and interpersonal and/or behavioral health barriers associated with a child/youth's behavioral health needs. The intent of PSR is to restore, rehabilitate, and support a child/youth's functional level as possible and as necessary for the integration of the child/youth as an active and productive member of their community and family with minimal ongoing professional interventions. Activities included must be intended to achieve the identified goals or objectives as set forth in the child/youth's individualized treatment plan. Please refer to "Children's Health and Behavioral Health Services Transformation-Medicaid State Plan Provider Manual for Children's BH Early and Periodic Screening and Diagnostic Treatment (EPSDT) Services" for additional information regarding this service. This service is available for children from birth to 21 years of age.

Admission to Psychosocial Rehabilitation

All criteria must be met:

- 1. The child/youth has a behavioral health diagnosis that demonstrates symptoms consistent or corresponding with the DSM; AND
- 2. The child/youth is likely to benefit from and respond to the service to prevent the onset or the worsening of symptoms; AND
- 3. The service is needed to meet rehabilitative goals by restoring, rehabilitating, and/or supporting a child/youth's functional level to facilitate integration of the child/youth as participant of their community and family AND
- 4. The services are recommended by the following Licensed Practitioners of the Healing Arts operating within the scope of their practice under State License:

- Licensed Master Social Worker
- Licensed Clinical Social Worker
- Licensed Mental Health Counselor
- Licensed Creative Arts Therapist
- Licensed Marriage and Family Therapist
- Licensed Psychoanalyst
- Licensed Psychologist
- Physician's Assistant
- Psychiatrist
- Another treating Physician
- Registered Professional Nurse or
- Nurse Practitioner

Continued Stay:

All criteria must be met:

- 1. The child/youth continues to meet admission criteria; AND
- 2. The child/youth shows evidence of engagement toward resolution of symptoms but has not fully reached established service goals and there is expectation that if the service continues, the child/youth will continue to improve; AND
- 3. The child/youth does not require an alternative and/or higher, more intensive level of care or treatment; AND
- 4. The child/youth is at risk of losing skills gained if the service is not continued; AND
- 5. Treatment planning includes family/caregiver(s) and/or other support systems, unless not clinically indicated or relevant.

Discharge:

Any one of criteria 1-6 must be met:

- The child/youth no longer meets admission criteria and/or meets criteria for another level of care, either more or less intensive; OR
- 2. The child/youth has successfully met the specific goals outlined in the treatment plan for discharge; OR
- 3. The child/youth or parent/caregiver(s) withdraws consent for services; OR

- 4. The child/youth is not making progress on established service goals, nor is there expectation of any progress with continued provision of services; OR
- 5. The child/youth is no longer engaged in the service, despite multiple attempts on the part of the provider to apply reasonable engagement strategies; OR
- 6. The child/youth and/or family/caregiver(s) no longer needs this service as he/she is obtaining a similar benefit through other services and resources.

PSR Limits/Exclusions:

Limits/Exclusions:

- The provider agency will assess the child prior to developing a treatment plan for the child. A licensed CPST practitioner or OLP must develop the treatment plan, with the PSR worker implementing the intervention identified on the treatment plan.
- A child with a developmental disability diagnosis without a co-occurring behavioral health condition is ineligible to receive this rehabilitative service.
- Group limit refers to number of child/youth participants, regardless of payor. Groups cannot exceed 8 children/youth. Ratio of facilitator to participants should be 1:4.
- Consideration for group limits, or, the inclusion of an additional group clinician/facilitator, should be based on, but not limited to: the purpose/nature of the group, the clinical characteristics of the participants, age of participants, developmental level and severity of needs of the participants, inclusion of collaterals in group; as well as the experience and skill of the group clinician/facilitator
- Treatment services must be a part of a treatment plan including goals and activities necessary to correct or ameliorate conditions discovered during the initial assessment visits.

Family Peer Support Services (FPSS):

Family Peer Support Services (FPSS) are an array of formal and informal activities and supports provided to families caring for/raising a child who is experiencing social, emotional, medical, developmental, substance use, and/or behavioral challenges in their home, school, placement, and/or community. FPSS provide a structured, strength-based relationship between a Family Peer Advocate (FPA) and the parent/family member/caregiver for the benefit of the child/youth.

The service is needed to allow the child the best opportunity to remain in the community. Activities included must be intended to achieve the identified goals or objectives as set forth in the child/youth's treatment plan.

This service is needed to achieve specific outcome(s), such as: strengthening the family unit, building skills within the family for the benefit of the child, promoting

empowerment within the family, and strengthening overall supports in the child's environment.

Please refer to "Children's Health and Behavioral Health Services Transformation-Medicaid State Plan Provider Manual for Children's BH Early and Periodic Screening and Diagnostic Treatment (EPSDT) Services" for additional information regarding this service. This service is available for children from birth to 21 years of age.

Admission to Family Peer Support Services

Criteria 1 OR 2, AND 3 AND 4 AND 5 must be met:

- 1. The child/youth has a behavioral health diagnosis that demonstrates symptoms consistent or corresponding with the DSM OR
- 2. The child/youth displays demonstrated evidence of skill(s) lost or undeveloped as a result of the impact of their physical health diagnosis; AND
- 3. The child/youth is likely to benefit from and respond to the service to prevent the onset or the worsening of symptoms; AND
- 4. The child/youth's family is available, receptive to and demonstrates need for improvement in the following areas such as but not limited to:
 - a. strengthening the family unit
 - b. building skills within the family for the benefit of the child
 - c. promoting empowerment within the family
 - d. strengthening overall supports in the child's environment; AND
- 5. The services are recommended by the following Licensed Practitioners of the Healing Arts operating within the scope of their practice under State License:
 - Licensed Master Social Worker
 - Licensed Clinical Social Worker
 - Licensed Mental Health Counselor
 - Licensed Creative Arts Therapist
 - Licensed Marriage and Family Therapist
 - Licensed Psychoanalyst
 - Licensed Psychologist
 - Physician's Assistant
 - Psychiatrist
 - Another treating Physician
 - Registered Professional Nurse or

Nurse Practitioner

Continued Stay:

All criteria must be met:

- 1. The child/youth continues to meet admission criteria; AND
- 2. The child/youth is making progress but has not fully reached established service goals and there is a reasonable expectation that continued services will increase the Child/youth meeting services goals; AND
- 3. Family/caregiver(s) participation in treatment is adequate to meaningfully contribute to the child/youth's progress in achieving service goals; AND
- 4. Additional psychoeducation or training to assist the family/caregiver understanding the child's progress and treatment or to care for the child would contribute to the child/youth's progress; AND
- 5. The child/youth does not require an alternative and/or higher, more intensive level of care or treatment; AND
- 6. The child/youth is at risk of losing skills gained if the service is not continued; AND
- 7. Treatment planning includes family/caregiver(s) and/or other support systems, unless not clinically indicated or relevant.

Discharge

Any one of criteria 1-6 must be met:

- 1. The child/youth and/or family no longer meets admission criteria OR
- 2. The child/youth has successfully met the specific goals outlined in the treatment plan for discharge; OR
- 3. The family withdraws consent for services; OR
- 4. The child/youth and/or family is not making progress on established service goals, nor is there expectation of any progress with continued provision of services; OR
- 5. The child/youth and/or family is no longer engaged in the service, despite multiple attempts on the part of the provider to apply reasonable engagement strategies; OR
- 6. The family/caregiver(s) no longer needs this service as they are obtaining a similar benefit through other services and resources.

FPSS Limits/Exclusions

Limits/Exclusions:

- The provider agency will assess the child prior to developing the treatment plan for the child.
- Treatment services must be part of the treatment plan including goals and activities necessary to correct or ameliorate conditions discovered during the initial assessment visits.
- A child with a developmental disability diagnosis without a co-occurring behavioral health condition is ineligible to receive this rehabilitative service.
- A group cannot exceed more than 12 individuals in total.

Medicaid family support programs will not reimburse for the following:

- 12-step programs run by peers.
- General outreach and education including participation in health fairs, and other activities designed to increase the number of individuals served or the number of services received by individuals accessing services; community education services, such as health presentations to community groups, PTAs, etc.
- Contacts that are not medically necessary.
- Time spent doing, attending, or participating in recreational activities.
- Services provided to teach academic subjects or as a substitute for educational personnel such as, but not limited to, a teacher, teacher's aide, or an academic tutor.
- Time spent attending school (e.g., during a day treatment program).
- Habilitative services for the beneficiary (child) to acquire self-help, socialization, and adaptive skills necessary to reside successfully in community settings.
- Child Care services or services provided as a substitute for the parent or other individuals responsible for providing care and supervision.
- Respite care.
- Transportation for the beneficiary or family. Services provided in the car are considered transportation and time may not be billed under rehabilitation.
- Services not identified on the beneficiary's authorized treatment plan.
- Services not in compliance with the service manual and not in compliance with State Medicaid standards.
- Services provided to children, spouse, parents, or siblings of the eligible beneficiary under treatment or others in the eligible beneficiary's life to address problems not directly related to the eligible beneficiary's issues and not listed on the eligible beneficiary's treatment plan.

• Any intervention or contact not documented or consistent with the approved treatment/recovery plan goals, objectives, and approved services will not be reimbursed.

Youth Peer Support (YPS):

Youth Peer Support (YPS) services are formal and informal services and supports provided to youth, who are experiencing social, medical, emotional, developmental, substance use, and/or behavioral challenges in their home, school, placement, and/or community centered services. These services provide the training and support necessary to ensure engagement and active participation of the youth in the treatment planning process and with the ongoing implementation and reinforcement of skills.

Youth Peer Support activities must be intended to develop and achieve the identified goals and/or objectives as set forth in the youth's individualized treatment plan.

The structured, scheduled activities provided by this service emphasize the opportunity for the youth to expand the skills and strategies necessary to move forward in meeting their personal, individualized life goals, develop self-advocacy skills, and to support their transition into adulthood.

Please refer to "Children's Health and Behavioral Health Services Transformation-Medicaid State Plan Provider Manual for Children's BH Early and Periodic Screening and Diagnostic Treatment (EPSDT) Services" for additional information regarding this service. This service is available for children from birth to 21 years of age.

Admission to Youth Peer Support

Criteria 1 OR 2, AND 3, 4, 5, 6 must be met:

- The youth has a behavioral health diagnosis that demonstrates symptoms consistent or corresponding with the DSM; OR
- 2. The youth displays demonstrated evidence of skill(s) lost or undeveloped as a result of the impact of their physical health diagnosis; AND
- 3. The youth requires involvement of a Youth Peer Advocate to implement the intervention(s) outlined in the treatment plan, AND
- 4. The youth demonstrates a need for improvement in the following areas such as but not limited to:
 - a. enhancing youth's abilities to effectively manage comprehensive health needs
 - b. maintaining recovery
 - c. strengthening resiliency, self-advocacy
 - d. self-efficacy and empowerment

- e. developing competency to utilize resources and supports in the community
- f. transition into adulthood or participate in treatment; AND
- 5. The youth is involved in the admission process and helps determine service goals; AND
- 6. The youth is available and receptive to receiving this service; AND
- 7. The services are recommended by the following Licensed Practitioners of the Healing Arts operating within the scope of their practice under State License:
- Licensed Master Social Worker
- Licensed Clinical Social Worker
- Licensed Mental Health Counselor
- Licensed Creative Arts Therapist
- Licensed Marriage and Family Therapist
- Licensed Psychoanalyst
- Licensed Psychologist
- Physician's Assistant
- Psychiatrist
- Another treating Physician
- Registered Professional Nurse or
- Nurse Practitioner

Continued Stay:

All criteria must be met:

- 1. The youth continues to meet admission criteria; AND
- 2. The youth shows evidence of engagement toward resolution of symptoms but has not fully reached established service goals and there is expectation that if the service continues, the youth will continue to improve; AND
- 3. The youth does not require an alternative and/or higher, more intensive level of care or treatment; AND
- 4. The youth is at risk of losing skills gained if the service is not continued.; AND
- 5. Treatment planning includes family/caregiver(s) and/or other support systems, unless not clinically indicated.

Discharge:

Any of criteria 1-6 must be met:

- 1. The youth no longer meets admission criteria; OR
- 2. The youth has successfully met the specific goals outlined in the treatment plan for discharge; OR
- 3. The youth or parent/caregiver withdraws consent for services; OR
- 4. The youth is not making progress on established service goals, nor is there expectation of any progress with continued provision of services; OR
- 5. The youth is no longer engaged in the service, despite multiple attempts on the part of the provider to apply reasonable engagement strategies; OR
- 6. The youth no longer needs this service as they are obtaining a similar benefit through other services and resources.

YPS Limits/ Exclusions

Limits/Exclusions:

- The provider agency will assess the child prior to developing the treatment plan for the child.
- Treatment services must be part of the treatment plan including goals and activities necessary to correct or ameliorate conditions discovered during the initial assessment visits.
- A youth with a developmental disability diagnosis without a co-occurring behavioral health condition is ineligible to receive this rehabilitative service.
- o Group limit refers to number of child/youth participants, regardless of payor. Groups cannot exceed 8 children/youth.
- o Consideration for group limits, or, the inclusion of an additional group clinician/facilitator, should be based on, but not limited to: the purpose/nature of the group, the clinical characteristics of the participants, age of participants, developmental level and severity of needs of the participants, inclusion of collaterals in group; as well as the experience and skill of the group clinician/facilitator.

Medicaid family support programs will not reimburse for the following:

- 12-step programs run by peers.
- General outreach and education including participation in health fairs, and other activities designed to increase the number of individuals served or the number of services received by individuals accessing services; community education services, such as health presentations to community groups, PTAs, etc.
- Contacts that are not medically necessary.

- Time spent doing, attending, or participating in recreational activities.
- Services provided to teach academic subjects or as a substitute for educational personnel such as, but not limited to, a teacher, teacher's aide, or an academic tutor.
- Time spent attending school (e.g., during a day treatment program).
- Habilitative services for the beneficiary (child) to acquire self-help, socialization, and adaptive skills necessary to reside successfully in community settings.
- Child Care services or services provided as a substitute for the parent or other individuals responsible for providing care and supervision.
- Respite care.
- Transportation for the beneficiary or family.
- Services not identified on the beneficiary's authorized treatment plan.
- Services not in compliance with the service manual and not in compliance with State Medicaid standards.
- Services provided to children, spouse, parents, or siblings of the eligible beneficiary under treatment or others in the eligible beneficiary's life to address problems not directly related to the eligible beneficiary's issues and not listed on the eligible beneficiary's treatment plan.
- Any intervention or contact not documented or consistent with the approved treatment/recovery plan goals, objectives, and approved services will not be reimbursed.

State Assurances

The state assures that rehabilitative services do not include and FFP is not available for any of the following in accordance with section 1905(a0(13) of the Act.

- Educational, vocational and job training services;
- Room and board
- Habilitation services
- Services to inmates in public institutions as defined in 42 CFR 435.1010;
- Services to individuals residing in institutions for mental disease as described in 42 CFR 435.1010
- Recreational and social activities
- Services that must be covered elsewhere in the state Medicaid plan

References (Updated 2024)

1. New York State Department of Health – New York State Medicaid Update – December 2018 Volume 34 – Number 12 – Children's Medicaid Health and

- Behavioral Health System Transformation. Available: New York State Medicaid Update December 2018 Volume 34 Number 12 (ny.gov).
- 2. New York State Department of Health Children's Behavioral Health Child and Family Treatment and Support Services website: Children and Family Treatment and Support Services (ny.gov)
- 3. New York State Department of Health Children and Family Treatment and Support Services Provider Manual for EPSDT Services updated June 2022 (PDF) Available: CFTSS Manual Updated June 2022 (ny.gov).

Customer Product	Management Requirements*		
New York Products			
HMO	Not A Covered Benefit		
PPO in Plan	Not A Covered Benefit		
PPO OOP	Not A Covered Benefit		
POS in Plan	Not A Covered Benefit		
POS OOP	Not A Covered Benefit		
Essential Plan	Not A Covered Benefit		
MVP Medicaid Managed Care	Potential for Retrospective Review		
MVP Child Health Plus	Potential for Retrospective Review		
MVP Harmonious Health Care Plan	Not a Covered Benefit		
MVP Medicare Complete Wellness	Not A Covered Benefit		
MVP Medicare Secure HMO POS	Not A Covered Benefit		
MVP Medicare Secure Plus HMO POS	Not A Covered Benefit		
MVP Medicare WellSelect PPO	Not A Covered Benefit		
MVP Medicare WellSelect Plus PPO	Not A Covered Benefit		
MVP Medicare Patriot Plan PPO	Not a Covered Benefit		
MVP DualAccess D-SNP HMO	Not A Covered Benefit		
MVP DualAccess Complete D-SNP HMO	Not A Covered Benefit		
MVP DualAccess Plus D-SNP HMO	Not A Covered Benefit		
UVM Health Advantage Select PPO	Not A Covered Benefit		
USA Care	Not A Covered Benefit		
Healthy NY	Not A Covered Benefit		
MVP Premier	Not A Covered Benefit		
MVP Premier Plus	Not A Covered Benefit		
MVP Premier Plus HDHP	Not A Covered Benefit		
MVP Secure	Not A Covered Benefit		
MVP EPO	Not A Covered Benefit		
MVP EPO HDHP	Not A Covered Benefit		
MVP PPO	Not A Covered Benefit		
MVP PPO HDHP	Not A Covered Benefit		
Student Health Plans	Not A Covered Benefit		
ASO	Not A Covered Benefit		
Vermont Products			
POS in Plan	Not A Covered Benefit		
POS OOP	Not A Covered Benefit		
MVP Medicare Preferred Gold HMO POS	Not A Covered Benefit		
MVP Medicare Secure Plus HMO POS	Not A Covered Benefit		
MVP VT HMO	Not A Covered Benefit		
MVP VT HDHP HMO	Not A Covered Benefit		
MVP VT Plus HMO	Not A Covered Benefit		
MVP VT Plus HDHP HMO	Not A Covered Benefit		
MVP Secure	Not A Covered Benefit		
ASO	Not A Covered Benefit		

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Management Requirements

Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Revision History

12/01/2022 – Annual Review; added coverage criteria for Community Psychiatric Supports and Treatment, Crisis Intervention, updated overview and grammar in policy based on NY State CTTSS Manual.

01/01/2023 – Added coverage to Child Health Plus plans.

02/01/2025 – added NYS plan amendment updates to Mobile Crisis Services.



MVP Health Care Medical Policy

Chiropractic Care

Type of Policy: Medical

Prior Approval Date: 10/03/2022

Approval Date: 05/06/2024

Effective Date: 08/01/2024

Related Polices: MVP Investigational Procedures,

Devices, Medical Treatments and

Tests

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

N/A

Codes Requiring Retrospective Review

N/A

Experimental/Investigational

CPT Code: 97037 - Application of a modality to 1 or more areas; low-level laser therapy (i.e., nonthermal and non-ablative) for post-operative pain reduction.

Common Diagnosis Codes

N/A

Common Procedure Codes

CPT Codes: 97010, 97012, 97014, 97016, 97018, 97022, 97032, 97033, 97034, 97035, 97039, 97110, 97124, 97139, 97140, 97530, 98940, 98941, 98942, 98943

Please refer to the product grid for detailed authorization requirements for specific plans. Code lists may not be all inclusive. Codes requiring prior authorization for some products may be retrospectively reviewed for plans that do not require prior authorization. Common diagnosis and procedure codes are included for informational purposes. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Chiropractic Care Page 1 of 9

Overview

Chiropractic care is health care that is focused on disorders of the musculoskeletal system and the effects of these disorders, particularly of the spinal column and nervous system, on the function and health of the patient. Chiropractors emphasize manual treatments including spinal manipulation and other joint and soft-tissue mobilization in the care of the patient.

Chiropractic care is covered in connection with the detection or correction by manual or mechanical means of structural imbalance, distortion, or subluxation in the human body for the purposes of removing nerve interference and the effects thereof, where such interference is the result of or related to distortion, manipulation, and any modalities.

Indications/Criteria

Medically necessary chiropractic care is covered if the benefit is listed in the patient's base contract or certificate of coverage.

Any applicable benefit plan exclusions and limitations for covered chiropractic care benefit would apply to chiropractic care. Please check benefit plan descriptions for details.

Coverage of chiropractic care is limited to medically necessary services provided by a licensed healthcare professional, acting within the scope of their license, in connection with the detection or correction of spinal misalignment or mechanical/myofascial extremity pain.

Chiropractic care is covered for a musculoskeletal or neuromusculoskeletal condition, creating a functional impairment, necessitating an appropriate, medically necessary evaluation and treatment services; and

There must be a reasonable expectation of recovery or improvement in function to support the onset and continuation of a therapeutic level care plan; and

Treatment is provided in accordance with standards of generally accepted chiropractic practice; and

The diagnostic procedures and therapeutic interventions are clearly related to the patient's symptoms/condition being treated.

Maintenance therapy includes services that seek to prevent disease, promote health, prolong and enhance the quality of life, or maintain or prevent deterioration of a chronic condition. When further clinical improvement cannot reasonably be expected from continuous ongoing care, and the chiropractic treatment becomes supportive rather than corrective in nature, the treatment is then considered maintenance therapy. Maintenance therapy is not covered.

Passive Therapeutic Modalities

Chiropractic Care Page 2 of 9

MVP Health Care Medical Policy

A passive therapeutic (or physical) modality is any physical agent applied to produce therapeutic changes in biological tissues. These modalities include heat, cold, mechanical traction, electrical stimulation, iontophoresis, and ultrasound.

Passive therapeutic (or physical) modalities may be indicated for conservative management of neuromusculoskeletal conditions and have been demonstrated to provide some therapeutic benefit in the acute phase of treatment.

The use of passive therapeutic (or physical) modalities should have clearly defined goals of pain reduction and improved function. These patient-centered objectives should be accompanied by physical performance goals and functional outcome measurement.

Passive therapeutic (or physical) modalities are considered medically necessary when all of the following criteria have been met:

- there are no documented contraindications to the therapy in the patient's medical record; and
- the patient is not able to self-administer the therapy; and
- the modality has been proven to be safe and effective for the condition which it is being administered; and
- the therapy is not considered to be maintenance.

Ordering and Providing of Plain Films

Plain film must be related to the spine and medically necessary to be covered.

Advanced Radiologic Studies

Ordering MRIs and CTs of the neck and spine must be medically necessary to be covered. Ordering of MRIs and CTs may require prior authorization through eviCore.

Ordering Laboratory Tests

Diagnostic services performed by clinical laboratories must be related to the practice of chiropractic and medically necessary to be covered.

Exclusions

- Absence of musculoskeletal or neuromusculoskeletal dysfunction.
- Worsening of signs and symptoms with care.
- Chiropractic Services for ongoing maintenance and/or preventive treatment.
- Articular derangement such as:
 - o rheumatoid arthritis;
 - o acute (unhealed) fractures and dislocations; or
 - o osodontoideum.

Chiropractic Care Page 3 of 9

MVP Health Care Medical Policy

- The treatment of non-neuromusculoskeletal conditions including, but not limited to asthma, allergies or any other conditions lacking a sufficient evidence base to warrant chiropractic care.
- The treatment of any visceral condition arising from problems or dysfunctions of the abdominal or thoracic organs.
- Chiropractic services may be covered if the customer is receiving physical therapy at the same time; however, duplicative services to the same anatomic region will not be covered.
- When outcome assessment fails to demonstrate significant improvement.
- Thermography and other tests and/or procedures not proven to be efficacious in the literature are considered to be not medically necessary.
- Mechanized spinal distraction therapy (Refer to the MVP Investigational Procedures, Devices, Medical Treatments and Tests medical policy.).
- Spinal manipulation under anesthesia.
- Providing advanced radiologic studies, e.g., CT, MRI, PET.
- Ordering, requesting or providing durable medical equipment (DME)
- Osteopathic manipulation is a non-covered benefit unless specifically identified in the customer's contract or required to be covered by regulation.
- Low Level Laser Therapy (LLLT), (CPT Code: 97037) also known as cold laser, photobiomodulation therapy, or high power laser therapy for any indication is considered experimental and investigational because there is inadequate evidence of the effectiveness of these treatments in nationally recognized peer-reviewed medical literature.

MVP Medicaid Managed Care Variation

Chiropractic care is only covered for children under the age of 21 as per the Early Periodic Screening Diagnosis and Treatment (EPSDT) program when ordered by a physician. It is not covered for adults 21 and over.

Medicaid Managed Care plans are limited to coverage of chiropractic services to treatment by means of manual manipulation (that is, by use of the hands) of the spine to correct a subluxation.

The coverage is for the following chiropractic treatments: 98940 (chiropractic manipulative treatment; spinal, one to two regions); 98941 (three to four regions), and 98942 (five regions). Chiropractic treatments to extraspinal regions (CPT 98943), which includes the head, upper and lower extremities, rib cage and abdomen are not a covered benefit for Medicaid Managed Care Plans.

Chiropractic Care Page 4 of 9

Coverage extends only to treatment by means of manual manipulation of the spine to correct a subluxation. No other diagnostic or therapeutic services furnished by a chiropractor or under a chiropractor's order is covered. This includes x-ray, other diagnostic tests, durable medical equipment, massage therapy or acupuncture.

MVP Child Health Plus Variation

Chiropractic care is not a covered benefit.

Medicare Variation

Medicare plans are limited to coverage of chiropractic services to treatment by means of manual manipulation (that is, by use of the hands) of the spine to correct a subluxation. The customer must require treatment by means of manual manipulation of the spine to correct a subluxation, and the manipulative services the Doctor of Chiropractic provides must have a direct therapeutic relationship to the patient's condition and provide reasonable expectation of recovery or improvement of function.

According to Medicare, the coverage is for the following chiropractic treatments: 98940 (chiropractic manipulative treatment; spinal, one to two regions); 98941 (three to four regions), and 98942 (five regions).

Chiropractic treatments to extraspinal regions (CPT 98943), which includes the head, upper and lower extremities, rib cage and abdomen are not covered for MVP Medicare Products.

Maintenance therapy includes services that seek to prevent disease, promote health, prolong and enhance the quality of life, or maintain or prevent deterioration of a chronic condition. When further clinical improvement cannot reasonably be expected from continuous ongoing care, and the chiropractic treatment becomes supportive rather than corrective in nature, the treatment is then considered maintenance therapy. Maintenance therapy is not covered.

Coverage extends only to treatment by means of manual manipulation of the spine to correct a subluxation. No other diagnostic or therapeutic services furnished by a chiropractor or under a chiropractor's order is covered. This includes x-ray, other diagnostic tests, durable medical equipment, massage therapy or acupuncture. ((CMS Publication 100-02, *Medicare Benefit Policy Manual*, Chapter 15, Section 240.1.1)

For full CMS/Medicare coverage and limitation detail refer to the following Medicare Local Coverage Article: National Government Services, Inc. Chiropractic Services – Medical Policy Article (A57889) Effective Date: 01/01/2020 Available: MCD Search (cms.gov)

Refer to the following link for the full MLN Matters® Special Edition article regarding medical record documentation requirements that MVP Health Care, as well as Medicare, require for initial and subsequent chiropractic visits: https://www.cms.gov/Outreach-

Chiropractic Care Page 5 of 9

References (Reviewed 2024)

- 1. Blancette MA, et al. Effectiveness and Economic Evaluation of Chiropractic Care for the Treatment of Low Back Pain: A Systematic Review of Pragmatic Studies. PLoS One 2016 Aug 3;11(8):e0160037.
- 2. Bronfort G, et al. Spinal manipulation, medication, or home exercise with advice for acute and subacute neck pain: a randomized trial. Ann Intern Med 2012 Jan 3;156(1 Pt 1):1-10.
- 3. Bronfort G, et al. Spinal manipulation and home exercise with advice for subacute and chronic back-related leg pain: a trial with adaptive allocation. Ann Intern Med 2014 Sep 16;161(6):381-91.
- 4. Bryans R, et al. Evidence-based guidelines for the chiropractic treatment of adults with headache. J Manipulative Physiol Ther 2011 Jun;34(5):274-89.
- 5. Bryans R, et al. Evidence-based guidelines for the chiropractic treatment of adults with neck pain. J Manipulative Physiol Ther 2014 Jan;37(1):42-63.
- 6. Center for Medicare Services (CMS)/Medicare National Government Services, Inc. Local Coverage Article (LCA) for Chiropractic Services (A57889). Effective Date: 01/01/2020
- 7. Center for Medicare Services (CMS) Publication 100-02, Medicare Benefit Policy Manual, Chapter 15, Section 240.1.1-1.3
- 8. Hawk C, et al. Best practices for chiropractic care for older adults: a systematic review and consensus update. J Manipulative Physiol Ther 2017 May;40(4):217-229.
- 9. Hawk C, et al. Best Practices for chiropractic management of patients with chronic musculoskeletal pain: a clinical practice guideline. J Altern Complement Med 2020 Oct;26(10):884-901.
- 10. Hays RD, et al. Group and individual-level change on health-related quality of life in chiropractic patients with chronic low back or neck pain. Spine (Phila Pa 1976) 2019 May 1;44(9):647-651.
- 11. Lisi AJ, et al. Chiropractic integrated care pathway for low back pain in veterans: results of a Delphi consensus process. J Manipulative Physiol Ther 2018 Feb;41(2):137-148.
- 12. New York State Education Department. Office of the Profession. Chiropractic. Education Law. Article 132. Available: http://www.op.nysed.gov/prof/chiro/article132.htm

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- 13. eMedNY. New York State Medicaid Program. Chiropractor Manual Policy Guidelines. Available: https://www.emedny.org/ProviderManuals/index.aspx
- 14. Centers for Medicare & Medicaid Services (CMS). Article SE1601, Medicare Coverage for Chiropractic Servcies Medical Record Documentation Requirements for Initial and Subsequent Visits; May 7, 2019 Available: https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE1601.pdf
- 15. Vermont Statute 26 V.S.A. §521(3) Chapter 9 and 10: Chiropractic Available: https://legislature.vermont.gov/statutes/title/26
- 16. Walker BF, et al. Short-term usual chiropractic care for spinal pain: a randomized controlled trial. Spine (Phila Pa 1976) 2013 Nov 15;38(24):2071-8.
- 17. *Westrom KK, et al. Individualized chiropractic and integrative care for low back pain: the design of a randomized clinical trial using a mixed-methods approach. Trials 2010 Mar 8 11:24.
- 18. Wirth B, et al. An observational study on trajectories and outcomes of chronic low back pain patients referred from a spine surgery division for chiropractic treatment. Chiropr Man Therap 2019 Feb 5;27:6.

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Customer Product	Medical Management Requirements*		
New York Products	-		
НМО	Potential for Retrospective Review		
PPO in Plan	Potential for Retrospective Review		
PPO OOP	Potential for Retrospective Review		
POS in Plan	Potential for Retrospective Review		
POS OOP	Potential for Retrospective Review		
Essential Plan	Potential for Retrospective Review		
MVP Medicaid Managed Care	Potential for Retrospective Review		
MVP Child Health Plus	Not A Covered Benefit		
MVP Harmonious Health Care Plan	Potential for Retrospective Review		
MVP Medicare Complete Wellness	Potential for Retrospective Review		
MVP Medicare Preferred Gold HMO POS	Potential for Retrospective Review		
MVP Medicare Secure HMO POS	Potential for Retrospective Review		
MVP Medicare Secure Plus HMO POS	Potential for Retrospective Review		
MVP Medicare WellSelect PPO	Potential for Retrospective Review		
MVP Medicare WellSelect Plus PPO	Potential for Retrospective Review		
MVP Medicare Patriot Plan PPO	Potential for Retrospective Review		
MVP DualAccess D-SNP HMO	Potential for Retrospective Review		
MVP DualAccess Complete D-SNP HMO	Potential for Retrospective Review		
MVP DualAccess Plus D-SNP HMO	Potential for Retrospective Review		
UVM Health Advantage Select PPO	Potential for Retrospective Review		
USA Care	Potential for Retrospective Review		
MVP Premier	Potential for Retrospective Review		
MVP Premier Plus	Potential for Retrospective Review		
MVP Premier Plus HDHP	Potential for Retrospective Review		
UVM Health Advantage Preferred PPO	Potential for Retrospective Review		
Healthy NY	Potential for Retrospective Review		
MVP Secure	Potential for Retrospective Review Potential for Retrospective Review		
MVP EPO	Potential for Retrospective Review		
MVP EPO HDHP	Potential for Retrospective Review		
Student Health Plans	Potential for Retrospective Review		
ASO	See SPD		
	See Sr D		
Vermont Products	Determinists on Determinist De 1		
PPO in Plan PPO OOP	Potential for Retrospective Review		
MVP Medicare Preferred Gold HMO POS	Potential for Retrospective Review Potential for Retrospective Review		
MVP Medicare Preferred Gold HIMO POS MVP Medicare Secure Plus HMO POS	Potential for Retrospective Review Potential for Retrospective Review		
MVP VT HMO	Potential for Retrospective Review		
MVP VT HDHP HMO	Potential for Retrospective Review		
MVP VT Plus HMO	Potential for Retrospective Review		
MVP Vermont Plus HDHP HOM	Potential for Retrospective Review		
MVP Secure	Potential for Retrospective Review		
ASO	See SPD		

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

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Revision History:

10/01/2021 – No changes to the indications or criteria for coverage. Updated policy grid to current prior authorization requirements for each line of business.

01/01/2023 – Removed prior authorization (PA) from manipulation, therapeutic procedures, and modalities for all lines of business that previously required PA. Added laboratory testing, CT and MRI of the spine and Medicaid Managed Care coverage.

08/01/2024 – Added 97037 to policy as investigational.

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MVP Health Care Clinical Guidelines

Clinical Guidelines Development, Implementation, and Review Process

Type of Policy: N/A

Prior Approval Date: 02/07/2022

Approval Date: 02/05/2023

Effective Date: 04/01/2024

Related Polices: N/A

Overview

MVP clinical guidelines are developed and maintained to address the need for standards of care across the health plan for preventive care and clinical conditions that are relevant to MVP membership.

Policy

- 1. MVP Health Plan acknowledges that clinical practice guidelines have sound scientific basis that include clinical literature and expert consensus.
- 2. MVP adopts clinical guidelines from governmental sources and nationally recognized professional societies that provide evidence-based clinical support and background information. Guidelines are not meant to replace the role of clinical judgment of individual practitioners. Instead, they are to assist practitioners in the delivery of good medical care.
- Practitioner usage of clinical practice guidelines is encouraged by MVP to reduce inter-practitioner variation in the diagnosis and treatment of specific conditions.
 Clinical practice guidelines also encourage following the established best practices for specific conditions, therefore, improving care.
- 4. Since certain behavioral disorders have a high prevalence, MVP seeks to endorse or develop clinical practice guidelines that support appropriate care of behavioral health services that address adult, children and adolescent populations.

- 5. MVP maintains clinical practice guidelines that provide the clinical basis for the MVP disease management programs.
- 6. National sources for MVP clinical guidelines include, but are not limited to, organizations such as The United States Preventive Services Task Force (USPSTF), The National Institutes of Health and its affiliates, peer reviewed medical literature, the American Diabetes Association, Centers for Medicare and Medicaid Services (CMS), the American Psychiatric Association (APA), The American College of Obstetricians and Gynecologists (ACOG), and the Centers for Disease Control and Prevention (CDC). In cases where there is no nationally recognized source, guidelines are derived from current scientific evidence with consultation by appropriate board-certified practitioners. Other sources include hospital delivery systems, plan providers, Individual Provider Associations (IPAs), Medical Management (MMC), and Quality Improvement Committee (QIC) members.
- 7. All existing clinical guidelines are reviewed at least annually by an MVP Medical Director, are reviewed by MVP internal departments and consulting physicians, and are presented to the Medical Management Committee and the Quality Improvement Committee. A comprehensive review, evaluation, and update will be done on each clinical guideline at least once every two years or more frequently when new evidence is available in the medical literature.
- 8. Proposed guidelines are compared to utilization management prior-authorization criteria, relevant benefit interpretations, protocols from the 24-hour nurse line, case/disease management programs, and customer education materials including those on the MVP web site to ensure that the documents are consistent and within the scope of MVP covered benefits.
- 9. To ensure that MVP guidelines are relevant to the local community, participating practitioners are involved in the guideline development and adoption process. Newly proposed guidelines are distributed for review and comment to participating physicians and Medical Directors. This includes guidelines developed at the local, regional collaborative or national level. The practitioners chosen to review the proposed guideline are selected from specialties that are relevant to the guideline being reviewed or developed. Practitioners are asked to comment on the guideline's relevance and suggest modifications that will enhance the guideline for the local community.
- 10. Similarly, established guidelines that were developed internally or as part of a regional collaborative that are due for re-evaluation are also distributed for review and comment to participating physicians, and Medical Directors. Physicians are asked to comment on the guideline's relevance.

- Guidelines from nationally recognized sources such as the NIH, CDC, USPSTF, or AAP that are due for a two-year re-evaluation will be presented to the Medical Management Committee (MMC) and the Quality Improvement Committee (QIC).
- 11. Once adopted by the MVP Quality Improvement Committee, the new and updated guidelines are available to all providers including primary care physicians (PCPs), hospitals and outpatient clinics, as applicable. Existing practitioners are alerted via the web site and by written notices from the plan via fax or newsletter. Copies of the guidelines are made available to all new providers either via a welcome letter distributed when the provider is accepted in-plan or via the MVP Provider Quality Improvement Manual (PQIM). All materials available via the web site are available in hard copy upon request. The guideline effective date is 30 days after the first day of the month following the QIC meeting when it was approved or reaffirmed.
- 12. Guidelines are also available to customers via the web site and preventive care guidelines are published annually in the customer newsletter.
- 13. MVP measures the impact of at least four clinical practice guidelines on patient outcomes every year. Of these four guidelines, two must pertain to a behavioral health condition. Guidelines selected for measurement must have been in place for a minimum of 12 months.
- 14. For each of the four selected guidelines, two of which relate to behavioral health, MVP measures performance against at least two important aspects that are most likely to affect care. One of the behavioral health measurements may be a behavioral health component of a medical guideline. Measurement may be population or practice based. Two of the behavioral health practice guidelines that MVP measures are depression screening and alcohol substance misuse. MVP providers are measured according to The United States Preventive Services Task Force (USPSTF) guidelines that allow billing for these screenings with no customer cost share. As a part of monitoring and reporting, the use of depression screening and alcohol substance misuse billing codes (96127, 96160, 96161, G0444, G0442) will be reviewed on a yearly basis based on the providers population or practice.

Procedure

Standard Review of New Clinical Guidelines

The following steps outline the procedure for adoption of a *new* guideline:

 Verify that the clinical condition is relevant to MVP customers. Sources to review include MVP's top twenty current inpatient and outpatient diagnosis encounter lists, retrospective claims analysis, geographic distribution of disease data from the Centers for Disease Control and Prevention and current peer reviewed medical literature.

- 2. Identify a potential source document and review to be sure that the document does not conflict with utilization management prior-authorization criteria, relevant benefit interpretations, case/disease management programs, protocols from the 24-hour nurse line and customer education materials including those on the MVP website.
- 3. Forward the document to the MVP Medical Director(s) for comment.

The draft clinical guideline is sent for internal and external review. External opinions are sought from participating physicians. Internal opinions are sought from a variety of areas including opinions from the Medical Director(s), Quality Improvement, Pharmacy, and Utilization Management departments. Additional opinions may be sought from other departments such as Operations, and Professional Relations.

The updated clinical guideline is presented to the Medical Management Committee for review and recommendation. The clinical guideline is presented to the Quality Improvement Committee for approval.

Standard Review of Existing Clinical Guidelines

The following steps outline the procedure for review, update, and approval for *existing* clinical guidelines.

- 1. Start the review process approximately three months prior to the deadline for presentation to the QIC.
- Verify that the clinical condition is still relevant to MVP customers. Sources to review include MVP's top 20 current inpatient and outpatient diagnosis encounter lists, retrospective claims analysis, geographic distribution of disease data from the Centers for Disease Control and Prevention and current peer reviewed medical literature.
- 3. Contact the original authorizing agency or source agency to verify that there have been no recent changes to the recommendation. Verify that there are no plans to announce an update within the near future, if applicable. Verify that the information is in the public domain and is not proprietary or copyrighted. If the information of interest is copyrighted, obtain and document permissions.
- 4. Request a copy if the authoring agency has made changes or is preparing to announce a revision, if applicable.
- 5. Review the guideline against current utilization management prior authorization criteria, relevant benefit interpretations, protocols from the 24-hour nurse line, case/disease management programs, and customer education materials including those on the MVP web site.
 - Clinical guidelines are presented to the Medical Management Committee (MMC) and the draft is sent for internal and external review. External opinions are sought from physicians who are in the relevant specialty. Internal opinions are sought from

a variety of areas including opinions from the Medical Director(s), Quality Improvement, Pharmacy, and Utilization Management departments. Additional opinions may be sought from other departments such as Operations, and Professional Relations.

The updated clinical guideline is presented to the Medical Management Committee for review and recommendation. The clinical guideline is presented to the Quality Improvement Committee for approval.

References:

- 1. U.S. Preventative Services Task Force (USPSTF) <u>Home page | United States Preventive Services Taskforce (uspreventiveservicestaskforce.org)</u>
- 2. National Institutes of Health <u>National Institutes of Health (NIH) | Turning Discovery Into Health</u>
- 3. American Diabetes Association About ADA Home
- 4. American Psychiatric Association https://www.psychiatry.org
- 5. Centers for Disease Control and Prevention https://www.cdc.gov/
- 6. Monroe County Medical Society https://www.mcms.org/

04/01/2022 - Annual review with no changes.

04/01/2024 - Annual review; updated and added references.



Cochlear Implants & Osseointegrated Devices

Type of Policy: Surgical

Prior Approval Date: 08/30/2024

Approval Date: 10/07/2024

Effective Date: 12/01/2024

Related Polices: N/A

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

CPT Codes: 69710, 69711, 69714, 69716, 69717, 69719, 69728, 69729, 69730, 69930

Experimental/Investigational

N/A

Common Diagnosis Codes

ICD-10- CM Diagnosis Codes: H90.0, H90.11, H90.12, H90.2, H90.3, H90.41, H90.42, H90.5

Common Procedure Codes

L7368, L8614, L8615, L8616, L8617, L8618, L8619, L8621, L8622, L8623, L8624, L8625, L8627, L8628, L8629, L8690, L8691, L8693, L8694

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

A cochlear implant is a prosthetic electronic device, part of which is implanted surgically to stimulate auditory nerve fibers and part of which is worn or carried by the individual

Cochlear Implants & Osseointegrated Devices

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to capture, analyze and code sound. Cochlear implants and auditory brainstem implants are devices that replace the function of cochlear structures or auditory nerves and provide electrical energy to auditory nerve fibers and other neural tissue via implanted electrode arrays.

Osseointegrated implants are devices implanted in the skull that replace the function of the middle ear and provide mechanical energy to the cochlea via mechanical transducer.

Degrees of hearing loss refer to the severity of the loss as measured by hearing tests. The following categories are typically used to describe the various degrees of hearing loss according to severity in decibels (dB):

Degree of Hearing Loss	Hearing Threshold
None	0-25 dB
Mild Hearing Loss	26-40 dB
Moderate Hearing Loss	41-55 dB
Severe Hearing Loss	71-90 dB
Profound Hearing Loss	91+ dB

Pure-tone average represents the hearing sensitivity in dB at 500 Hz, 1000 Hz, and 2000 Hz.

Open-set speech recognition is the ability to understand speech without visual clues.

Indications/Criteria

<u>Unilateral Osseointegrated Devices (Bone Anchored Hearing Aid (BAHA) (L8690, L8691, L8693, L8694):</u>

A bone anchored hearing aid is considered to be medically necessary when all of the following criteria have been met:

- five years of age or older for all surgically implanted devices (L8690, L8691);
- when air conduction hearing aids are contraindicated due to a medical condition such as congenital malformations, tumors or chronic infections;
- patients with conductive or mixed hearing losses, who can benefit from amplification of sound. The pure tone average bone conduction threshold for the indicated ear should be measured at 0.5, 1,2, and 3 KHz (same as 500, 1,000, 2,000 and 3,000 Hz) of better than or equal to:
 - 45 dB HL (BAHA Divino, OBC, BAHA BP100)
 - 55 dB HL (BAHA Intenso, Cochlear Baha 3 Power [BP110]) or
 - 65 dB HL (BAHA Cordelle II)

<u>Bilateral Osseointegrated Devices (Bone Anchored Hearing Aid (BAHA) (L8690, L8691, L8693, L8694)</u>:

- Requests for bilateral bone anchored hearing aids must meet all of the criteria listed above.
- Bilateral fitting is covered only for patients having a symmetrically conductive or mixed hearing loss.
- Symmetric bone conduction threshold is defined as less than:
 - The difference between the left and right sides bone conduction thresholds should be less than 10dB on average measured at 500, 1000, 2000, and 4000Hz, or less than 15dB at individual frequencies (BAHA Divino, BAHA BP100, Ponto Pro); or
 - The difference between the left and right sides bone conduction thresholds should be less than 10dB on average measured at 500, 1000, 2000, and 3000Hz, or less than 15dB at individual frequencies (BAHA Cordelle II, BAHA Intenso).

Cochlear Implants (L8614, L8619, L8627, L8628):

The following must be documented in the customers record and made available upon request: [3]

- diagnosis of moderate-to-profound sensorineural hearing impairment;
- freedom from middle ear infection, an accessible cochlear lumen that is structurally suited to implantation and freedom from lesions in the auditory nerve and acoustic areas of the central nervous system;
- no contraindications to surgery; and
- the device must be used in accordance with Food and Drug Administration (FDA) approved labeling. [4]

Unilateral or bilateral cochlear implants are covered for individuals with bilateral prelinguistic, peri or post-linguistic sensorineural moderate to profound hearing loss when the following criteria are met:

Note: The presentation level for speech recognition testing must be at a normal conversational speech level.

Adults (age 18+)

- pure tone average of 70dB hearing loss or greater at 500 Hz, 1000 Hz, and 2000 Hz;
- limited benefit from appropriately fitted binaural hearing aids defined by test scores of 40% correct or less in best aided listening condition on open set sentences recognition in quiet (e.g., Central Institute for the Deaf sentences).

Children (12 months to 5 years of age)

- pure tone average of 90 dB hearing loss or greater at 500 Hz, 1000 Hz, and 2000 Hz;
- limited benefit from appropriately fitted binaural hearing aids, defined by failure to reach auditory related developmental milestones, despite participation in intensive aural habilitation over a three-month period (as age appropriate).

Children (5 years 1 month to 17 years 11 months)

pure tone average of 90 dB hearing loss or greater at 500 Hz, 1000 Hz, and 2000 Hz;

 limited benefit from appropriately fitted binaural hearing aids, defined by less than 30% correct on open set sentence discrimination on the Multi-Syllabic Lexical Neighborhood Test or Lexical Neighborhood Test (depending on the child's ability/skill), despite participation in intensive aural habilitation over a three- month period.

Replacement of an existing cochlear implant and/or component is covered when all the following are met:

- the currently used component is no longer functional, cannot be repaired and is not covered under a manufacturer's warranty; and
- the replacement must not be solely for better technology or improved aesthetics;

Exclusions

- Not meeting criteria listed under Indications/Criteria of this policy.
- Bone anchored hearing aids that are held against the skull with a softband or headband (L8692) are considered hearing aids rather than prosthetic devices. They are covered up to what is allowed in the customers hearing aid benefit or what is available through the customers network of participating providers for hearing aids.
- customers with abnormalities of the acoustic nerve or central auditory pathway;
- customers who have an active or chronic middle ear infection:
- devices not utilizing multichannel compression signal processing technology;
- upgrading of a traditional cochlear implant system or component (e.g., upgrading processor from body-worn to behind-the-ear, upgrading from single to multichannel electrodes) of an existing, properly functioning traditional cochlear implant is considered not medically necessary.
- a cochlear implant is considered investigational for all indications not listed in this policy.

Medicaid Managed Care Variation

Bone Anchored Hearing Aid held against the skull with a softband or headband (L8692) are covered under the hearing aid benefit when the following criteria are met:

- can be used in any age group; and
- when air conduction hearing aids are contraindicated due to a medical condition such as congenital malformations, tumors or chronic infections; and
- patients with conductive or mixed hearing losses, who can benefit from amplification of sound. The pure tone average bone conduction threshold for the indicated ear should be measured at 0.5, 1,2, and 3 KHz (same as 500, 1,000, 2,000 and 3,000 Hz) of better than or equal to 45 dB (BAHA Divino, BAHA BP100), 55 dB (BAHA Intenso, Cochlear Baha 3 Power [BP110]) or 65 dB (BAHA Cordelle II).
- either a body-worn sound processor (L8692) or a behind-the-ear sound processor (L8691) is covered but not both.

Medicare Managed Care Variation

- 1. Cochlear implantation may be covered for treatment of bilateral pre- or-post-linguistic, sensorineural, moderate-to-profound hearing loss in individuals who demonstrate limited benefit from amplification. Limited benefit from amplification is defined by test scores of less than or equal to 60% correct in the best-aided listening condition on recorded tests of open-set sentence recognition. Medicare coverage is provided only for those patients who meet all of the following criteria:
 - Diagnosis of bilateral moderate-to-profound sensorineural hearing impairment with limited benefit from appropriate hearing (or vibrotactile) aids;
 - Cognitive ability to use auditory clues and a willingness to undergo an extended program of rehabilitation;
 - Freedom from middle ear infection, an accessible cochlear lumen that is structurally suited to implantation, and freedom from lesions in the auditory nerve and acoustic areas of the central nervous system;
 - No contraindications to surgery; and
 - The device must be used in accordance with Food and Drug Administration (FDA)-approved labeling.
- 2. Cochlear implantation may be covered for individuals not meeting the coverage criteria above when the provider is participating in, and patients are enrolled in, either an FDA-approved category B investigational device exemption clinical trial as defined at 42 CFR 405.201, or as a routine cost in clinical trials under the Centers for Medicare & Medicaid (CMS) Clinical Trial Policy as defined at section 310.1 of the National Coverage Determinations Manual titled Routine Costs in Clinical Trials.

There is a Medicare National Coverage Decision (NCD) for Cochlear Implantation (50.3) Effective Date 03/24/2023. Available: MCD Search (cms.gov)

References (Reviewed 2024)

- 1. American Speech-Language Hearing Association. Degrees of hearing loss. Available: https://www.asha.org/public/hearing/degree-of-hearing-loss/
- 2. American Academy of Audiology (AAA). Clinical practice guideline: cochlear implants. July 2019. Accessed Sep 2, 2021. Available at URL address: https://www.audiology.org/wp-content/uploads/2021/05/CochlearImplantPracticeGuidelines.pdf
- 3. American Academy of Otolaryngology—Head and Neck Surgery (AAO-HNS). Position statement: pediatric cochlear implants. Apr 15, 2020. Accessed Sep 2, 2021. Available at URL address: https://www.entnet.org/resource/position-statement-pediatric-cochlear-implantation-candidacy/
- 4. Boyd PJ (2015) Potential benefits from cochlear implantation of children with unilateral hearing loss. Cochlear Implants Int 16(3):121-36.
- 5. Centers for Medicare and Medicaid Services. CMS Manual System Pub 100-02 Medicare Benefit Policy November 10, 2005. Auditory osseointegrated and auditory brainstem devices. Available: www.cms.gov
- 6. Centers for Medicare & Medicaid (2005). NCD for Cochlear Implantation (50.3). Effective Date 07/25/2005. Available: MCD Search (cms.gov)
- 7. Papsin, B.C., and Gordon, K.A. Cochlear implants for children with severe-to-profound hearing loss. *New England Journal of Medicine* 2007;357:2380-7. Available: www.nejm.org
- 8. American Speech-Language Hearing Association. (2004) Cochlear Implants [Technical Report]. Available: http://www.infanthearing.org/coordinator_orientation/section2/10 asha guidelines.p
- 9. HAYES Medical Technology Directory™. Bilateral Cochlear implantation in Children. HAYES, Inc.; Jul 15, 2013. Annual Review: June 20, 2017 ARCHIVED August 15, 2018 Available to subscribers: www.hayesinc.com
- 10. U. S. Food and Drug Administration. FDA-Approved Cochlear Implants. Available: www.fda.gov
- 11. American Academy of Audiology. Position Statement: Cochlear implants in children. Available: www.audiology.org
- 12. American Speech-Language Hearing Association. (2004) Guidelines for the Audiologic Assessment of Children From Birth to 5 Years of Age [Guidelines]. Available: www.asha.org/policy

- 13. U.S. Food and Drug Administration. Device Approvals and Clearances [Database]. Available: www.fda.gov
- 14. Centers for Medicare and Medicaid Services. MLN Matters Articles. Available: www.cms.hhs.gov/MLNMattersArticles/
- 15. Dillon MT, Buss E, Rooth MA, King ER, Deres EJ, Buchman CA, Pillsbury HC, Brown KD. Effect of Cochlear Implantation on Quality of Life in Adults with Unilateral Hearing Loss. Audiol Neurootol. 2017;22(4-5):259-271.
- 16. Gifford, R.H., et al. Evidence in the expansion of adult cochlear implant candidacy. Ear. Hearing. 2010 Apr; 31(2): 186-194. Available: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4092164/
- 17. New York State Medicaid Program Hearing Aid/Audiology Services Procedure Codes Hearing Aid Manual Version 2013-1 (04/01/2013) Available: eMedNY: Provider Manuals
- 18. Nicholson N, Christensen L, Dornhoffer J, et al. Verification of speech spectrum audibility for pediatric Baha softband users with craniofacial anomalies. Cleft Palate Craniofac J. 2011 Jan;48(1):56-65.
- 19. Ramakrishnan Y, Marley S, Leese D, et al. Bone-anchored hearing aids in children and young adults: the Freeman Hospital experience. J Laryngol Otol. 2011 Feb;125(2):153-7.
- 20. Wackym PA, Tran A. Ch 158. Cochlear implantation: patient evaluation and device selection. In: Cummings Otolaryngology, sixth edition. Elsevier, 2015. 2428-2443.e2.
- 21. U.S. Food and Drug Administration (FDA). Cochlear implants. Oct 2015. Current as of Feb 9, 2021. Accessed Sep 2, 2021. Available at URL address: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandPro sthetics/CochlearImpl ants/default.htm?utm_source=fdaSearch&utm_medium=website&utm_term=Cochle ar implants&utm_content=3
- 22. Wang Y, Fan X, Wang P, et al. Hearing improvement with softband and implanted bone-anchored hearing devices and modified implantation surgery in patients with bilateral microtia-atresia. Int J Pediatr Otorhinolaryngol. 2018 Jan;104:120-125.

Customer Product	Medical Management Requirements*
New York Products	
HMO	Prior Auth
PPO in Plan	Prior Auth
PPO OOP	Prior Auth
POS in Plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Prior Auth
MVP Child Health Plus	Prior Auth
MVP Harmonious Health Care Plan	Prior Auth
MVP Medicare Complete Wellness	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure HMO POS	Prior Auth
MVP Medicare Secure HMO POS	Prior Auth
MVP Medicare WellSelect PPO	Prior Auth
MVP Medicare WellSelect Plus PPO	Prior Auth
MVP Medicare Patriot Plan PPO	Prior Auth
MVP DualAccess D-SNP HMO	Prior Auth
MVP DualAccess Complete D-SNP HMO	Prior Auth
MVP DualAccess Plus D-SNP HMO	Prior Auth
UVM Health Advantage Select PPO	Prior Auth
USA Care PPO	Potential for Retrospective Review
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	
POS in Plan	Prior Auth
POS OOP	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Aith
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP VT HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD

[♦] Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro ReviewRetrospective Review RequiredNot CoveredService is not a covered benefit.See SPDSee Specific Plan Design

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Revision History:

04/01/2022 – Annual review with no changes to the indications or criteria for Commercial, ASO and Medicaid plans. Added Medicare variation criteria with indications for participation in clinical trial. References and websites sections updated.

04/01/2023 - Removed prior authorization from L7368.

09/22/2023 - Updated Medicare variation according to Medicare NCD 50.3

12/01/2023 – Formal review of 9/22 changes completed.

10/01/2024 - Removed L8619, L8627, L8628, L8690, L8691, L8693, L8694 from prior authorization.

12/01/2024 - Completed formal review of 10/01/2024 fast-track update.



Cold Therapy Devices

Type of Policy: DME

Prior Approval Date: 08/01/2021

Approval Date: 05/01/2023

Effective Date: 08/01/2023

Related Polices: Durable Medical Equipment

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

HCPCS Codes	Code Description
E0218	Fluid circulating cold pad with pump, any type
E0236	Pump for water circulating pad

Codes Requiring Retrospective Review

N/A

Experimental/Investigational

CPT Codes	Code Description
0662T	Scalp cooling, mechanical; initial measurement and calibration of cap
0663T	Scalp cooling, mechanical; placement of device, monitoring, and removal of device

Common Diagnosis Codes

ICD-10- CM Diagnosis Codes

R22.0, R22.1, R22.3, R22.30, R22.31, R22.32, R2233, R22.40, R22.41, R22.42, R22.43, R22.9

Cold Therapy Devices Page 1 of 6

Common Diagnosis Codes associated with this policy have been provided for informational purposes only. The list of codes may not be all-inclusive and may be updated to reflect any applicable revisions to the ICD-10 code set and/or medical necessity quidelines applied in this policy.

Common Procedure Codes

N/A

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

A cold therapy device (i.e., cryocuff) is a specialized device that provides both cryotherapy and compression. Cooling devices may be referred to as cold therapy units, cryounits, or cryotherapy machines and may be passive or active and operate by gravity or the use of a mechanical or pneumatic pump. The intended purpose of these devices is to provide a combination of cooling and compression to treat musculoskeletal conditions.

The basic passive device consists of a cuff (designed for the corresponding body part i.e., ankle, knee, etc.) that is inflated via a connection to an elevated cooler containing iced water. Elevation of the cooler raises the pressure in the cuff by gravity to provide compression. [1]

A device in which ice water is put in a reservoir and then circulated through a pad by means of gravity is not considered durable medical equipment (DME). Other devices (not all-inclusive) which are also not considered to be DME are: single use packs which generate cold temperature by a chemical reaction; packs which contain gel or other material which can be repeatedly frozen; simple containers into which ice water can be placed. All of these types of devices must be coded A9270 if claims are submitted. [7, 8]

Scalp cooling devices and caps (i.e., cryocap) are intended to reduce the likelihood of chemotherapy induced alopecia by inducing vasoconstriction, thereby reducing the local uptake of chemotherapeutic agent, the metabolic rate of the hair follicle, or both. The devices are available either as nonautomated, ice-filled cooling caps that require changing during treatment because of thawing, or automated systems connected to cooling caps that continuously circulate cooling solution to maintain the proper scalp temperature.

Indications/Criteria

The use of active or passive cooling devices has not been proven to provide significant differences in pain; swelling or a decrease in use of analgesics compared to standard ice packs and is considered to be not medically necessary.

Cold Therapy Devices Page 2 of 6

Scalp Cooling Devices for the prevention of chemotherapy induced alopecia (i.e., DigniCap Scalp Cooling System, Paxman Scalp Cooler) are considered investigational as peer-reviewed medical literature has not proven the technology to improve health outcomes.

Medicare Variation

For a complete description of the indications and limitations of coverage for scalp cooling devices for Medicare members, please refer to the National Coverage Determination (NCD) for Scalp Hypothermia During Chemotherapy to Prevent Hair Loss (110.6) located at: MCD Search (cms.gov)

For a complete description of the indications and limitations of coverage for Cold Therapy for Medicare members, please refer to the Local Coverage Article: Cold Therapy (A52460) located at: MCD Search (cms.gov)

References (Reviewed 2023)

- 1. Alfuth M(1), Strietzel M, Vogler T, Rosenbaum D, Liem D. Cold versus cold compression therapy after shoulder arthroscopy: a prospective randomized clinical trial. Knee Surg Sports Traumatol Arthrosc. 2016 Jul;24(7):2209-15. Available: https://www.ncbi.nlm.nih.gov/pubmed/25677503
- 2. Bech M, Moorhen J, Cho M, Lavergne MR, Stothers K, Hoens AM. Device or ice: the effect of consistent cooling using a device compared with intermittent cooling using an ice bag after total knee arthroplasty. *Physiother Can.* 2015;67(1):48-55.
- 3. Cochrane Review, Thermotherapy for treatment of osteoarthritis L. Brosseau, M.G. Judd, S. Marchand, V.A. Robinson, P. Tugwell, G. Wells, K. Yonge, 2003. Available: http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD004522/abstract;jsessionid= 271275626D9859815E6B6D8F1DA430A6.f04t01
- 4. Hayes Comparative Effectiveness Review Cold Compression Therapy for Patients Undergoing Orthopedic Procedures to Major Joints (Other than Knee) Hayes © 2021 Hayes, a symplr company. November 22, 2019. (Annual Review March 25, 2021)
- 5. Hayes Comparative Effectiveness Review Of Cold Compression Therapy For Patients Undergoing Total Knee Arthroplasty (TKA). Hayes © 2021 Hayes, a symplr company. March 28, 2019 (Annual review July 13,2020)
- 6. Hayes Medical Technology Directory: Scalp Cooling Devices for the Prevention of Chemotherapy-Induced Alopecia: A Review of Reviews. Hayes, Inc.; © 2021 Hayes, a symplr company. October 23, 2018. (Annual Review February 9,2021)
- 7. Noridian Healthcare Solutions, LLC. Local Coverage Determination (LCD) for Cold Therapy (L33735). Revision Effective Date 01/01/2020. Available: https://med.noridianmedicare.com/web/jddme/policies/lcd/active

Cold Therapy Devices Page 3 of 6

- 8. Noridian Healthcare Solutions, LLC. Local Coverage Article: Cold Therapy (A52460). Revision Effective Date 01/01/2020. Available: https://med.noridianmedicare.com/web/jddme/policies/lcd/active
- 9. Centers for Medicare and Medicaid Services National Coverage Determination (NCD) for Scalp Hypothermia During Chemotherapy to Prevent Hair Loss (110.6). Available: http://www.cms.gov/

Cold Therapy Devices Page 4 of 6

Customer Product	Medical Management Requirements*
New York Products	
НМО	Prior Auth
PPO In Plan	Prior Auth
PPO OOP	Prior Auth
POS In Plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Prior Auth
MVP Child Health Plus	Prior Auth
MVP Harmonious Health Care Plan	Prior Auth
MVP Medicare Complete Wellness	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP Medicare WellSelect PPO	Prior Auth
MVP Medicare WellSelect Plus PPO	Prior Auth
MVP Medicare Patriot Plan PPO	Prior Auth
MVP DualAccess D-SNP HMO	Prior Auth
MVP DualAccess Complete D-SNP HMO	Prior Auth
MVP DualAccess Plus D-SNP HMO	Prior Auth
UVM Health Advantage Select PPO	Prior Auth
USA Care PPO	Potential for Retrospective Review
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	
POS In Plan	Prior Auth
POS OOP	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP Medicare WellSelect PPO	Prior Auth
MVP VT HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD
	, 300 31 0

[♦] Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

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Revision History:

12/01/2021 – Annual Review; no changes to the indications or criteria.

08/1/2023- no changes to criteria, formatted to include Medicare NCD/LCD.

Cold Therapy Devices Page 6 of 6



Colorectal Cancer Susceptibility Genetic Testing

Type of Policy: Medical

Prior Approval Date: 01/09/2023

Approval Date: 06/03/2024

Effective Date: 08/01/2024

Related Polices: MVP Genetic Counseling

and Testing Medical Policy

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

CPT Codes:	Description:
81201	APC (adenomatous polyposis coli) (eg, familial adenomatosis polyposis
	[FAP], attenuated FAP) gene analysis; full gene sequence
81202	APC (adenomatous polyposis coli) (eg, familial adenomatosis polyposis
	[FAP], attenuated FAP) gene analysis; known familial variants
01202	APC (adenomatous polyposis coli) (eg, familial adenomatosis polyposis
81203	[FAP], attenuated FAP) gene analysis; duplication/deletion variants
91210	BRAF (B-Raf proto-oncogene, serine/threonine kinase) (eg, colon cancer,
81210	melanoma), gene analysis, V600 variant(s)
	MLH1 (mutL homolog 1, colon cancer, nonpolyposis type 2) (eg,
81288	hereditary non-polyposis colorectal cancer, Lynch syndrome) gene
	analysis; promoter methylation analysis
	MLH1 (mutL homolog 1, colon cancer, nonpolyposis type 2) (eg,
81292	hereditary non-polyposis colorectal cancer, Lynch syndrome) gene
	analysis; full sequence analysis
81293	MLH1 (mutL homolog 1, colon cancer, nonpolyposis type 2) (eg,
	hereditary non-polyposis colorectal cancer, Lynch syndrome) gene
	analysis; known familial variants

81294	MLH1 (mutL homolog 1, colon cancer, nonpolyposis type 2) (eg,
	hereditary non-polyposis colorectal cancer, Lynch syndrome) gene
	analysis; duplication/deletion variants
	MSH2 (mutS homolog 2, colon cancer, nonpolyposis type 1) (eg,
81295	hereditary non-polyposis colorectal cancer, Lynch syndrome) gene
	analysis; full sequence analysis
	MSH2 (mutS homolog 2, colon cancer, nonpolyposis type 1) (eg,
81296	hereditary non-polyposis colorectal cancer, Lynch syndrome) gene
	analysis; known familial variants
	MSH2 (mutS homolog 2, colon cancer, nonpolyposis type 1) (eg,
81297	hereditary non-polyposis colorectal cancer, Lynch syndrome) gene
	analysis; duplication/deletion variants
81298	MSH6 (mutS homolog 6 [E. coli]) (eg, hereditary non-polyposis
01230	colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis
	MSH6 (mutS homolog 6 [E. coli]) (eg, hereditary non-polyposis
81299	colorectal cancer, Lynch syndrome) gene analysis; known familial
	variants
	MSH6 (mutS homolog 6 [E. coli]) (eg, hereditary non-polyposis
81300	colorectal cancer, Lynch syndrome) gene analysis; duplication/deletion
	variants
	Microsatellite instability analysis (eg, hereditary non-polyposis colorectal
81301	cancer, Lynch syndrome) of markers for mismatch repair deficiency (eg,
01301	BAT25, BAT26), includes comparison of neoplastic and normal tissue, if
l	performed
	PMS2 (postmeiotic segregation increased 2 [S. cerevisiae]) (eg,
81317	hereditary non-polyposis colorectal cancer, Lynch syndrome) gene
	analysis; full sequence analysis
81318	PMS2 (postmeiotic segregation increased 2 [S. cerevisiae]) (eg,
	hereditary non-polyposis colorectal cancer, Lynch syndrome) gene
	analysis; known familial variants
	PMS2 (postmeiotic segregation increased 2 [S. cerevisiae]) (eg,
81319	hereditary non-polyposis colorectal cancer, Lynch syndrome) gene
	analysis; duplication/deletion variants

Codes Requiring Retrospective Review

CPT Codes:	Description:
	Hereditary colon cancer disorders (eg, Lynch syndrome, PTEN
81435	hamartoma syndrome, Cowden syndrome, familial adenomatosis
	polyposis); genomic sequence analysis panel

	Hereditary colon cancer disorders (eg, Lynch syndrome, PTEN
81436	hamartoma syndrome, Cowden syndrome, familial adenomatosis
	polyposis); duplication/deletion analysis panel

Experimental/Investigational

N/A

Common Diagnosis Codes

ICD-10 CM Diagnosis Codes: NA

Common Diagnosis Codes associated with this policy have been provided for informational purposes only. The list of codes may not be all-inclusive and may be updated to reflect any applicable revisions to the ICD-10 code set and/or medical necessity quidelines applied in this policy.

Common Procedure Codes

CPT Codes: 81401, 81403, 81406

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

General

Genetic testing is "the analysis of human DNA, RNA, chromosomes, proteins, and certain metabolites in order to detect heritable disease-related genotypes, mutations, phenotypes, or karyotypes for clinical purposes." This definition reflects the broad range of techniques that can be used in the testing process. Genetic tests also have diverse purposes, including the diagnosis of genetic disease in newborns, children, and adults; the identification of future health risks; the prediction of drug responses; and the assessment of risks to future children.

Genetic testing should only be done after the customer has a thorough history reviewed and testing is felt to be necessary by both customer and physician because of potential changes in management.

It is important that the purpose of the test is clear and that both the physician and customer understand how testing is intended to change management.

Colorectal Cancer Conditions

Familial Adenomatous Polyposis: Familial adenomatous polyposis (FAP) is an uncommon inherited condition. Less than 1% of all colorectal cancer is thought to be due to FAP.

Nearly 100 percent of people with this condition will develop colorectal cancer during their lifetime, and most of these cancers occur before the age of 50 years. FAP causes hundreds of polyps to develop throughout the colon beginning in adolescence. A subset of individuals with attenuated familial adenomatous polyposis (AFAP) which is associated with fewer than 100 cumulative colorectal adenomas. The average age of colorectal cancer onset for attenuated familial adenomatous polyposis is 55 years.

There are other rarer inherited conditions that increase risk of colorectal cancer, including MUTYH-associated polyposis. MUTYH-associated polyposis (MAP): MUTYH-associated polyposis (MAP) is a hereditary condition. Individuals with MAP tend to develop multiple adenomatous colon polyps during their lifetime and will have an increased risk of colorectal cancer. An adenomatous polyp is an area where the normal cells that line the inside of the colon begin to form a mass. At first, a polyp is benign and will not spread. However, some polyps can eventually turn malignant, and cancers can spread to other parts of the body. It is likely that individuals with MAP will develop multiple polyps, and therefore their risk for colorectal cancer may be increased if these polyps cannot be removed.

In some individuals, MAP is associated with developing 100s of polyps, and appears to be similar to other hereditary conditions of familial adenomatous polyposis (FAP) and attenuated familial adenomatous polyposis (AFAP). In other cases, MAP can be diagnosed with fewer polyps (less than 20) and/or colorectal cancer at a young age.

Hereditary Nonpolyposis Colon Cancer: Hereditary nonpolyposis colon cancer (HNPCC, also called Lynch syndrome) is another inherited condition associated with an increased risk of colorectal cancer. Lynch syndrome is caused by genetic defects in one or more DNA mismatch repair (MMR) genes, including MLH1, MSH2, MSH6, PMS2, and EPCAM. Microsatellite instability (MSI) and/or immunohistochemistry (IHC) testing is performed to analyze colon tumor tissue samples for features suggestive of Lynch syndrome. MSI testing will identify tumors that have microsatellite instability which detect an abnormal number of microsatellite repeats. IHC testing will detect the presence or absence of the protein products of the mismatch repair genes (MLH1, MSH2, PMS2 and MSH6).

Lynch syndrome is more common than FAP, but is still uncommon, accounting for 1 in 30 cases of colorectal cancer. About 70 percent of people with HNPCC will experience colorectal cancer by the age of 65. Cancer also tends to occur at younger ages. People with HNPCC are also at risk for other types of cancer, including cancer of the uterus, stomach, bladder, kidney, and ovary.

Medical Record Documentation

Medical necessity must be documented in the medical record and available upon request. Documentation must include third generation pedigree analysis for any genetic test and intends to provide pre** and post-test counseling. Documentation of a pre-

disposing condition for genetic counseling and testing should be submitted upon request.

**NYS Article 26 (ISC § 2615) and Article 79-1 (CVR §) 79-1 requires informed consent.

Close blood relatives include first, second, and third-degree relatives.

1st degree relatives include; parents, siblings and children.

2nd degree relatives include; grandparents, grandchildren, aunts, uncles, half-siblings, nieces and nephews.

3rd degree relatives include great grandmother, great grandfather, great granddaughter, great grandson, great aunt, great uncle, grand-niece, grand-nephew, first female cousin or first male cousin.

Indications/Criteria

In all circumstances, MVP only covers testing if:

- there is a clear plan how the testing results could change the customer management and that the customer agrees with the plan;
- history, physical exam, and conventional testing are insufficient to develop a treatment plan;
- testing is only covered for covered care and services. Services in conjunction with non-covered services are not covered;
- the testing has been proven to be accurate outside the investigational setting;
- signs, symptoms, family history, and /or clinical guidelines (e.g. National Comprehensive Cancer Network®) recognized by MVP support testing;
- genetic testing is ordered by an adequately trained physician or health care professional with certification and/or expertise in genetics.

<u>Familial Adenomatous Polyposis (FAP) and Attenuated Adenomatosis Polyposis (APAP)</u>

[APC gene testing for full sequence (81201) single-mutation analysis (81202,) and duplication/deletion analysis of APC gene (81203)].

Genetic testing for the Adenosis Polyposis Coli gene (APC) is covered in a customer when all of the following are met:

- an adequately trained physician or health care professional with certification and/or expertise in genetics has taken a third-generation pedigree targeted to the cancers of this syndrome* which supports the need for testing, and intends to provide pre** and post-test counseling; and
- one of the following criteria are met:
 - o personal history of > 10 adenomas or >20 colonic polyps;

- personal history of a desmoid tumor; hepatoblastoma or cribiform morular variant of papillary thyroid cancer;
- o first or second-degree relatives with FAP or attenuated FAP (AFAP); or
- o known deleterious APC mutation in a first or second degree relative.

*FAP associated cancers include colorectal cancers, medulloblastoma, papillary carcinoma of the thyroid, hepatoblastoma, pancreatic and gastric cancers.

**NYS Article 26 (ISC § 2615) and Article 79-1 (CVR §) 79-1 requires informed consent.

MUTYH-Associated Polyposis (MAP)

[sequence analysis (81401) or targeted mutation analysis (81406)]

MUTYH-Associated Polyposis testing is considered medically necessary for individuals with any of the following:

- a personal history of ≥ 10 adenomatous polyps; or
- Known deleterious MUTYH mutation(s) in first degree relative; or
- Individual with at least one (1) adenoma and one of the following:
 - has at least five (5) serrated polyps proximal to the sigmoid colon with two or more of these being >10 mm; or
 - o has \geq 20 serrated polyps of any size.

<u>Lynch syndrome (LS) or (hereditary nonpolyposis colorectal cancer, (HNPCC)</u> [mutations of MLH1 (81292, 81294), MSH2 (81295, 81297), MSH6 (81298, 81300), PMS2 (81317, 81319), EPCAM (81403)].

Lynch syndrome includes individuals with an existing cancer (affected) and individuals who have not yet developed cancer (unaffected).

Testing (of the MLH1, MSH2, MSH6, PMS2 genes) of unaffected family customers in the absence of having tested affected family customers significantly limits the interpretation of test results. Test interpretation is also limited for affected individuals in the absence of Microsatellite instability (MSI) testing or immunohistochemical (IHC) analysis of the tumor (colorectal and/or endometrial). As such, genetic review of family history and MSI/IHC results are considered medically necessary as an initial evaluation in persons with colorectal cancer or with family histories in order to identify those individuals who should proceed with HNPCC mutation analysis and to guide towards targeted gene or mutation testing.

Results of genetic testing and MSI/IHC that have been done on family customers in the third-generation pedigree must be submitted with the coverage request.

- Genetic testing for the Lynch Syndrome genes (MLH1, MSH2, MSH6, and PMS2, EPCAM)* is covered in a customer with Lynch associated ** cancer (affective) when all the following criteria are met:
 - o an adequately trained physician has taken a three-generation pedigree targeted to the cancers of this syndrome, intends to provide pre*** and post-test counseling, and attempted to order tumor studies (colorectal or endometrial);

AND one of the following:

- o diagnosis of colorectal cancer or endometrial cancer under the age of 50; or
- diagnosis of synchronous or metachronous LS-related cancer;** or
- 1 first-degree or second-degree relative with an LS-related cancer diagnosed under the age of 50; or
- 2 or more first-degree or second-degree relatives with and LS-related cancer regardless of age

*Genetic testing should be considered with the following priority: Testing of the MSH6 gene is performed only following a negative test result in the MLH1 or MSH2 gene. Testing of the PMS2 gene is performed only following a negative result in the MLH1, MSH2, and MSH6.

**Lynch-syndrome (LS) - related tumors include colorectal, endometrial, stomach, ovarian, pancreas, bladder, ureter and renal pelvis, biliary tract, brain (usually glioblastoma as seen in Turcot Syndrome), sebaceous gland adenomas and keratoacanthomas in Muir-Torre syndrome, and carcinoma of the small bowel.

***NYS Article 26 (ISC § 2615) and Article 79-1 (CVR §) 79-1 requires informed consent.

**** MSI testing can detect an abnormal number of microsatellite repeats, which indicates that the cancer more likely arose from cells with defective mismatch repair genes. A result of "MSI-high" means that a high number of microsatellite repeats were found. IHC testing can detect the presence or absence of the protein products of the mismatch repair genes. A missing protein suggests a mutation in the gene that codes for that protein.

Genetic testing for Lynch Syndrome. for expression of MLH1, MSH2, MLH6 and PMS2

- o Microsatellite instability (MSI) testing or immunohistochemical (IHC) analysis of tumor tissue (colorectal and/or endometrial) as an initial evaluation in an individual with colorectal and/or endometrial cancer or colorectal adenomas (when malignant tissue is not available) for any of the following indications:
- o individual with colorectal or endometrial cancer, or colorectal adenomas whose family meets the Amsterdam II criteria (see below) or the revised Bethesda guidelines (see below); or
- o individual with colon or endometrial cancer diagnosed before age 50.

Tumor testing for the BRAF V600E (81210) and MLH1 promoter hypermethylation (81288) should be done to rule out sporadic cause when IHC tumor screening identifies a loss of MLH1 expression.

<u>Unaffected Individuals (those without cancer) with a Family History of Lynch Syndrome-</u> Related cancer

Genetic testing for the Lynch Syndrome genes MLH1 (81292, 81294), MSH2 (81295, 81297), MSH6 (81298, 81300), PMS2 (81317, 81319), EPCAM (81403) are covered in a customer when:

 an adequately trained physician has taken a three-generation pedigree targeted to the cancers of this syndrome* which supports the need for testing, intends to provide pre** and post-test counseling;

AND one of the following:

- one or more first-degree relative with a colorectal or endometrial cancer diagnosed under 50; or
- one or more first degree relative with a colorectal or endometrial cancer and a synchronous or metachronous LS-related cancer** regardless of age; or
- o two or more first-degree or second-degree relatives with LS-related including one or more diagnosed before 50; or
- three or more first-degree or second-degree relatives with LS-related cancers regardless of age.

The Revised Bethesda Guidelines:

- Colorectal cancer diagnosed in a patient who is less than 50 years of age
- Presence of synchronous (two cancers diagnosed within six months of each other), metachronous (two cancers diagnosed more than six months apart) colorectal or other HNPCC-associated tumors,** regardless of age
- Colorectal cancer with the MSI-high histology‡ diagnosed in a patient who is less than 60 years of age
- Colorectal cancer diagnosed in a customer with one or more first-degree relatives with an HNPCC-related tumor,** with one of the cancers being diagnosed under age 50 years
- Colorectal cancer diagnosed in a customer with two or more first- or second-degree relatives with HNPCC-related tumors, regardless of age
- ** Lynch-syndrome (LS) related tumors include: colorectal, endometrial, stomach, ovarian, pancreas, bladder, ureter and renal pelvis, biliary tract, brain (usually glioblastoma as seen in Turcot Syndrome), sebaceous gland adenomas and keratoacanthomas in Muir-Torre syndrome, and carcinoma of the small bowel.

Amsterdam II Criteria

There should be at least three relatives with a Lynch/HNPCC-associated cancer** (see above); and

- one should be a first-degree relative to the other two;
- at least two successive generations should be affected;
- at least one should be diagnosed before age 50;
- familial adenomatous polyposis should be excluded;
- tumors should be verified by pathological examination.

Exclusions

- Not meeting criteria under Indications/Criteria of this policy.
- Full sequence analysis is not indicated when there is a known mutation in the family, therefore targeted analysis is most appropriate.
- Genetic cancer susceptibility testing panels (e.g. myRisk™, BreastNext™, OvaNext™, PancNext™, CancerNext™, GYNplus™, ColoNext™, RenalNext™) using nextgeneration sequencing for hereditary cancer are considered investigational as the entire panel have not been proven to improve health outcomes.
 - There may be one portion/component of the genetic panel that is medically necessary, however there may be portion/components of the genetic panel that a patient is not at risk and therefore the entire genetic panel does not meet medical policy criteria.
- Diagnostic genetic testing using panels of genes (with or without next generation sequencing), including but not limited to whole genome and whole exome sequencing: Any test/component of the genetic panel that does not meet the criteria listed in the Indications/Criteria section above and therefore the entire genetic panel does not meet medical policy criteria.
- Genetic cancer susceptibility testing panels or diagnostic genetic testing using panels of genes (CPT 81435, 81436):
 - There may be one portion/component of the genetic panel that is medically necessary, however the medical literature does not support the entire genetic panel improves health outcomes and therefore the entire panel is considered investigational.

MVP Medicare Variation

For full CMS/Medicare coverage and limitation details refer to the following Medicare National Decision: Colorectal Cancer Screening Tests (210.3) Effective date: 01/01/2023. Available: MCD Search (cms.gov)

There is a Medicare Article for colorectal cancer screening. For full coverage details refer to: Centers for Medicare & Medicaid Services (CMS). National Government Services, Inc. Article (A52378). Revision Effective date: 01/19/2021. Available: MCD Search (cms.gov)

References (Updated 2024)

- The National Comprehensive Cancer Network (NCCN). Clinical Practice Guidelines in Oncology. Genetic/Familial High-Risk Assessment: Colorectal. Version 1.2022. Available: www.nccn.org
- 2. Recommendations from the EGAPP working group: genetic testing strategies in newly diagnosed individuals with colorectal cancer aimed at reducing morbidity and mortality from Lynch syndrome in relatives. Genet Med 2009 Jan;11(1):35-41.
- 3. Palomaki, GE., et al. EGAPP supplementary evidence review: DNA testing strategies aimed at reducing morbidity and mortality from Lynch syndrome. Genetics in Medicine. January 2009; 11:42-65.
- 4. Chang GJ, Kaiser AM, Mills S, Rafferty JF, Buie WD. American Society of Colon and Rectal Surgeons Medical Specialty Society. Practice parameters for the management of colon cancer. Dis Colon Rectum. 2012 Aug; 55(8):831-43. Available: https://fascrs.org/healthcare-providers/education/clinical-practice-quidelines
- 5. Goodenberger M, Lindor NM. Lynch syndrome and MYH-associated polyposis: review and testing strategy. J Clin Gastroenterol. 2011 Jul;45(6):488-500.
- 6. Hendriks YM, de Jong AE, Morreau H, Tops CM, Vasen HF, Wijnen JT, et al. Diagnostic approach and management of Lynch syndrome (hereditary nonpolyposis colorectal carcinoma): a guide for clinicians. CA Cancer J Clin. 2006 Jul-Aug;56(4):213-25.
- 7. Kempers MJ, Kuiper RP, Ockeloen CW, Chappuis PO, Hutter P, Rahner N, et al. Risk of colorectal and endometrial cancers in EPCAM deletion-positive Lynch syndrome: a cohort study. Lancet Oncol. 2011 Jan;12(1):49-55. Epub 2010 Dec 8.
- 8. Kohlmann W, Gruber S. Lynch Syndrome. Gene Reviews. Funded by the NIH. Developed at the University of Washington, Seattle. Initial Posting: February 5, 2004; Last Update: 04/12/18. Available: http://www.ncbi.nlm.nih.gov/bookshelf/br.fcgi?book=gene&part=hnpcc
- 9. National Cancer Institute (NCI) a. Genetics of colorectal cancer (PDQ®). Updated: 06/14/18. Available: http://www.cancer.gov/types/colorectal/hp/colorectal-genetics-pdq
- 10. Robson ME, Storm CD, Weitzel J, Wollins DS, Offit K; American Society of Clinical Oncology. American Society of Clinical Oncology policy statement update: genetic and genomic testing for cancer susceptibility. J Clin Oncol. 2010 Feb 10;28(5):893-901.

- 11. U. S. Preventive Services Task Force (USPSTF). Colorectal cancer screening. Published Final Recommendations. Available: https://www.uspreventiveservicestaskforce.org/BrowseRec/Index/browse-recommendations
- 12. American Gastroenterological Association Medical Position Statement: Hereditary Colorectal Cancer and Genetic Testing. Gastroenterology 2001, 121:195-197.
- 13. Umar A, Boland C, Terdiman J, Syngal S, de la Chapelle A, Ruschoff J, et al. Revised Bethesda Guidelines for hereditary nonpolyposis colorectal cancer (Lynch syndrome) and microsatellite instability. J Natl Cancer Inst. 2004 Feb 18; 96:261-268.
- 14. The National Comprehensive Cancer Network, Colorectal Cancer Screening. Clinical Practice Guidelines in Oncology, Version 2.2021. [On-line]: www.nccn.org
- 15. ACR Appropriateness Criteria® colorectal cancer screening. 1998 (revised 2018). NGC: 010144American College of Radiology Medical Specialty Society. Available: https://acsearch.acr.org/list
- 16. New York State Department of Health Medicaid Program. Medicaid Update. October 2015. Volume 31. Number 11. Available: http://www.health.ny.gov/health_care/medicaid/program/update/2015/oct15_mu.p_df
- 17. Umar, A., et al. Revised Bethesda Guidelines for hereditary nonpolyposis colorectal cancer (Lynch Syndrome) and microsatellite instability. JNCI. Jnl of National Cancer InstituteVolume 96, Issue 4 Pp. 261-268. Accessed: 06/30/16. Available: http://jnci.oxfordjournals.org/content/96/4/261.full
- Vasen, H., Watson, P., Mecklin, J.-P., & Lynch, H. (1999). New clinical criteria for hereditary nonpolyposis colorectal cancer (HNPCC, Lynch syndrome) proposed by the International Collaborative Group on HNPCC. Gastroenterology, 116(6), 1453– 1456. Accessed: 06/30/16. Available: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2740877/
- 19. Blue Cross Blue Shield Association. Special report. Fecal DNA analysis for colon cancer screening. TEC Assessment, 2014; 29(8).
- 20. New York State Department of Health. Genetic Testing and Screening in the Age of Geonomic Medicine. Updated 2011. Available:

 http://educationnewyork.com/files/Genetic%20Testing%20and%20Screening%20in%20the%20Age%20of%20Genomic%20Medicine.pdf
- 21. Itzkowitz S, Brand R, Jandorf L, et al. A simplified, noninvasive stool DNA test for colorectal cancer detection. Am J Gastroenterol. 2008; 103(11):2862-2870.

- 22. Rex DK, Johnson DA, Anderson JC, et al. American College of Gastroenterology guidelines for colorectal cancer screening 2009 [corrected]. Am J Gastroenterol. 2009; 104(3):739-750.
- 23. Lin JS, Webber EM, et al. Fecal DNA Testing in screening for colorectal cancer in average-risk adults. [Internet]. Rockville (MD): Agency for Healthcare Research and Quality (US); 2012. Available at: https://www.ncbi.nlm.nih.gov/books/NBK91369/.
- 24. Ned RM, Melillo S, Marrone M. Fecal DNA testing for colorectal cancer screening: the ColoSure™ test. PLoS Curr. 2011 Mar 22;3:RRN1220.
- 25. Centers for Medicare & Medicaid Services, Decision Memo for Screening Colorectal Cancer Stool DNA Testing (CAG 00440N). October 9, 2014. Available: http://www.cms.gov/Medicare/Medicare.html
- 26. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for Colorectal Cancer Screening Tests (210.3) Effective Date 01/01/2023. Available: https://www.cms.gov

Customer Product	Medical Management Requirements*
New York Products	
HMO	Prior Auth
PPO In Plan	Prior Auth
PPO OOP	Retrospective Review
POS In Plan	Prior Auth
POS OOP	Retrospective Review
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Prior Auth
MVP Child Health Plus	Prior Auth
Harmonious Health Care Plan	Prior Auth
MVP Medicare Complete Wellness	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP Medicare WellSelect PPO	Prior Auth
MVP Medicare WellSelect Plus PPO	Prior Auth
MVP Medicare Patriot Plan PPO	Prior Auth
MVP DualAccess D-SNP HMO	Prior Auth
MVP DualAccess Complete D-SNP HMO	Prior Auth
MVP DualAccess Plus D-SNP HMO	Prior Auth
UVM Health Advantage Select PPO	Prior Auth
USA Care PPO	Potential for Retrospective Review
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	See Si D
	D'. A II
POS in Plan	Prior Auth
POS OOP	Retrospective Review
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP VT HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
ASO	See SPD

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro ReviewRetrospective Review RequiredNot CoveredService is not a covered benefit.See SPDSee Specific Plan Design

Revision History:

06/01/2021 - Annual review with no changes to the indications or criteria. Added definitions of blood relatives, synchronous and metachronous cancers.

02/01/2022 – Age for Cologuard coverage decreased to 45 years or older, added coverage for Medicaid plans for Lynch Syndrome, blood-based biomarker genetic testing panels excluded from all plans as investigational except for Medicare plans have coverage based on the indicated Medicare NCD.

04/01/2023 - Criteria for Lynch Syndrome genetic testing was updated to reflect NCCN criteria and references to Bethesda and Amsterdam II criteria were deleted. The Medicaid variation was deleted because our criteria is now equivalent NYS Medicaid and variation is no longer necessary; references updated.

08/01/2024 – Blood based biomarkers for Colorectal Cancer Screening (HCPCS Code: G0327) removed from policy and is now being managed in the Serum Tumor Markers for Malignancies Payment Policy. Cologuard FIT-DNA test (CPT Code: 81528) removed from policy and now being managed in the Colorectal Cancer Screening Payment Policy.



Compression Devices

Type of Policy: DME

 Prior Approval Date:
 06/03/2024

 Approval Date:
 02/18/2025

 Effective Date:
 06/01/2025

Related Polices: Lymphedema Compression

Garments/Compression Stockings

Durable Medical Equipment

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

For Durable Medical Equipment (DME) that requires Prior Authorization, refer to https://www.mvphealthcare.com/providers/reference-library/#utilization

CPT Code:	Description:
E0650	Pneumatic compressor, nonsegmental home model
E0651	Pneumatic compressor, segmental home model without calibrated gradient pressure
E0652	Pneumatic compressor, segmental home model with calibrated gradient pressure
E0655	Nonsegmental pneumatic appliance for use with pneumatic compressor, half arm
E0656	Segmental pneumatic appliance for use with pneumatic compressor, trunk
E0657	Segmental pneumatic appliance for use with pneumatic compressor, chest
E0660	Nonsegmental pneumatic appliance for use with pneumatic compressor, full leg
E0665	Nonsegmental pneumatic appliance for use with pneumatic compressor, full arm

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Nonsegmental pneumatic appliance for use with pneumatic compressor, half leg
Segmental pneumatic appliance for use with pneumatic compressor, full leg
Segmental pneumatic appliance for use with pneumatic compressor, full arm
Segmental pneumatic appliance for use with pneumatic compressor, half leg
Segmental pneumatic appliance for use with pneumatic compressor, integrated, two full legs and trunk
Segmental gradient pressure pneumatic appliance, full leg
Segmental gradient pressure pneumatic appliance, full arm
Segmental gradient pressure pneumatic appliance, half leg
Pneumatic compression device, high pressure, rapid inflation/deflation cycle, for arterial insufficiency
Intermittent limb compression device (includes all accessories), not otherwise specified
Non-pneumatic sequential compression garment, trunk
Nonpneumatic sequential compression garment, full leg
Nonpneumatic sequential compression garment, half leg
Nonpneumatic compression controller with sequential calibrated gradient pressure
Nonpneumatic compression controller without calibrated gradient pressure
Nonpneumatic sequential compression garment, full arm
Nonpneumatic, nonsequential, peristaltic wave compression pump

Codes Subject to Retrospective Review

N/A

Experimental/Investigational

E0677	Non-pneumatic sequential compression garment, trunk	
E0678	Nonpneumatic sequential compression garment, full leg	
E0679	Nonpneumatic sequential compression garment, half leg	
E0680	Nonpneumatic compression controller with sequential calibrated gradient pressure	
E0681	Nonpneumatic compression controller without calibrated gradient pressure	
E0682	Nonpneumatic sequential compression garment, full arm	
E0683	Nonpneumatic, nonsequential, peristaltic wave compression pump	

Common Diagnosis Codes

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N/A

Common Procedure Codes

N/A

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy.

Overview

Edema:

Edema is a non-specific term for the accumulation of fluid in tissue, most often in the extremities. There are numerous causes for edema, ranging from systemic disorders (e.g., congestive heart failure, etc.) to local conditions (post-surgery, congenital abnormalities, etc.). (Examples are not all-inclusive).

Lymphedema, as discussed below, is just one group of conditions that can be a cause of accumulation of fluid in the tissue. Lymphedema arises from disorders of the lymphatic system. It is essential to rule out other causes of edema in order to diagnose lymphedema. Edema from other causes is not classified as lymphedema.

<u>Primary Lymphedema</u>

Primary lymphedema is a disorder of the lymphatic system that occurs on its own. It is inherited and uncommon. Examples (not all-inclusive) are:

- congenital lymphedema due to lymphatic aplasia or hypoplasia;
- Milroy's disease, an autosomal dominant familial form of congenital lymphedema;
- lymphedema praecox; or
- lymphedema tarda.

Secondary Lymphedema

Secondary lymphedema is a disorder of lymphatic flow that is caused by some other disease or condition. It is more common than primary lymphedema. It is most commonly caused by surgery (especially lymph node dissection, such as for breast cancer), radiation therapy (especially axillary or inguinal), trauma, lymphatic obstruction by tumor, and, in developing countries, lymphatic filariasis. Secondary lymphedema may also result from compression of the lymphatic and venous channels resulting from leakage of fluid into interstitial tissues in patients with chronic venous insufficiency.

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A pneumatic compression device (PCD) uses compression to assist with the elimination of retained excess fluid and swelling. The pump uses a sleeve-type device that mobilizes arm or leg edema through the use of cycled times and pressure.

There are three main types of pneumatic compression devices (PCD) that are described below:

- non-segmented (single chamber non-programmable pump) pneumatic compressor (E0650);
- segmented (multi-chamber non-programmable pump) pneumatic compressor without calibrated gradient pressure (no manual control of pressure) (E0651); and
- segmented (multi-chamber) pneumatic compressor with (manually) calibrated gradient pressure (E0652).

A non-segmented pneumatic compressor/single-chamber non-programmable pump (E0650) is a device that has a single outflow port on the compressor.

A segmented pneumatic compressor (E0651, E0652) is a device that has multiple outflow ports on the compressor that lead to distinct segments of the appliance that inflate sequentially. A segmented device without calibrated gradient pressure (E0651) is one in which either (a) the same pressure is present in each segment or (b) there is a pre-determined pressure gradient in successive segments but no ability to individually set or adjust pressures in each of several segments. In an E0651 device, the pressure is usually set by a single control on the distal segment. A segmented device with calibrated gradient pressure (E0652) is characterized by a manual control on at least three outflow ports that can deliver an individually determined pressure to each segmental unit.

Single-or multi-chamber programmable pumps are similar to the pumps described above except that it is possible to make manual adjustments in the pressure in the individual compartments and/or the length and frequency of the inflation cycles.

Compression appliances include compression bandages, compression garments, and non-elastic binders. Compression garments are made of elastic compression material used to provide static compression to promote venous and/or lymphatic circulation. The compression garment may be prefabricated or custom fabricated for adequate graduated compression. Non-elastic binders provide static compression of the extremity without the use of elastic, but use wraps, adjustable Velcro or buckle straps).

A Non-Pneumatic Compression pumps has recently been approved by the FDA in April 2021. The Koya Dayspring system uses a compression device that uses an alloy of nickel and titanium to create a shape memory that can be programmed with a controller and a mobile phone application to apply active gradient pressure.

Medical Record Documentation Requirements

Compression Devices Page 4 of 16

The determination by the physician of the medical necessity of a pneumatic compression device must include symptoms and objective findings, including measurements which establish the severity of the condition.

The trial of conservative therapy must be thoroughly documented in the medical record before prescribing any type of pneumatic compression device (E0650-E0652).

At a minimum, re-assessments conducted for a trial must include detailed measurements, obtained in the same manner and with reference to the same anatomic landmarks, prior to and at the conclusion of the various trials and therapy, with bilateral comparisons where appropriate.

The trial of conservative therapy must be documented in the customer's medical record before prescribing any type of pneumatic compression device (E0650-E0652). This assessment may be performed by the prescribing physician or any other licensed/certified medical professional (LCMP) directly involved in the beneficiary's lymphedema treatment. The LCMP may not have any financial relationship with the supplier providing the device. If the assessment is performed by an LCMP, the prescribing physician must receive and review the report of the evaluation. In addition, the prescribing physician must sign and date the report, and state concurrence or disagreement with the assessment.

Indications/Criteria

Lymphedema:

Treatment of primary or secondary Lymphedema with a pneumatic compression device (E0650 or E0651) is covered when all the following criteria is met:

- Diagnosis of either primary or secondary lymphedema;
- Persistence of chronic and severe lymphedema as identified by the documented presence of at least one of the following clinical findings:
 - Marked hyperkeratosis with hyperplasia and hyperpigmentation
 - Papillomatosis cutis lymphostatica,
 - o Deformity of elephantiasis,
 - o Skin breakdown with persisting lymphorrhea,
 - Detailed measurements over time confirming the persistence of the lymphedema with a history evidencing a likely etiology, and

A four-week trial of conservative therapy demonstrating failed response to treatment is required. The four-week trial of conservative therapy must include all of the following:

 Regular and compliant use of an appropriate compression bandage system or compression garment to provide adequate graduated compression.

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- (Adequate compression is defined as (1) sufficient pressure at the lowest pressure point to cause fluid movement and (2) sufficient pressure across the gradient [from highest to lowest pressure point] to move fluid from distal to proximal.) The compression used must not create a tourniquet effect at any point
- The garment may be prefabricated or custom-fabricated but must provide adequate graduated compression starting with a minimum of 30 mmHg distally
- Regular exercise
- Elevation of the limb

Only when no further improvement has occurred in the most recent four weeks and the above indications/criteria for lymphedema are met, may the lymphedema be considered unresponsive to conservative therapy, and coverage for a pneumatic compression device (E0650, E0651) considered.

At the end of the four-week trial, if there has been improvement, then reimbursement for a PCD is not justified. Where improvement has occurred, the trial of conservative therapy must be continued with subsequent reassessment at intervals at least a week apart.

Chronic Venous Insufficiency With Venous Stasis Ulcers

Treatment of chronic venous insufficiency with venous stasis ulcers with a pneumatic compression device (E0650 or E0651) is covered when all the following criteria is met:

- Edema in the affected lower extremity
- One or more venous stasis ulcer(s)
- A six-month trial of conservative therapy demonstrating failed response to treatment is required.

The six-month trial of conservative therapy must include all of the following:

- Compliant use of an appropriate compression bandage system or compression garment to provide adequate graduated compression
 - Adequate compression is defined as (1) sufficient pressure at the lowest pressure point to cause fluid movement and (2) sufficient pressure across the gradient [from highest to lowest pressure point] to move fluid from distal to proximal. The compression used must not create a tourniquet effect at any point.
 - The garment may be prefabricated or custom-fabricated but must provide adequate graduated compression starting with a minimum of 30 mmHg distally.

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- Medications as appropriate (e.g., diuretics and/or other treatment of congestive failure, etc.)
- o Regular exercise
- Elevation of the limb
- Appropriate wound care for the ulcer (including sharp debridement where appropriate)

Only when no further improvement has occurred for a continuous period of six months and the above indications/criteria chronic venous insufficiency are still met for the use of a pneumatic compression device (E0650, E0651) to treat chronic venous insufficiency is covered.

At the end of the six-month trial, if there has been improvement, then coverage for pneumatic compression device is considered not medically necessary. Where improvement has occurred, the trial of conservative therapy must be continued with subsequent reassessments.

Lymphedema extending Onto The Chest, Trunk, and/or Abdomen

The only time that a segmented, calibrated gradient pneumatic compression device (HCPCS code E0652) would be covered is when the individual has unique characteristics that prevent them from receiving satisfactory pneumatic compression treatment using a non-segmented device in conjunction with a segmented appliance or a segmented compression device without manual control of pressure in each chamber.

Treatment of lymphedema extending onto the chest, trunk and/or abdomen with a pneumatic compression device (E0652) is covered when all the following criteria is met:

- Diagnosis of either primary or secondary lymphedema;
- the above indications/criteria for lymphedema for a pneumatic compression device (E0650 or E0651) are met;
- the lymphedema extends onto the chest, trunk and/or abdomen that extends past the limits of a standard compression sleeve, and the chest, trunk and/or abdominal lymphedema;
- A four-week trial of conservative therapy demonstrating failed response to treatment with and E0650 or E0651 is required. The four-week trial of conservative therapy must include all of the following:
 - At least four weeks of regular, daily, multiple-hour home usage of the E0650 or E0651 after careful, in-person fitting, training and supervision by a technician who is skilled in and who regularly and successfully uses the appliance provided;
 - Compliant use of an appropriate compression bandage system or compression garment to provide adequate graduated compression

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- Adequate compression is defined as (1) sufficient pressure at the lowest pressure point to cause fluid movement and (2) sufficient pressure across the gradient [from highest to lowest pressure point] to move fluid from distal to proximal. The compression used must not create a tourniquet effect at any point. The garment may be prefabricated or custom-fabricated but must provide adequate graduated compression starting with a minimum of 30 mmHg distally;
- Regular exercise;
- Elevation where appropriate;
- Manual lymphatic drainage (where available) and self-manual lymphatic drainage (MLD) for at least 30 minutes per day;
- o Evaluation of diet and implementation of any necessary change;
- Medications as appropriate (e.g., diuretics and/or other treatment of congestive failure, etc.);
- o Correction (where possible) of anemia and/or hypoproteinemia.

Where improvement has occurred, the trial of conservative therapy must be continued with subsequent reassessment at intervals at least a week apart. When and only when no further improvement has occurred in the most recent four weeks and the above indications/criteria above for lymphedema extending onto the chest, trunk and/or abdomen are met, a pneumatic compression device (E0652) is covered.

At the end of the four-week trial, if there has been any improvement of the lymphedema extending onto the chest, trunk and/or abdomen, then the pneumatic compression device (E0652) is not covered.

For any pneumatic compression device, equipment purchase or equipment rental will be considered on an individual case-by-case basis. A trial of a three-month rental period is required prior to purchase. Continued coverage beyond the first three months requires documented improvement and adherence with use as ordered by the healthcare professional, clinical documentation from the health care professional confirms clinical improvement (e.g., improvement in venous stasis ulcers, decrease in lymphedema). Equipment may be purchased with improvement in condition and adherence.

A non-segmented pneumatic compressor (E0650) is used with appliances/sleeves coded by E0655-E0666 or E0671-E0673. Segmented pneumatic compressors (E0651 or E0652) are used with appliances/sleeves coded by E0667-E0669. Sleeves E0656 and E0657 are only used with E0652.

When a foot or hand segment is used in conjunction with any leg or arm appliance respectively, there must be no separate billing for this segment. It is considered included in the code for the leg or arm appliance.

Exclusions

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Not meeting criteria under Indications/Criteria in this policy.

Pneumatic compression device (E0562) is not covered for the treatment of lymphedema of the extremities alone even if the above lymphedema indications/criteria are met.

Pneumatic compression device (E0562) is not covered for the treatment of chronic venous insufficiency even if the above chronic venous insufficiency indications/criteria are met.

Pneumatic Compression Devices (E0650 or E0651) used to treat edema from causes other than lymphedema are not covered.

Pneumatic compression devices (E0675 and E0676) have not been proven to be effective in the treatment of other conditions (e.g., peripheral artery disease, arterial ischemic ulcers of the lower extremities, fracture and soft-tissue healing) and in the prevention of venous thromboembolism, including deep vein thrombosis and pulmonary embolism in the home setting.

Non-Pneumatic Compression Devices (Koya Dayspring system - HCPCS codes E0677, E0678, E0680, E0681, E0682) are not covered because there is insufficient evidence in the peer reviewed medical literature to support the safety and effectiveness of these devices.

Nonpneumatic, nonsequential, peristaltic wave compression pump (for example; Venowave VW5 (HCPCS Code E0683) are considered experimental and investigational for any indication because there currently is not enough published peer reviewed medical literature to support the safety and effectiveness of these devices.

MVP Medicaid Managed Care Variation:

Pneumatic compression devices (lymphedema pumps) are covered for the treatment of generalized or refractory lymphedema, or refractory edema from chronic venous insufficiency, only when all less invasive treatments have been attempted and are unsuccessful.

Pneumatic Compression Devices (HCPCS Codes: E0650 and E0651):

Pneumatic Compression Devices (HCPCS Codes: E0650 and E0651) are covered for Medicaid Managed Care customers when the following coverage criteria are met:

- I. Lymphedema
 - The member has a diagnosis of lymphedema, and
 - Persistence of chronic and severe lymphedema as documented by presence of at least one of the following:
 - o Marked hyperkeratosis with hyperplasia and hyperpigmentation
 - o Papillomatosis cutis lymphostatica

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- Deformity of limb or involved area i.e., elephantiasis (measurements to support compared to contralateral limb)
- Skin breakdown with persisting lymphorrhea
- Detailed measurements over time confirming the persistence of lymphedema with a history evidencing a likely etiology, and

A documented 4-week trial of conservative therapy demonstrating failed response to the treatment is required. The trial must include ALL the following:

- Regular compliance with an appropriate compression bandage system or compression garment to provide adequate compression. (Adequate compression is defined as having sufficient pressure at lowest pressure point to cause fluid movement, and sufficient pressure across the gradient (from highest to lowest pressure point) to move fluid from distal to proximal.) The compression should not create a tourniquet effect at any point.
- The garment may be prefabricated or custom-fabricated but must provide adequate graduated compression with a minimum of 30mmHg distally.
- Regular exercise program
- Elevation of limb
- Evidence of participation in a manual lymph drainage (MLD) program and results.
- Evidence of appropriate medication treatment for co-morbidities, i.e., congestive heart failure (CHF) and results.
- Symptoms and objective findings, including measurements which establish the severity of the condition
- Reason the device is required, including treatments which have been tried and failed
- II. Chronic Venous Insufficiency (CVI)

Pneumatic compression devices (HCPCS codes E0650 or E0651) are covered for treatment of CVI of the lower extremities ONLY if the member has ALL the following:

- Edema in the affected lower extremity
- One or more venous stasis ulcer(s)
- Non-healing ulcers after a six-month trial of conservative therapy directed by the treating practitioner. The six-month trial includes:
 - The 4-week lymphedema trial criteria outlined above; AND

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 Appropriate wound care for the ulcer(s) (including sharp debridement where appropriate)

Segmented, calibrated gradient pneumatic compression devices (HCPCS code E0652):

A segmented, calibrated gradient pneumatic compression device (HCPCS code E0652) is only covered when the Medicaid Managed Care Customer has unique characteristics which prevent them from receiving adequate satisfactory pneumatic compression treatment using a non-segmented device along with a segmented appliance or compression device without manual control of the pressure in each chamber.

A segmented, calibrated gradient pneumatic compression device (HCPCS code E0652) is covered for the treatment of lymphedema extending onto the chest, trunk and/or abdomen when ALL the following are met:

- Diagnosis of lymphedema of an extremity
- Coverage criteria for E0650 and E0651 are met
- The member has lymphedema extending onto the chest, trunk and/or abdomen that extends past the limits of a standard compression sleeve, and the chest, trunk and/or abdominal lymphedema has failed to improve with a four-week trial. 4-week trial includes all the requirements for the 4-week trial outlined above under Lymphedema, AND:
 - Manual lymph drainage (MLD) (where available) and self MLD for at least 30 minutes/day
 - o Evaluation of diet and implementation of necessary changes
 - o Medications as appropriate (i.e., diuretics and/or treatment of CHF, etc.)
 - o correction (where possible) of anemia and/or hyponatremia

Coverage criteria are according to the New York State Medicaid Program eMedNY DME Procedure Codes Guidelines and Coverage Guidelines manual.

Medicare

There is a CMS National Coverage Determination (NCD) for Pneumatic Compression Devices (280.6). For full coverage and limitation details refer to: Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD) for Pneumatic Compression Devices (280.6). Effective Date: 01/14/2002. Available: www.cms.gov/

There is a CMS Local Coverage Determination (LCD) for Pneumatic Compression Devices. For full coverage and limitation details refer to: Noridian Healthcare Solutions Local Coverage Decision (LCD) LCD ID Number: L33829 Pneumatic Compression Devices RETIREMENT Date:11/14/2024. Available:

https://med.noridianmedicare.com/web/jddme/policies/lcd/active

Compression Devices Page 11 of 16

References (Updated 2025)

- Agency for Health Care Research and Quality. Technology Assessment. Diagnosis and Treatment of Secondary Lymphedema. May 2010. Available at: https://www.cms.gov/determinationprocess/downloads/id66aTA.pdf
- 2. Berliner E, Berrin O, Zarin D. A systematic review of pneumatic compression for treatment of chronic venous insufficiency and venous ulcers. J Vasc Surg. 2003; 37:539-44.
- 3. Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD) for Pneumatic Compression Devices (280.6). Effective Date: 01/14/2002. Available: www.cms.gov/
- 4. Devoogdt, N. Et al. Different physical treatment modalities for lymphedema developing after axillary lymph node dissection for breast cancer: a review. European Journal of Obstetrics and Gynecology Reproductive Biology. 2010 Mar;149(1):3-9.
- 5. Eliasson AH, Lettieri CJ. Sequential compression devices for treatment of restless legs syndrome. Medicine (Baltimore). 2007 Nov; 86(6):317-23.
- eMedNY. Provider Manuals. DME. Procedure Codes. New York State Medicaid Program. Durable Medical Equipment, Orthotics, Prosthetics, and Supplies. Procedure Codes and Coverage Guidelines. Available: https://www.emedny.org/ProviderManuals/DME/index.aspx
- 7. Feist WR, et al. Problems with measuring compression device performance in preventing deep vein thrombosis. Throm Res 2011 Sep; 128(3):207-9.
- 8. Fife CE, Davey S, Maus EA, Guilliod R, Mayrovitz HN. A randomized controlled trial comparing two types of pneumatic compression for breast cancer-related lymphedema treatment in the home. Support Care Cancer. 2012 Dec; 20(12):3279-86.
- 9. Flexi touch® system information for Healthcare Professionals. Available: https://www.tactilemedical.com/professionals/
- 10. Handoll HH, Madhok R, Howe TE. Rehabilitation for distal radial fractures in adults. Cochrane Database Syst Rev. 2006 Jul 19; (3):CD003324.
- 11. Hardwick ME, Pulido PA, Colwell CW Jr. A mobile compression device compared with low-molecular-weight heparin for prevention of venous thromboembolism in total hip arthroplasty. Orthop Nurs. 2011 Sep-Oct; 30(5):312-6.
- 12. Hayes Evidence Analysis Research Brief: Dayspring (Koya Medical Inc.) for Treatment of Lymphedema. Hayes Inc. March 27, 2023.
- 13. Hayes Evidence Analysis Research Brief: Venowave VW5 (Therma Bright) for Treatment of Lower-Extremity Lymphedema. © 2024 Hayes, a symplr company. September 9, 2024

Compression Devices Page 12 of 16

- 14. International Society of Lymphology. The diagnosis and treatment of peripheral lymphedema. Consensus document of the International Society of Lymphology. 2009. Available: https://www.internationalsocietyoflymphology.org/wp-content/uploads/2017/12/20106-35060-1-PB.pdf
- 15. Kakkos SK, Caprini JA, Geroulakos G, Nicolaides AN, Stansby GP, Reddy DJ. Combined intermittent pneumatic leg compression and pharmacological prophylaxis for prevention of venous thromboembolism in high-risk patients. Cochrane Database Syst Rev. 2008 Oct 8; (4):CD005258.
- 16. Khanna A, Gougoulias N, Maffulli N. Intermittent pneumatic compression in fracture and soft-tissue injuries healing. Br Med Bull. 2008; 88(1):147-156.
- 17. Koya Medical. Dayspring compression [product information]. Accessed March 3, 2022. Available at URL address: https://www.koyamedical.com/
- 18. Labropoulos N, Wierks C, Suffoletto B. Intermittent pneumatic compression for the treatment of lower extremity arterial disease: a systematic review. Vasc Med. 2002 May; 7(2):141-8.
- 19. Lettieri CJ, Eliasson AH. Pneumatic compression devices are an effective therapy for restless legs syndrome: a prospective, randomized, double-blinded, sham-controlled trial. Chest. 2009 Jan;135(1):74-80.
- 20. Naccarato M, et al. Physical methods for preventing deep vein thrombosis in stroke. Cochrane Database Syst Rev 2010 Aug 4;(8):CD001922.
- 21. National Lymphedema Network NLN). Position statement of the national lymphedema network. Treatment. February 2011. Available: https://lymphnet.org/position-papers/
- 22. Noridian Healthcare Solutions, LLC Local Coverage Decision (LCD) LCD: L33829 Pneumatic Compression Devices RETIREMENT Date: 11/14/2024. Available: https://med.noridianmedicare.com/web/jddme/policies/lcd/active
- 23. Ridner, SH, et al. Home-based lymphedema treatment in patients with cancer-related lymphedema or noncancerous-related lymphedema. Oncology Nursing Forum. 2008. July; 35(4):671-80.
- 24. Rockson SG, Karaca-Mandic P, Skoracki R, Hock K, Nguyen M, Shadduck K, Gingerich P, Campione E, Leifer A, Armer J. Clinical Evaluation of a Novel Wearable Compression Technology in the Treatment of Lymphedema, an Open-Label Controlled Study. Lymphat Res Biol. 2022 Apr;20(2):125-132. doi: 10.1089/lrb.2020.0126. Epub 2021 Jul 2. PMID: 34227842; PMCID: PMC9081034.
- 25. Wilburn, O. et al. A Pilot, Prospective Evaluation of a Novel Alternative for Maintenance Therapy of Breast Cancer-Associated Lymphedema. BMC Cancer. 2006 Mar 29; 6 (1):84.

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26. Women's Health and Cancer Rights Act of 1998. Pub. L. 105-277. October 21, 1998. Available: https://www.cms.gov/cciio/programs-and-initiatives/other-insurance-protections/whcra_factsheet.html

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Customer Product	Medical Management Requirements*
New York Products	-
HMO	Prior Auth
PPO In Plan	Prior Auth
PPO OOP	Prior Auth
POS In Plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Prior Auth
MVP Child Health Plus	Prior Auth
MVP Harmonious Health Care Plan	Prior Auth
MVP Medicare Complete Wellness	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP Medicare WellSelect PPO	Prior Auth
MVP Medicare WellSelect Plus PPO	Prior Auth
MVP Medicare Patriot Plan PPO	Prior Auth
MVP DualAccess D-SNP HMO	Prior Auth
MVP DualAccess Complete D-SNP HMO	Prior Auth
MVP DualAccess Plus D-SNP HMO	Prior Auth
UVM Health Advantage Select PPO	Prior Auth
USA Care	Potential for Retrospective Review
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	
POS In Plan	Prior Auth
POS OOP	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP VT HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

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Revision History:

8/1/2021 – Annual Review. Updated to new format. No changes to indications or criteria.

8/1/2023 – Annual review, policy name changed to compression devices because policy includes both pneumatic and non-pneumatic compression devices. Koya dayspring added as an exclusion.

01/01/2024 – Updated HCPCS codes, deleted K1024, K1025, K1031, K1032, K1033. Replaced with new HCPCS codes E0678, E0679, E0680, E0681, E0682.

04/01/2024 – Medicaid Managed Care variation updated to reflect new coverage criteria for E0650 – E0652 pneumatic compression devices.

06/01/2025 – Added exclusion for E0683 - Nonpneumatic, nonsequential, peristaltic wave compression pump.

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Continuous Glucose Monitoring

Type of Policy: DME

Prior Approval Date: 03/24/2023

Approval Date: 07/01/2024

Effective Date: 10/01/2024

Related Polices: Durable Medical Equipment

Insulin Infusion Pump

(External)

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

CPT Codes:	Description:
A4238	Supply Allowance for Adjunctive Continuous Glucose Monitor (CGM),
A4230	includes all supplies and accessories, 1 month supply = 1 unit of service
	Supply allowance for nonadjunctive, nonimplanted continuous glucose
A4239	monitor (CGM), includes all supplies and accessories, 1 month supply =
	1 unit of service
A9276	Sensor; invasive (e.g., subcutaneous), disposable, for use with interstitial
A9270	continuous glucose monitoring system
A9277	Transmitter; external, for use with interstitial continuous glucose
	monitoring system
A9278	Receiver (monitor); external, for use with interstitial continuous glucose
A9216	monitoring system
E2102	Adjunctive Continuous Glucose monitor or receiver
E2103	Nonadjunctive, nonimplanted continuous glucose monitor (CGM) or
E2103	receiver
S1030	Continuous noninvasive glucose monitoring device, purchase
S1031	Continuous noninvasive glucose monitoring device, rental, including
31031	sensor, sensor replacement, and download to monitor

Codes Subject to Retrospective Review as Experimental/Investigational:

N/A

Common Diagnosis Codes

ICD-10- CM Diagnosis Codes:

E10.65, E11.21, E11.311, E11.319, E11.36, E11.39, E11.40, W11.51, E11.65, E11.69, E11.8, E15, E16.2, O24.32, O24.319, O24.419, O24.429, O24.911, O24.912, O24.913, O24.92, O24.93, O99.81, O99.810, O99.814, O99.815

Common Procedure Codes

CPT Codes:	Description:
95250	Ambulatory continuous glucose monitoring of interstitial tissue fluid via
	a subcutaneous sensor for a minimum of 72 hours; physician (office)
	provided equipment, sensor placement, hook-up, calibration of monitor,
	patient training, removal of sensor, and printout of recording
	Ambulatory continuous glucose monitoring of interstitial tissue fluid via
95251	a subcutaneous sensor for a minimum of 72 hours; analysis,
	interpretation and report
	Creation of subcutaneous pocket with insertion of implantable
0446T	interstitial glucose sensor, including system activation and patient
	training
0447T	Removal of implantable interstitial glucose sensor from subcutaneous
04471	pocket via incision
0448T	Removal of implantable interstitial glucose sensor with creation of
	subcutaneous pocket at different anatomic site and insertion of new
	implantable sensor, including system activation

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy.

Overview

Continuous glucose monitoring systems (CGMS) are minimally invasive or non-invasive devices that measure glucose levels in interstitial fluid at frequent intervals over a period of several days. Continuous glucose monitoring systems consist of a sensor, transmitter, and receiver. Some monitors provide real-time information while others require data to be downloaded and reviewed retrospectively. The goal of continuous glucose monitoring systems is to guide adjustments to therapy and improving overall glycemic control.

Continuous glucose monitoring may be used either as a one-time evaluation for a minimum of 72 hours, three-day period or on a long-term continuous basis.

Short term glucose monitoring or 72-hour ambulatory glucose monitoring is performed on CGM systems that are owned by healthcare providers and are loaned to an individual to use over a short period of time to record and store glucose data. The individual returns to the physician's office where the data can be analyzed and used to prescribe an appropriate insulin regimen.

Long-term continuous glucose monitors are owned by individuals and provide real-time glucose values that allow users to track patterns and possibly identify episodes of low and high blood glucose levels. There are two types of long-term continuous glucose monitors. Non-therapeutic CGMS devices are intended to be used as an adjunctive device to complement, not replace, blood glucose monitors. Therapeutic CGMS are approved to replace traditional blood glucose monitors.

Combined external insulin pumps with continuous glucose monitor systems are devices that have integrated continuous glucose monitors with the insulin pump. These systems incorporate features including predictive alerts that give early warnings so action can be taken to prevent dangerous high or low blood glucose events.

Implanted interstitial glucose sensors (I-CGM) are intended for long-term use (worn up to 180 days), the sensor is implanted subcutaneously in the upper arm to measure glucose in the interstitial fluid. The measurement is then relayed to the removable transmitter that sends data to a smart device. The measurement and display of glucose values is done automatically without the need for user intervention. An example of an implantable continuous glucose monitor is the Eversense. The Eversense system consists of a glucose sensor, which can be worn for up to 90 days, that is inserted under the skin by a physician and an externally worn transmitter. The inserter sensor collects readings and sends them to the transmitter. The transmitter calculates, stores, and transmits the glucose data to a mobile device.

Indications/Criteria

72-Hour Ambulatory Continuous Glucose Monitoring of Interstitial Fluid (95250, 95251)

72-hour ambulatory continuous glucose monitoring of interstitial fluid with an FDA approved device is covered up to twice per year for customers who are insulin dependent when all the following are met:

- customers with poorly controlled diabetes despite evidence of optimized diabetic treatment as indicated by the following clinical situations:
 - difficulty achieving blood glucose control; or frequent, unexplained hypoglycemic unawareness episodes (<50 mg/dl) despite optimized diabetic treatment; or recurrent ketoacidosis; and

- compliance with recommended regimen, including glucose self-testing an average of four times/day; and
- under the care of an endocrinologist or a provider with experience in diabetes treatment; and
- has completed a comprehensive diabetic education program.
- 72-hour ambulatory continuous glucose monitoring of interstitial tissue fluid does not require prior authorization (95250, 95251).

External Interstitial Continuous Glucose Monitoring System

A therapeutic or non-therapeutic continuous glucose monitoring system (A4238, A4239, E2103) with an FDA approved device is covered for customers when all of the following are met:

- 1. The customer has type 1, type 2, or gestational diabetes; and
- 2. The customer is insulin dependent requiring multiple (three or more) daily administrations of insulin or on an external insulin pump; and
- 3. The customer's insulin treatment plan requires frequent adjustments by the customer on the basis of blood glucose measurement (BGM) or continuous glucose monitor (CGM) testing results; and
- 4. Within six (6) months prior to ordering the CGM, the treating practitioner has an inperson visit with the customer to evaluate their diabetes control and determine that customer meets the criteria above: and
- 5. The customer is followed every six (6) months following the initial prescription of the CGM to assess adherence to the CGM regimen and diabetes plan.

Implantable Interstitial Continuous Glucose Monitoring System

An implantable continuous glucose monitoring device system (0446T, 0447T, 0448T) is covered for customers when the following is met:

- The customer meets the criteria for an external CGM; and
- 18 years of age or older; and
- One or more of the following indications:
 - o Physical disability, such as impairment in vision, hearing, or dexterity; or
 - A severe sensitivity to adhesives or plastics used in transcutaneous CGM components; or
 - o Any significant condition or situation requiring vibration alerts.

Replacement continuous glucose monitors are covered when the following criteria are met:

- Every six (6) months following the initial prescription of the CGM, the treating practitioner has an in-person visit with the beneficiary to assess adherence to their CGM regimen and diabetes treatment plan, and
- Does not have an existing fully functional device; and,
- Replacement will be considered when medically necessary and with documentation confirming that the monitor/component is malfunctioning, is outside of manufacturer's warranty and cannot be repaired; and,
- Replacement of the continuous glucose monitor due to slight damage to the device without causing the device to malfunction or replacement desired due to advanced technology is considered not medically necessary.

Additional Continuous Glucose Monitoring (CGM) Guidelines:

- Interstitial continuous glucose monitors in combination with insulin infusion pumps must also meet criteria outlined in the MVP Insulin Infusion Pump (External) medical policy.
- In addition to the above coverage criteria, ordering providers should verify that their patients meet manufacturer's recommendations for appropriate age range, testing and calibration requirements, etc., prior to prescribing the CGM device.
- Customers must comply with the manufacturer's specified finger stick testing recommendations for the CGM device prescribed.
- Only one type of monitor will be covered: either therapeutic (such as but not limited to DexComG6) or non-therapeutic (such as but not limited to Medtronic's Minimed).
 Ancillary devices (such as but not limited: smart phones, tablets, personal computers) are not covered
- Ancillary devices (such as but not limited: smart phones, tablets, personal computers)
 are not covered

Therapeutic Devices

The supply allowance for therapeutic continuous glucose monitors (A4239) includes all supplies necessary for monitoring glucose levels using CGM, which includes but is not limited to therapeutic sensors, therapeutic transmitters, test strips, home glucose monitor, lancets, alcohol wipes, batteries.

Non-Therapeutic Devices

For adjunctive CGMs, the supply allowance (A4238) encompasses <u>all items</u> necessary for the use of the device and includes but is not limited to, CGM sensors and transmitters.

Exclusions

Not meeting criteria under Indications/Criteria in this policy.

- Additional software or hardware required for downloading data to a device such as a personal computer, smart phone, or tablet is considered a convenience item and not medically necessary.
- Replacement of the continuous glucose monitor due to slight damage to the device without causing the device to malfunction or replacement desired due to advanced technology is considered not medically necessary.
- Over-the-counter (OTC) integrated Continuous Glucose Monitors (iCGM) (i.e., including but not limited to Dexom Stelo, Abbott Lingo) are not considered Durable Medical Equipment (DME) as they are sold OTC without prescription.

MVP Medicaid Products Variation

Effective April 1, 2023, providers are no longer able to bill MVP Managed Medicaid or HARP members for pharmacy and pharmacy related durable medical equipment and supplies because NYS Medicaid covers these items. This includes certain durable medical equipment (DME), enteral and parenteral nutrition, family planning supplies, medical/surgical supplies, miscellaneous supplies and hearing aid batteries as designated by the New York State Department of Health.

The full list of codes that must be billed to Medicaid Fee-For-Service is located at https://www.emedny.org/ProviderManuals/Pharmacy/index.aspx - See the OTC and Supply Fee Schedule.

Providers should bill these directly to New York State Medicaid Fee-For-Service using the Medicaid member client identification number (CIN) after 04/01/2023. Claims submitted directly to MVP for items that are carved out to Fee-For-Service will deny as not a covered benefit.

MVP Medicare Products Variation

To be eligible for coverage of a CGM and related supplies, the Medicare plan customer must meet all of the following initial coverage criteria (1)-(5):

- 1. The Medicare plan customer has diabetes mellitus; and,
- 2. The Medicare customer's treating practitioner has concluded that the Medicare customer (or customer's caregiver) has sufficient training using the CGM prescribed as evidenced by providing a prescription; and,
- 3. The CGM is prescribed in accordance with its FDA indications for use; and,
- 4. The Medicare customer for whom a CGM is being prescribed, to improve glycemic control, meets at least one of the criteria below:
 - A. The Medicare customer is insulin-treated; or,
 - B. The Medicare customer has a history of problematic hypoglycemia with documentation of at least one of the following:

- Recurrent (more than one) level 2 hypoglycemic events (glucose <54mg/dL (3.0mmol/L)) that persist despite multiple (more than one) attempts to adjust medication(s) and/or modify the diabetes treatment plan; or,
- A history of one level 3 hypoglycemic event (glucose <54mg/dL (3.0mmol/L)) characterized by altered mental and/or physical state requiring third-party assistance for treatment of hypoglycemia
- 5. Within six (6) months prior to ordering the CGM, the treating practitioner has an in-person or Medicare-approved telehealth visit with the Medicare plan customer to evaluate their diabetes control and determined that criteria (1)-(4) above are met.

Medicare customers have coverage for medically necessary supplies using either a therapeutic (non-adjunctive) or non-therapeutic (adjunctive) continuous glucose monitor on a monthly basis. Max Units/Frequency: 3 units every 3 months.

Medicare only covers a therapeutic CGM receiver that has an expected life of at least 3 years.

For full coverage details for glucose monitors refer to the Noridian Healthcare Solutions Local Coverage Determination (LCD) for Glucose Monitors (L33822). Revision Effective Date: 04/16/2023. Available:

https://med.noridianmedicare.com/web/jddme/policies/lcd/active

Refer to the MVP Health Care Payment Policy Durable Medical Equipment for coding and claims payment.

References (Updated 2024)

- American Diabetes Association (ADA). Diabetes Care; Standards of Medical Care in Diabetes-2022. Diabetes Care. December 2021; Vol. 45: S1-S2. Available: https://doi.org/10.2337/dc22-Sppc
- 2. Garg, S.K., et al. Continuous home monitoring of glucose: improved glycemic control with real-life use of glucose sensors in adult subjects with Type 1 diabetes. Diabetes Care. 2007; 30(12); 3023-3025.
- 3. Bode, B. et al. Alarms based on real-time sensor glucose values alert patients to hypo-hyperglycemia: the guardian continuous monitoring system. Diabetes technology Therapy. 2004; 6(2): 105-113.
- 4. Taneberg, R. et al. Use of the continuous glucose monitoring system to guide therapy in patients with insulin-treated diabetes: a randomized controlled trial. Mayo Clin Proc. 2004; 79 (12); 1521-1526.
- 5. National Institute for Health and Clinical Excellence (NICE). Type 1 diabetes: diagnosis and management of Type 1 diabetes in children and young people.

- Clinical guideline. September 2004. Updated July 2014. Available: http://www.nice.org.uk/guidance/cg15
- 6. Hayes Health Technology Assessment. Continuous Glucose Monitoring Systems. HAYES, Inc.; © 2021 Hayes, a symplr company. August 13, 2015; Annual Review: October 1, 2019. Archived September 13, 2020.
- 7. Bode, B. et al. Continuous glucose monitoring used to adjust diabetes therapy improves glycosylated hemoglobin: A pilot study. Diabetes Research and Clinical Practice. 1999 46, 183-190.
- 8. U.S. Food and Drug Administration, Office of Public Affairs. FDA approves new glucose monitoring system for members with diabetes. <u>FDA Talk</u> 1999 June. Available: www.fda.gov
- 9. Langendam MW., Luijf YM, Hooft L, DeVries JH, Mudde AH, Scholten RJPM. Continuous glucose monitoring systems for type 1 diabetes mellitus. Cochrane Database of Systematic Reviews 2012, Issue 1. Art. No.: CD008101. DOI: 10.1002/14651858.CD008101.pub2.
- 10. Gandhi GY, Kovalaske M, Kudva Y, Walsh K, Elamin MB, Beers M, Coyle C, Goalen M, Murad MS, Erwin PJ, Corpus J, Montori VM, Murad MH. Efficacy of continuous glucose monitoring in improving glycemic control and reducing hypoglycemia: a systematic review and meta-analysis of randomized trials. J Diabetes Sci Technol. 2011 Jul 1; 5(4):952-65.
- 11. Noridian Healthcare Solutions, Local Coverage Decision for Glucose Monitors. (L33822). Updated 01/01/2020. Available: https://med.noridianmedicare.com/web/jddme/policies/lcd/active.
- 12. Noridian Healthcare Solutions, Local Coverage Article for Glucose Monitors. (A52464). Updated 01/01/2020. Available: https://med.noridianmedicare.com/web/jddme/policies/lcd/active.
- 13. Endocrine Society. Clinical practice guidelines. Diabetes technology—Continuous subcutaneous insulin infusion therapy and continuous glucose monitoring in adults. 2016. Available: Clinical Practice Guidelines | Endocrine Society
- 14. U.S. Food and Drug Administration (FDA). U.S. Department of Health and Human Services. Dexcom G6 Mobile Continuous Glucose Monitoring System. P120005/S041. Approval letter. 06/28/2019. Available: www.fda.gov
- 15. Hayes Health Technology Assessment. Eversense Continuous Glucose Monitoring System for Maintaining Glycemic Control in Adults with Diabetes Mellitus. HAYES, Inc.; © 2021 Hayes, a symplr company. March 14, 2022. Wang X, Ioacara S, DeHennis A. Long-term home study on nocturnal hypoglycemic alarms using a new

- fully implantable continuous glucose monitoring system in type 1 diabetes. *Diabetes Technol Ther.* 2015;17(11):780-786.
- 16. Senseonics. Eversense CGM sensor insertion and removal instructions. 2017. Available: download (fda.gov).
- 17. Barnard KD, Kropff J, Choudhary P, et al. Acceptability of implantable continuous glucose monitoring sensor. *J Diabetes Sci Technol.* 2018;12(3):634-638.
- 18. Kropff J, Choudhary P, Neupane S, et al. Accuracy and longevity of an implantable continuous glucose sensor in the precise study: a 180-day, prospective, multicenter, pivotal trial. *Diabetes Care*. 2017;40(1):63-68.
- 19. American Diabetes Association (ADA). Consumer guide. CGMs. 2021. Available: https://consumerguide.diabetes.org/collections/cgm.
- 20. American Diabetes Association (ADA). Management of Diabetes in Pregnancy: Standards of Medical Care in Diabetes—2021. Diabetes Care 2021g;44(Suppl. 1):S200-S210. Available: 14. Management of Diabetes in Pregnancy: Standards of Medical Care in Diabetes—2021 | Diabetes Care | American Diabetes Association (diabetesjournals.org).
- 21. New York State Department of Health Medicaid Update April 2021 Volume 37 Number 5 Available: New York State Medicaid Update April 2021 Volume 37 Number 5 (ny.gov)
- 22. American Diabetes Association Professional Practice Committee; 7. Diabetes Technology: Standards of Medical Care in Diabetes—2022. Diabetes Care 1 January 2022; 45 (Supplement_1): S97–S112. 7. Diabetes Technology: Standards of Medical Care in Diabetes—2022 | Diabetes Care | American Diabetes Association (diabetesjournals.org)

Customer Product	Medical Management Requirements*
New York Products	
HMO	Prior Auth
PPO in Plan	Prior Auth
PPO OOP	Prior Auth
POS in Plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Carved out to Medicaid FFS
MVP Child Health Plus	Prior Auth
MVP Harmonious Health Care Plan	Carved out to Medicaid FFS
MVP Medicare Complete Wellness	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP Medicare WellSelect PPO	Prior Auth
MVP Medicare WellSelect Plus PPO	Prior Auth
MVP Medicare Patriot Plan PPO	Prior Auth
MVP DualAccess D-SNP HMO	Prior Auth
MVP DualAccess Complete D-SNP HMO	Prior Auth
MVP DualAccess Plus D-SNP HMO	Prior Auth
UVM Health Advantage Select PPO	Prior Auth
USA Care PPO	Potential for Retrospective Review
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	3330.2
POS in Plan	Prior Auth
POS OOP	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP VT HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD
7.00	300 31 0

[♦] Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

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Revision History:

07/01/2021 – updated Medicaid Managed Care variation according to NYS that addresses who can order the devices and the number of glucose tests to be performed. As of 7/18/21, Medicare plans no longer require glucose testing as a prerequisite for coverage.

03/01/2022 – Exclusion was added to the Medicaid Managed Care variation for type 1 diabetics according to NYS Medicaid guidelines instead of a medical necessity requirement. Medicare variation updated according to the CMS Medicare final rule for coverage of CGM adding coverage for non-therapeutic CGM as DME.

04/01/2022 – Added coverage to Medicaid for gestational diabetes and type 2 diabetes, eliminated requirement for finger stick glucose testing and added coverage for non-therapeutic CGM supplies for Medicare.

10/01/2022 – Removed requirement for 72-hour CGM, added coverage for implantable CGM, Medicare variation removed.

04/01/2023 – Updated to reflect NYS Medicaid is covering CGM supplies.

04/16/2023 – Updated Medicare variation to match national Medicare changes to coverage for Medicare plan customers.

10/01/2024 – Added coverage for gestational diabetes. Added exclusion for over-the-counter (OTC) integrated continuous glucose monitors (iCGM).



Continuous Passive Motion Device

Type of Policy: DME

Prior Approval Date: 05/02/2022

Approval Date: 06/03/2024

Effective Date: 08/01/2024

Related Polices: Temporomandibular Joint Dysfunction

New York

Temporomandibular Joint Dysfunction

Vermont

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

MVP Durable Medical Equipment (DME) Prior Authorization List

https://www.mvphealthcare.com/utilization

Codes Requiring Retrospective Review

N/A

Experimental/Investigational

HCPCS Codes:

E0935 - Continuous passive motion exercise device for use on knee only;

E0936 - Continuous passive motion exercise device for use other than knee

Common Diagnosis Codes

ICD-10 Diagnosis Codes: M23.50, M25.9, M65.9, Q74.9, S83.8X9A, S86.819A

Please refer to the product grid for detailed authorization requirements for specific plans. Code lists may not be all inclusive. Codes requiring prior-authorization for some products may be retrospectively reviewed for plans that do not require prior-authorization. Common diagnosis and procedure codes are included for informational purposes. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

A continuous passive motion (CPM) device is intended to aid rehabilitation after orthopedic surgery. The device moves the joint, e.g., flexion/extension without assistance. CPM devices are used as an adjunct to physical therapy to increase range of motion and decrease joint swelling and stiffness while allowing wound healing. Passive motion may also be used in reducing anatomical misalignment.

Indications/Criteria

Due to the lack of evidence from peer-reviewed literature demonstrating improved patient outcomes, continuous passive motion (CPM) devices are considered investigational.

Exclusions

Rehabilitation (post total knee arthroplasty, knee manipulation, or knee surgery) using stationary cycling (e.g., ROMTech PortableConnect Adaptive Telemed Technology) as an adjunct to conventional physical therapy has not been medically proven to be effective and is considered not medically necessary.

Medicare Variation

CPM device is covered for total knee replacement only.

- Device must be started within 2 days of surgery.
- Coverage is limited to 3-weeks following surgery.

References (Updated 2024)

- 1. Centers for Medicare & Medicaid Services (CMS). Medicare Coverage Database. NCD for Durable Medical Equipment Reference List (280.1) Effective Date May 5, 2005. Available: www.cmc.hhs.gov
- Milne S, Brosseau L, Welch V, Noel MJ, Davis J, Drouin H, Wells GA, Tugwell P. Continuous passive motion following total knee arthroplasty. Cochrane Database of Systematic Reviews 2003, Issue 2. Art. No.: CD004260. DOI: 10.1002/14651858.CD004260.
- 3. Spindler KP, and Wright RW. Anterior cruciate ligament tear. N Engl J Med 2008;359:2135-42.
- 4. Wright RW, Preston E, Fleming BC, et al. A systematic review of anterior cruciate ligament reconstruction rehabilitation: part II: open versus closed kinetic chain exercises, neuromuscular electrical stimulation, accelerated rehabilitation, and miscellaneous topics. J Knee Surg 2008; 21:225-34.
- 5. Truelove E, Huggins KH, Mancl L, Dworkin SF. The efficacy of traditional, low-cost and non-splint therapies for temporomandibular disorder: a randomized controlled trial. J Am Dent Assoc. 2006 Aug;137(8):1099-107.
- 6. Fitzsimmons SE, Vazquez EA, Bronson MJ. How to treat the stiff total knee arthroplasty?: a systematic review. Clin Orthop Relat Res. 2010 Apr;468(4):1096-106.

- 7. Lessen, T., et al. Effectiveness of prolonged use of continuous passive motion (CPM), as an adjunct to physiotherapy, after total need arthroplasty. BMC Muscuoskeletal Disorders 2008, 9:60. Available: http://www.biomedcentral.com/1471-2474/9/60
- 8. Hayes Health Technology Assessment: Continuous Passive Motion For Knee Indications: A Review Of Reviews. HAYES, Inc.; © 2021 Hayes, a symplr company. March 15, 2018. Annual Review: May 6, 2021.
- 9. Hayes Evidence Analysis Research: Brief Postoperative Continuous Passive Motion for Elbow Indications. HAYES, Inc.; © 2021 Hayes, a symplr company. December 18, 2020.
- 10. Hayes Technology Assessment: Continuous Passive Motion Devices For Shoulder Indications. HAYES, Inc.; © 2021 Hayes, a symplr company. May 9, 2018. Annual review June 24, 2021.
- 11. American Board of Internal Medicine's (ABIM) Foundation Choosing Wisely® Initiative. Available at URL address: https://www.choosingwisely.org
- 12. American Academy of Orthopaedic Surgeons (AAOS) Clinical Practice Guidelines. Available at URL address: https://www.aaos.org/quality/quality-programs/
- 13. Hayes Evolving Evidence Review ROMTech/PortableConnect (ROM Technologies Inc.) for Telerehabilitation Following Total Knee Arthroplasty. March 10, 2022. Annual Review 05/19/2023.

Customer Product	Medical Management Requirements*
New York Products	
HMO	Retrospective Review
PPO in Plan	Retrospective Review
PPO OOP	Retrospective Review
POS In plan	Retrospective Review
POS OOP	Retrospective Review
Essential Plan	Retrospective Review
MVP Medicaid Managed Care	Retrospective Review
MVP Child Health Plus	Retrospective Review
MVP Harmonious Health Care Plan	Retrospective Review
MVP Medicare Complete Wellness	Retrospective Review
MVP Medicare Preferred Gold HMO POS	Retrospective Review
MVP Medicare Secure HMO POS	Retrospective Review
MVP Medicare Secure Plus HMO POS	Retrospective Review
MVP Medicare WellSelect PPO	Retrospective Review
MVP Medicare WellSelect Plus PPO	Retrospective Review
MVP Medicare Patriot Plan PPO	Retrospective Review
MVP DualAccess D-SNP HMO	Retrospective Review
MVP DualAccess Complete D-SNP HMO	Retrospective Review
MVP DualAccess Plus D-SNP HMO	Retrospective Review
UVM Health Advantage Select PPO	Retrospective Review
USA Care	Potential for Retrospective Review
Healthy NY	Retrospective Review
MVP Premier	Retrospective Review
MVP Premier Plus	Retrospective Review
MVP Premier Plus HDHP	Retrospective Review
MVP Secure	Retrospective Review
MVP EPO	Retrospective Review
MVP EPO HDHP	Retrospective Review
MVP PPO	Retrospective Review
MVP PPO HDHP	Retrospective Review
Student Health Plans	Retrospective Review
ASO	See SPD
Vermont Products	
POS in Plan	Retrospective Review
POS OOP	Retrospective Review
MVP Medicare Preferred Gold HMO POS	Retrospective Review
MVP Medicare Secure Plus HMO POS	Retrospective Review
MVP VT HMO	Retrospective Review
MVP VT HDHP HMO	Retrospective Review
MVP VT Plus HMO	Retrospective Review
MVP VT Plus HDHP HMO	Retrospective Review
MVP Secure	Retrospective Review
ASO	See SPD

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review.

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Revision History

08/01/2022 – Annual Review; E0935 CPM for the knee moved to experimental investigational except for Medicare plans, references reviewed and updated.

MVP Health Care Medical Policy 08/01/2024 -Annual Review; no changes to criteria. RomTech added to exclusions. References updated.



Cosmetic and Reconstructive Services

Type of Policy: Surgical

Prior Approval Date: 10/03/2022

Approval Date: 10/07/2024

Effective Date: 12/01/2024

Related Polices: Orthognathic Surgery, Breast Implantation, Breast

Reduction Surgery, Vitiligo,

Dermabrasion, Panniculectomy and Abdominoplasty, Gender Affirming Care,

Rhinoplasty

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

(See specific MVP Medical Policy)

Codes Requiring Retrospective Review

(See specific MVP Medical Policy)

Experimental/Investigational

Experimental codes are not covered.

(See specific MVP Medical Policy)

Common Diagnosis Codes

(See specific MVP Medical Policy)

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

Cosmetic surgery and services are commonly performed as an elective procedure to enhance the looks of a body part. Reconstructive surgery is usually performed to restore functionality to a body part due to congenital or developmental abnormalities, cancer, or from trauma such as severe burns or motor vehicle crashes.

Indications/Criteria

Documentation Requirements

Documentation of the patient's medical history must be submitted indicating the medical necessity of the procedure being requested. Documentation must indicate the exact nature of the functional impairment, when applicable, and that the impairment has a significant impact on the patient's activities of daily living (ADLs – including bathing, dressing, grooming, eating, or walking). Photographs required upon request.

Cosmetic Procedures

Any service or surgery that is performed primarily to enhance the appearance of a body part is considered cosmetic in nature and will be denied as not medically necessary.

However, the treatment of complications arising from a cosmetic surgical procedure such as an infection or functional impairment will be covered.

Reconstructive Surgery

Reconstructive surgery is considered medically necessary when the following criteria are met:

- the procedure is incidental to, or follows surgery (i.e., as soon as medically feasible, or as a staged procedure) resulting from trauma, infection or other diseases; or
- there is a child with a congenital disease or anomaly that resulted in a functional defect.

Note: Please refer to specific MVP policies that may indicate criteria for a particular procedure (e.g., Orthognathic Surgery, Vitiligo, Rhinoplasty, etc.).

Please refer to MVP policy on Gender Affirming Treatment for any procedures related to gender dysphoria.

Exclusions

- Requests for services or surgeries not meeting criteria listed under Indications/Criteria of this policy.
- Any service or surgery in connection with cosmetic care, which is primarily intended to improve appearance and self-esteem, will be denied as not medically necessary.

Medicare Variation

Dermal injections for the treatment of facial lipodystrophy syndrome are indicated when all of the following criteria have been met:

- dermal fillers that are used only for treatment of facial lipodystrophy syndrome in HIV-infected individuals with depression secondary to facial lipodystrophy caused by antiretroviral HIV treatments; and
- dermal fillers must be approved by the Food and Drug Administration for the treatment of facial lipodystrophy syndrome.

References (Reviewed 2024)

- 1. New York State Insurance Department Regulation 183 (11 NYCRR 56).
- 2. New York State Insurance Department Thirty-Fifth Amendment to Regulation 62 (11 NYCRR 52).
- 3. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for Plastic Surgery to Correct "Moon Face" (140.4). Available: www.cms.gov/.
- 4. Centers for Medicare and Medicaid Services. NCD for Dermal Injections for the Treatment of Facial Lipodystrophy Syndrome (LDS) (250.5). Effective date: 03/23/2010. Available: www.cms.gov/.

Customer Product	Medical Management Requirements*
New York Products	
HMO	See Specific Policy
PPO in Plan	See Specific Policy
PPO OOP	See Specific Policy
POS in Plan	See Specific Policy
POS OOP	See Specific Policy
Essential Plan	See Specific Policy
MVP Medicaid Managed Care	See Specific Policy
MVP Child Health Plus	See Specific Policy
MVP Harmonious Health Care Plan	See Specific Policy
MVP Medicare Complete Wellness	See Specific Policy
MVP Medicare Preferred Gold HMO POS	See Specific Policy
MVP Medicare Secure HMO POS	See Specific Policy
MVP Medicare Secure Plus HMO POS	See Specific Policy
MVP Medicare WellSelect PPO	See Specific Policy
MVP Medicare WellSelect Plus PPO	See Specific Policy
MVP Medicare Patriot Plan PPO	See Specific Policy
MVP DualAccess D-SNP HMO	See Specific Policy
MVP DualAccess Complete D-SNP HMO	See Specific Policy
MVP DualAccess Plus D-SNP HMO	See Specific Policy
UVM Health Advantage Select PPO	See Specific Policy
USA Care PPO	Potential for Retrospective Review
Healthy NY	See Specific Policy
MVP Premier	See Specific Policy
MVP Premier Plus	See Specific Policy
MVP Premier Plus HDHP	See Specific Policy
MVP Secure	See Specific Policy
MVP EPO	See Specific Policy
MVP EPO HDHP	See Specific Policy
MVP PPO	See Specific Policy
MVP PPO HDHP	See Specific Policy
Student Health Plans	See Specific Policy
ASO	See SPD
Vermont Products	300 3. 2
POS In Plan	See Specific Policy
POS OOP	See Specific Policy
MVP Medicare Preferred Gold HMO POS	See Specific Policy
MVP Medicare Secure Plus HMO POS	See Specific Policy
MVP VT HMO	See Specific Policy
MVP VT HDHP HMO	See Specific Policy
MVP VT Plus HMO	See Specific Policy
MVP VT Plus HDHP HMO	See Specific Policy
MVP Secure	See Specific Policy
ASO	See SPD
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[♦] Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review
Retro Review
Retro Review
Retrospective Review Required. May be subject to Retrospective Review
Retrospective Review Required

Retrospective Review Required Service is not a covered benefit. See Specific Plan Design

Revision History

Not Covered

See SPD

12/01/2022 – Annual Review; added definition to ADLs for documentation requirements, updated references.

12/01/2024 - Annual Review with no changes to policy indications or criteria.



Court Ordered Services

Type of Policy: Medical/Behavioral

Health

 Prior Approval Date:
 11/07/2022

 Approval Date:
 11/04/2024

 Effective Date:
 02/01/2025

Related Polices: N/A

Overview

Court Ordered Services are those services ordered by a court of competent jurisdiction and performed by or under the supervision of a licensed physician, psychiatrist, psychologist, dentist, or other provider qualified under New York State Law to furnish medical, dental, behavioral health (including referrals for evaluations and treatment for mental health and/or alcohol and/or substance use or dependence), or other services included in the Medicaid Managed Care benefit package.

Guidelines

Coverage for Court Ordered Services will be provided in accordance with the benefit package, customer's certificate of coverage (COC), or Medicaid Customer Handbook.

Coverage for Court Ordered services for Exchange Plans, fully insured Commercial Plans, Child Health Plus, Essential Plans, Medicaid Managed Care (including Medicaid and MVP Harmonious Health Care Plan [HARP]) must meet the following criteria:

- Ordered services are covered services under the customer's benefit package; and
- Ordered services are determined to be medically necessary according to MVP policies as regulated by law; and
- As applicable, the court's order is based on a behavioral care evaluation
 performed by a licensed psychiatrist or a doctoral level licensed psychologist,
 which includes a diagnosis and an individual treatment plan for care in the most
 appropriate, least restrictive environment; and

Court Ordered Services Page 1 of 3

 The care is provided by an MVP Participating Provider or by a Non-Participating Provider if appropriate care is not available through the plan or as required by state law or rule.

Utilization review decisions for Court Ordered services requiring prior authorization are made within 72 hours of receipt of the authorization request.

When submitting the Certification of Court Ordered Services and request for preauthorization of such services (if applicable), a copy of the signed court order is also requested for review. The signed order, however, is not a requirement for utilization determinations or expedited review.

Exclusions

Court Ordered Services that are not a covered benefit.

Court Ordered Services that are not otherwise medically necessary are not covered.

Court ordered services as a condition of parole or probation, with the exception of Medicaid Managed Care.

Administrative Court Ordered services, such as by the Department of Motor Vehicles

Medical reports/tests prepared in connection with legal actions or law enforcement.

Forensic evaluations conducted to answer specific legal questions including but not limited to:

- Adoption evaluations
- Custody evaluations
- Education classes for driving under influence (DUI) offenses
- Parental competency evaluations
- Personal injury evaluations
- Workers' compensation evaluations

Medicare

Court Ordered Services are excluded from Medicare contracts.

Medicaid Variation

Court Ordered Services for Medicaid Managed Care Plans (including Medicaid and HARP) are covered regardless of whether the court orders such services to be provided by a participating or non-participating provider.

Prior authorization for hospital admissions is not required when the admission is pursuant to a court order, or an order of detention issued by the local commissioner or director of public health.

Court Ordered Services provided by non-participating providers are reimbursed at the Medicaid fee schedule.

References (Updated 2025)

- 1. All current MVP Contracts
- 2. Insurance Law § 4903(b)(2)
- 3. Public Health Law § 4903(2)(b)
- 4. New York State Department of Financial Services: <u>Health Insurers: Guidance</u>

 <u>Regarding Court Ordered Services for Mental Health and/or Substance Use Disorder</u>

 <u>| Department of Financial Services (ny.gov)</u>
- 5. New York State Department of Health, Office of Health Insurance Programs, Medicaid Managed Care / Family Health Plus / HIV Special Needs Plan / Health and Recovery Plan Model Contract

Revision History

2/01/2023 – Policy updated and converted from internal policy to medical policy.

02/01/2025 – Annual review with no changes to the indications or criteria.

Court Ordered Services Page 3 of 3



Cranial Orthotics

Type of Policy: DME

Prior Approval Date: 03/03/2023

Approval Date: 01/06/2025

Effective Date: 04/01/2025

Related Polices: N/A

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

N/A

Codes Requiring Retrospective Review:

N/A

Experimental/Investigational

N/A

Common Diagnosis Codes

ICD-10- CM Diagnosis Codes: Q67.3 - Plagiocephaly

Common Procedure Codes

S1040 – Cranial remolding orthotic, pediatric, rigid, custom fabricated

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

Plagiocephaly is a condition characterized an asymmetrical distortion of the skull. It is characterized by the development of a flat spot on the back or one side of the head. Many factors can cause flat spots. Most babies develop plagiocephaly by sleeping regularly in one position. Other causes of plagiocephaly include premature birth,

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MVP Health Care Medical Policy restrictive intrauterine positioning, cervical abnormalities, birth trauma, or muscular torticollis.

Indications/Criteria

Documentation Requirements

- o Anthropometric measurements of moderate to severe plagiocephaly.
- Documentation of conservative therapy as outlined in the Indications/Criteria section of policy.

Cranial Orthotics

Cranial orthotics (e.g., helmet or cranial remodeling band) are covered when either the criteria for #1 or #2 are met:

- 1. Moderate to severe plagiocephaly: cranial orthosis is initiated at 3 to 12 months of age^[10] and cranial suture is open;
 - Documentation of a 2 month trial of conservative therapy (repositioning and stretching exercises) consisting of :
 - alternating back and side sleeping
 - supervised tummy time
 - o rearranging the crib relative to the primary light source
 - o limiting time spent in a supine position
 - o limiting time in strollers, carriers and swings
 - rotating chair activity
 - neck motion exercises
 - Anthropometric measurements of moderate to severe plagiocephaly when ≥
 1 (one) of the following is met:
 - skull base asymmetry > 6 mm;
 - cranial vault asymmetry > 6 mm;
 - o orbitotragial depth asymmetry> 6 mm;
 - o cephalic index/ratio 2 standard deviations (SD) above or below the mean*
 - brachycephaly evaluation, a cephalic index of 2 standard deviations (SDs) below mean(head wide for its length)*
- 2. Following craniosynostosis surgery.

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^{*}The cephalic index is considered abnormal if it is two standard deviations (SD) above or below the mean measurements (American Academy of Orthotists and Prosthetists

(AAOP), 2004; Farkas and Munro, 1987. The indices for infants up to 12 months may be found on the following table:

Table 1
Cephalic Index

Gender; Age	-2 SD	-1 SD	Mean	+1 SD	+2 SD
Male; 16 days – 6 mths	63.7	68.7	73.7	78.7	83.7
Male; 6 – 12 Mths	64.8	71.4	78.0	84.6	91.2
Female; 16 days – 6 mths.	63.9	68.6	73.3	78.0	82.7
Female; 6 – 12 mths.	69.5	74.0	78.5	83.0	87.5

A second cranial remodeling band or helmet is considered medically necessary for children who met the aforementioned criteria at the initiation of therapy if the asymmetry has not resolved or significantly improved after 2 to 4 months such that the severity of head deformity indicates another orthosis and the orthosis becomes ill-fitting after attempts to adjust and leaves little or no room for new growth.

In addition to the indications and criteria listed above (Indications/Criteria section), the following must be met:

- Cranial remodeling helmet must be ordered by a pediatrician, pediatric surgeon, or a craniofacial surgeon.
- Documentation of medical necessity from a pediatric neurosurgeon or a craniofacial surgeon.

Exclusions

- Not meeting any criteria listed in the Indications/Criteria section of the policy.
- Cranial orthotics as the sole treatment of synostotic plagiocephaly have not been medically proven to be effective and are therefore considered not medically necessary.
- Cranial orthotics (e.g., helmets) used primarily and customarily for convenience or safety, even though they may have some remote medically related use (e.g., head protection during seizures or self-injurious behavior), are not coverage.
- The use of a cranial remodeling band or helmet without surgery to correct asymmetry in infants with synostotic plagiocephaly as experimental and investigational; craniosynostosis that is not surgically corrected is a contraindication to use of cranial remodeling bands or helmets.
- The use of sleep positioning wrap for the treatment of infants with positional head shape deformities is considered experimental and investigational because its effectiveness has not been established.

Cranial Orthotics Page 3 of 8

 Cranial orthotics (or helmets) are contraindicated and considered not medically necessary after 24 months of age.

Medicaid Variation

- The customer has moderate to severe positional head deformities associated with premature birth, restrictive intrauterine positioning, cervical abnormalities, birth trauma, torticollis and/or sleeping positions in children.
- Anthropometric measurements verify that a moderate to severe plagiocephaly is documented by a physician experienced in such measurements.
- The customer is between the ages of 3-18 months old and is considered to have a reasonable likelihood of continued skull growth.
- There is documentation of, at minimum, a 2-month trial of repositioning and stretching exercises as follows:
 - 1. Alternating back and side sleeping
 - 2. Supervised tummy time
 - 3. Rearranging the crib relative to the primary light source
 - 4. Limiting time spent in a supine position
 - 5. Limiting time in strollers, carriers and swings
 - 6. Rotating chair activity
 - 7. Neck motion exercises

Not covered for:

- Customers over the age of 24 months.
- Unmanaged hydrocephalus
- Craniosynostosis

Documentation requirements:

- A valid fiscal order signed by a pediatrician, a general surgeon with specialty in pediatrics, and/or a craniofacial surgeon.
- Anthropometric measurements.
- Documentation of medical necessity from a pediatric neurosurgeon or a craniofacial surgeon.
- Documented trial of repositioning and stretching exercises as outlined above.

Medicare

Based on review there is no Medicare Local Coverage Determination (LCD) or Medicare National Coverage Determination (NCD) for Cranial Orthotics.

Cranial Orthotics Page 4 of 8

References (Reviewed 2025)

- 1. American Academy of Orthotists & Prosthetists (AAOP). Section 7: Orthotic treatment protocols for plagiocephaly. In: Orthotic Treatment of Deformational Plagiocephaly, Brachycephaly, and Scaphocephaly. Washington, D.C: AAOP; 2013.
- 2. American Academy of Orthotists and Prosthetists (AAOP). Orthotic Treatment of Deformational Plagiocephaly, Brachycephaly and Scaphocephaly. Clinical Standards of Practice (CSOP) Consensus Conference on Orthotic Management of Plagiocephaly, 2004.
- 3. Collett BR, et al. Development in toddlers with and without deformational plagiocephaly. Arch Pediatr Adolesc Med 2011 Jul;165(7):653-8
- 4. Farkas LG, Munro IR, editors. Anthropometric facial proportions in medicine. Springfield, IL: Charles C. Thomas; 1987.
- 5. Hayes, Inc. Hayes Medical Technology Directory Report. Cranial Orthotic Devices for the Treatment of Positional Cranial Deformity. Lansdale, PA: Hayes, Inc.; July 17,2014. Annual Review: June 25, 2018. ARCHIVED August 17, 2019
- 6. <u>Hutchison BL, et al. Deformational plagiocephaly: a follow-up of head shape, parental concern, and neurodevelopment at ages 3 and 4 years. Arch Dis Child 2011;96:85-90</u>
- Hutchison BL, Stewart AW, De Chalain TB, Mitchell EA. A randomized controlled trial of positioning treatments in infants with positional head shape deformities. Acta Paediatr. 2010;99(10):1556-1560. https://www.ncbi.nlm.nih.gov/pubmed/20491708
- 8. Jimenez, DF., Barone, CM; et al, Early Management of Craniosynostosis Using Endoscopic-Assisted Strip Craniectomies and Cranial Orthotic Molding Therapy. Pediatrics. July 2002; 110/Issue 1, pp 97-104.
- 9. Kabbani, and Raghuveer, Craniosynotosis. American Family Physician 2004; 69(12):2863-2870.
- 10. Kanev, PM. Congenital malformations of the skull and meninges. Otolaryngol Clin North Am. 2007 Feb;40(1):9-26, v. Available: https://www.ncbi.nlm.nih.gov/pubmed/17346559
- 11. <u>Kluba S, et al. What is the optimal time to start helmet therapy in positional plagiocephaly?</u> Plast Reconstr Surg 2011 Aug;128(2):492-8.
- 12. Koh, JL, Gries, H., et al. Perioperative management of pediatric patients with craniosynostosis. Anesthesiol Clin. 2007 Sep;25(3):465-81, viii. Available: https://www.ncbi.nlm.nih.gov/pubmed/17884704
- 13. Laughlin, J., Luerssen, T., et al. Clinical Report. Prevention and Management of Positional Skull Deformities in Infants American Academy of Pediatrics. Pediatrics.

Cranial Orthotics Page 5 of 8

December 2011, Volume 128 / Issue 6. 1236 – 1240. Available: http://pediatrics.aappublications.org/content/early/2011/11/22/peds.2011-2220

- 14. <u>Lin RS, Stevens PM, Wininger M, Castiglione CL. Orthotic management of deformational plagiocephaly: Consensus Clinical Standards of Care. Cleft Palate Craniofac J. 2016;53(4):394-403.</u>
- 15. New York State Department of Health Medicaid Program. eMedNY. Provider Manuals. DME. DME Manual. Procedure Codes. Available: https://www.emedny.org/ProviderManuals/index.aspx

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Customer Product	Medical Management Requirements*	
New York Products		
HMO	Potential for Retrospective Review	
PPO In Plan	Potential for Retrospective Review	
PPO OOP	Potential for Retrospective Review	
POS In Plan	Potential for Retrospective Review	
POS OOP	Potential for Retrospective Review	
Essential Plan	Potential for Retrospective Review	
MVP Medicaid Managed Care	Potential for Retrospective Review	
MVP Child Health Plus	Potential for Retrospective Review	
MVP Harmonious Health Care Plan	Potential for Retrospective Review	
MVP Medicare Complete Wellness	Potential for Retrospective Review	
MVP Medicare Preferred Gold HMO POS	Potential for Retrospective Review	
MVP Medicare Secure HMO POS	Potential for Retrospective Review	
MVP Medicare Secure Plus HMO POS	Potential for Retrospective Review	
MVP Medicare WellSelect PPO	Potential for Retrospective Review	
MVP Medicare WellSelect Plus PPO	Potential for Retrospective Review	
MVP Medicare Patriot Plan PPO	Potential for Retrospective Review	
MVP DualAccess D-SNP HMO	Potential for Retrospective Review	
MVP DualAccess Complete D-SNP HMO	Potential for Retrospective Review	
MVP DualAccess Plus D-SNP HMO	Potential for Retrospective Review	
UVM Health Advantage Select PPO	Potential for Retrospective Review	
USA Care	Potential for Retrospective Review	
Healthy NY	Potential for Retrospective Review	
MVP Premier	Potential for Retrospective Review	
MVP Premier Plus	Potential for Retrospective Review	
MVP Premier Plus HDHP	Potential for Retrospective Review	
MVP Secure	Potential for Retrospective Review	
MVP EPO	Potential for Retrospective Review	
MVP EPO HDHP	Potential for Retrospective Review	
Student Health Plans	Potential for Retrospective Review	
ASO	See SPD	
Vermont Products	See Si D	
POS In Plan	Potential for Potropostico Povious	
POS OOP	Potential for Retrospective Review	
MVP Medicare Preferred Gold HMO POS	Potential for Retrospective Review Potential for Retrospective Review	
MVP Medicare Preferred Gold HMO POS MVP Medicare Secure Plus HMO POS		
MVP VT HMO	Potential for Retrospective Review	
MVP VT HMO	Potential for Retrospective Review	
	Potential for Retrospective Review	
MVP VT Plus HMO MVP VT Plus HDHP HMO	Potential for Retrospective Review	
	Potential for Retrospective Review	
MVP Secure	Potential for Retrospective Review	
ASO	See SPD	

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. Maybe subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

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MVP Health Care Medical Policy Revision History

8/1/2021 – No changes to the indications and criteria.

04/01/2023 – Removed prior authorization from HCPCS Code S1040.

04/01/2025 - Annual review with no changes to the indications or criteria. Updated references.

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Custodial Care Long Term (LT) Placement in a Nursing Home (NH) for MVP Medicaid Managed Care

Type of Policy: Medical

Prior Approval Date: 03/07/2022

Approval Date: 04/01/2024

Effective Date: 06/01/2024

Related Polices: Personal Care and Consumer Directed Services

for MVP Medicaid Managed Care

Adult Day Health Care (ADHC) Services and AIDS Adult Day

Health Care (AIDS ADHC) Services

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

All Inpatient Custodial Nursing Home Care requires Prior Authorization.

Codes Requiring Retrospective Review

N/A

Experimental/Investigational

N/A

Common Diagnosis Codes

N/A

Common Procedure Codes

N/A

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

This policy addresses MVP Health Care's medical management criteria and requirements for coverage of custodial care within a nursing home/long term nursing home (LTNH) for Medicaid Managed Care customers. Custodial and/or non-skilled services are excluded under most other plans.

Custodial care is personal care that does not require the continuing attention of trained medical or paramedical personnel. Examples of custodial care are assistance walking, assistance transferring in and out of bed, bathing, dressing, preparation of food, feeding, using the toilet, and supervision of self-administered medications.

When custodial care within the nursing home is provided in conjunction with daily skilled nursing care or restorative therapy that meets guidelines for skilled nursing facility coverage, the custodial care is covered as part of the customer's skilled nursing facility benefit. When skilled nursing facility coverage guidelines are not met, custodial care may be covered according to the criteria outlined in this policy. Examples of circumstances when custodial care is sometimes covered outside of the skilled nursing facility benefit are when the patient is directly admitted from the community, when the customer's progress with therapy has plateaued, or when the customer is transferred from the hospital without the need for skilled nursing care every day. Custodial care under this benefit may be covered in conjunction with skilled services such as speech therapy, physical therapy, occupational therapy, nursing care and medical supervision when skilled nursing facility level of care criteria is not met.

As per the Medicaid Managed Care Model Contract, MVP Health Care will provide medically necessary custodial care services to meet the Customer's needs and safety in the most integrated and least restrictive setting.

Criteria for coverage of custodial care in other settings can be found in other MVP policies such as Personal Care and Consumer Directed Services and Adult Day Health Care (ADHC) Services and AIDS Adult Day Health Care (AIDS ADHC) Services.

Indications/Criteria

As per Section 10.40 of the Medicaid Managed Care Model Contract, admission to a facility for custodial care services will be covered for qualified MVP Managed Medicaid customers when **all** of the following criteria have been met:

- The nursing home physician or clinical peer completes and submits the appropriate certification –Physician Letter of Need, (Minimum Data Set [MDS]), NYSDOH Hospital and Community Review Instrument ([HC-PRI]) and LDSS-3559 to demonstrate all the following:
 - Customer is diagnosed by a physician as having one or more clinically determined illnesses or conditions that cause the customer to be so incapacitated, sick, invalid, infirm, disabled, or convalescent as to require at least medical and nursing care.

- Ordered by the nursing home physician or clinical peer and must be based on medical necessity.
- admission to a facility for custodial care services will be covered for qualified MVP Managed Medicaid customers 21 and older.
- Customer is unable or unwilling to meet their medical and care needs; and/ or caregiver is not able or is unwilling to meet the medical care needs of the customer in the community;
- the lack of availability of services in the community to meet the Customer's medical needs,
- Customer is unsafe at home (e.g. cognitive impairments without constant supervision make the Customer unsafe at home, no working telephone, no medications or means to acquire home, fall hazards, inadequate heat, inadequate plumbing, inadequate ventilation, etc.).
- o Customer or legal guardian agrees to long-term placement.
- And placement is consistent with plan of care (documentation that includes an interdisciplinary comprehensive assessment, customer's functional impairment and the frequency and duration of particular services that must be provided to a participant.)
- documentation that includes an interdisciplinary comprehensive assessment, customer's functional impairment and the frequency and duration of particular services that must be provided to a participant.

Reassessment

For custodial care services reassessment (every 6 months or with any change in status), the medical record documentation must include:

- the Uniform Assessment System (UAS), Person Centered Service Plan (PCSP) and Plan of Care (POC); and
- an interdisciplinary comprehensive assessment; and
- appropriateness of customer's continued stay in the program; and
- the customer's needs; and
- the necessity and suitability of services provided.

The potential for transferring responsibility for the care of the customer to other more integrated and less restrictive setting must be considered. The ultimate goal is to foster a care delivery model that promotes transitional planning across the health care delivery system with the focus on providing service in the community whenever possible. Once the documentation is received and the setting is determined, the concurrent review nurse (CCRN) completes the Person-Centered Service Plan (PCSP).

Exclusions

- Not meeting criteria listed under Indications\Criteria of this policy.
- Not meeting the Institutional rules, including a review of assets.

References (2024)

- New York State Department of Health. Transition of Nursing Home Populations and Benefits to Medicaid Managed Care. March 2015. Available: https://www.health.ny.gov/health_care/medicaid/redesign/2015-02-01 population transition nursing home.htm
- New York State Department of Health. Uniform Assessment System for New York.
 Revised October 2014. Available: https://www.health.ny.gov/health_care/medicaid/redesign/uniform_assessment_system/
- 3. USLegal[™]. Definitions. Custodial Care (Health Care) Law and Legal Definition. 2015. Available: http://definitions.uslegal.com/c/custodial-care-health-care/
- 4. New York State Department of Health Medicaid Managed Care/Family Health Plus/HIV Special Needs Plan Model Contract (pdf) accessed 1/2/2020: https://www.health.ny.gov/health_care/managed_care/mamctext.htm

Customer Product	Medical Management Requirements*		
New York Products			
НМО	Not Covered		
PPO in Plan	Not Covered		
PPO OOP	Not Covered		
POS in Plan	Not Covered		
POS OOP	Not Covered		
Essential Plan	Not Covered		
MVP Medicaid Managed Care	Prior Auth		
MVP Child Health Plus	Not Covered		
MVP Harmonious Health Care Plan	Prior Auth		
MVP Medicare Complete Wellness	Not Covered		
MVP Medicare Preferred Gold HMO POS	Not Covered		
MVP Medicare Secure HMO POS	Not Covered		
MVP Medicare Secure Plus HMO POS	Not Covered		
MVP Medicare WellSelect PPO	Not Covered		
MVP Medicare WellSelect Plus PPO	Not Covered		
MVP Medicare Patriot Plan PPO	Not Covered		
MVP DualAccess D-SNP HMO	Not Covered		
MVP DualAccess Complete D-SNP HMO	Not Covered		
MVP DualAccess Plus D-SNP HMO	Not Covered		
UVM Health Advantage Select PPO	Not Covered		
USA Care	Not Covered		
Healthy NY	Not Covered		
MVP Premier	Not Covered		
MVP Premier Plus	Not Covered		
MVP Premier Plus HDHP	Not Covered		
MVP Secure	Not Covered		
MVP EPO	Not Covered		
MVP EPO HDHP	Not Covered		
MVP PPO	Not Covered		
MVP PPO HDHP	Not Covered		
Student Health Plans	Not Covered		
ASO	See SPD		
Vermont Products			
POS in Plan	Not Covered		
POS OOP	Not Covered		
MVP Medicare Preferred Gold HMO POS	Not Covered		
MVP Medicare Secure Plus HMO POS	Not Covered		
MVP VT HMO	Not Covered		
MVP VT HDHP HMO	Not Covered		
MVP VT Plus HMO	Not Covered		
MVP VT Plus HDHP HMO	Not Covered		
MVP Secure	Not Covered		
ASO	See SPD		

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review.

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Revision History

06/01/2022 – Annual Review with no changes to the indications or criteria.

06/01/2024 - Annual Review with no changes to the indications or criteria.



Deep Brain Stimulation for Movement Disorders

Type of Policy: Surgical

Prior Approval Date: 03/10/2023

Approval Date: 12/02/2024

Effective Date: 04/01/2025

Related Polices: Vagus Nerve Stimulation

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

N/A

Codes Requiring Retrospective Review

N/A

Experimental/Investigational

N/A

Common Diagnosis Codes

ICD-10-CM Diagnosis Codes: G20, G21.11, G21.19, G21.8, G24.01, G24.1, G24.3, G24.4, G24.5, G25.0, G25.1, G25.1, G25.89, G24.9

Common Procedure Codes

CPT Codes: 61863, 61864, 61867, 61868, 61880, 61885, 61886, 61888, 95836, 95961, 95962, 95976, 95977, 95983, 95984, C1767, C1778, C1787, C1816, C1822, C1883, C1897, L8679, L8680, L8681, L8682, L8683, L8685, L8686, L8687, L8688

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Deep Brain Stimulation Page 1 of 7

Overview

Deep brain stimulation refers to high-frequency electrical stimulation of anatomic regions deep within the brain utilizing neurosurgically implanted electrodes. Deep brain stimulation electrodes are placed within one or both sides of the brain.

Essential tremor is a progressive, disabling tremor most often affecting the hands. Essential tremor may also affect the head, voice, and legs. Medications are usually the first line treatments for reducing the severity of tremor. Many patients, however, do not adequately respond or cannot tolerate these medications. In these medically refractory essential tremor patients, deep brain stimulation may be helpful for symptomatic relief of tremor.

Parkinson's disease is an age-related progressive neurodegenerative disorder characterized by tremor, rigidity, bradykinesia, and progressive postural instability. For patients who are unresponsive to medical treatments and/or have intolerable side effects from medications, deep brain stimulation may be helpful for relief of symptoms.

Indications/Criteria

MVP Health Care will cover unilateral or bilateral thalamic ventral intermedius nucleus deep brain stimulation for the treatment of essential tremor and/or Parkinsonian tremor and unilateral or bilateral subthalamic nucleus or globus pallidus interna deep brain stimulation for the treatment of Parkinson's disease only under the following conditions:

 MVP Health Care will consider deep brain stimulation devices to be reasonable and necessary if they are Food and Drug Administration approved devices for deep brain stimulation or devices used in accordance with FDA approved protocols governing Category B Investigational Device Exemption deep brain stimulation clinical trials.

For thalamic ventral intermedius nucleus (VIM) Deep Brain Stimulation to be considered reasonable and necessary, patients must meet all of the following criteria:

- diagnosis of essential tremor based on postural or kinetic tremors of hand(s) without other neurologic signs, or diagnosis of idiopathic Parkinson's Disease, presence of at least two cardinal Parkinson's Disease features (tremor, rigidity, bradykinesia, and progressive postural instability), which is of a tremor-dominant form; and
- disabling tremor in the extremity intended for treatment, causing significant limitation in daily activities despite optimal medical therapy. (The patient has difficulty with feeding and drinking i.e., due to severe kinetic tremor, the patient must use a straw for drinking); and
- willingness and ability to cooperate during conscious operative procedure, as well as during post-surgical evaluations, adjustments of medications, and stimulator settings.

Deep Brain Stimulation Page 2 of 7

For subthalamic nucleus or globus pallidus interna deep brain stimulation to be considered reasonable and necessary, patients must meet all of the following criteria:

- diagnosis of Parkinson's Disease (PD) based on the presence of at least two cardinal Parkinson's Disease (PD) features (tremor, rigidity, bradykinesia, and progressive postural instability); and
- Levodopa responsive with clearly defined "on" periods; and persistent disabling Parkinson's symptoms or drug side effects (e.g., dyskinesias, motor fluctuations, or disabling "off" periods) despite optimal medical therapy; and
- willingness and ability to cooperate during conscious operative procedure, as well as during post-surgical evaluations, adjustments of medications, and stimulator settings.

The replacement/revision of a deep brain stimulator generator/battery and/or lead/electrode and/or patient programmer is considered medically necessary for an individual who meets all of the above criteria, and the existing generator/lead/programmer is no longer under warranty and cannot be repaired.

• For battery replacement, the Elective Replacement Indicator (ERI) volt level from the manufacturer must be indicated and the volt level of the battery must be at that level or lower. The average battery life is usually 3 to 5 years.

Exclusions

- There is insufficient clinical evidence to support the safety and efficacy of deep brain stimulation for all other conditions other than Parkinson's Disease and the treatment of essential tremor and is therefore considered investigational for any other indication.
- The following indications are not supported in peer reviewed literature and, therefore, are considered investigational. This list should not be considered all inclusive:
 - o non-idiopathic Parkinson's disease or "Parkinson's Plus" syndromes;
 - obsessive compulsive disorder;
 - Multiple Sclerosis (MS);
 - o post-traumatic dyskinesia; and
 - tardive dyskinesia.
 - o structural lesions such as basal ganglionic stroke, tumor, or vascular malformation as the etiology of the movement disorder.

Deep Brain Stimulation Page 3 of 7

- Patients with cognitive impairment, dementia, or depression who would be worsened by or would interfere with the patient's ability to benefit from deep brain stimulation.
- Patients with current psychosis, alcohol abuse, or other drug abuse.
- Patients with previous movement disorder surgery within the affected basal ganglion.
- Significant medical, surgical, neurologic, or orthopedic co-morbidities contraindicating deep brain surgery or stimulation.

Patients who undergo deep brain stimulation implantation should not be exposed to diathermy (deep heat treatment including shortwave diathermy, microwave diathermy and ultrasound diathermy) or any type of MRI, which may adversely affect the deep brain stimulation system or adversely affect the brain around the implanted electrodes.

Deep brain stimulation implantation should be performed with extreme caution in patients with cardiac pacemakers or other electronically controlled implants, which may adversely affect or be affected by the deep brain stimulation implantation system.

Medicare Variation

This policy follows Medicare Guidelines. For full coverage details refer to the Medicare National Coverage Decision (NCD) for Deep Brain Stimulation for Essential Tremor and Parkinson's Disease (160.24). Effective date: Apr 01, 2003. Available: Medicare Coverage Database Search

References (Reviewed 2024)

- 1. Centers for Medicare & Medicaid Services (CMS). Medicare Coverage Database. NCD for Deep Brain Stimulation for Essential Tremor and Parkinson's Disease (160.24). Effective date: Apr 01, 2003. Available: Medicare Coverage Database Search
- 2. Deuschl, G, M.D., Ph.D., Singer, C., M.D., Deep Brain Stimulation May Help in Early Stages of Parkinson's, Feb. 14, 2013, New England Journal of Medicine.
- 3. Mallet, L., Polosan, M., Nematollah, J., et al. Subthalamic nucleus stimulation in severe obsessive-compulsive disorder. N Engl J Med. 2008; 359(20):2121-2134. Available: www.nejm.org
- 4. Phillips, L., Litcofsky, K.A., Pelster, M., et al. Subthalamic Nucleus Deep Brain Stimulation Impacts Language in Early Parkinson's Disease. August 2012. PloS One. Vol 7; Issue 8; e42829.
- 5. Marjama-Lyons, J, M.D., Okun, MS, M.D. Parkinson's Disease: Guide to Deep Brain Stimulation Therapy. National Parkinson Foundation. © 2013 National Parkinson Foundation. Available: www.parkinson.org

Deep Brain Stimulation Page 4 of 7

- 6. Fahn, Tolosa, Marin Tremor rating Scale. Available: https://www.yumpu.com/en/document/view/11254127/fahn-tolosa-marin-tremor-rating-scale
- 7. Hoehn and Yahr stage or Unified Parkinson's Disease Rating Scale (UPDRS) part III motor subscale. Available: https://img.medscape.com/fullsize/701/816/58977_UPDRS.pdf
- 8. Mallet L, Polosan M, Jaafari N, et al; STOC Study Group. Subthalamic nucleus stimulation in severe obsessive-compulsive disorder. N Engl J Med. 2008;359(20):2121-2134.
- 9. Foote KD, Seignourel P, Fernandez HH, et al. Dual electrode thalamic deep brain stimulation for the treatment of posttraumatic and multiple sclerosis tremor. Neurosurgery. 2006;58(4 Suppl 2):ONS-280-285; discussion ONS-285-286
- 10. American Academy of Neurology. Evidence Based Guideline: Treatment of Tardive Syndromes: Report of the Guideline Development Subcommittee of the American Academy of Neurology. Roongroj Bhidayasiri, Stanley Fahn, William J. Weinter, et al. Neurology 2013; 81; 463-469. Reaffirmed July 16, 2016.
- 11. Hoehn M, Yahr M (1967). "Parkinsonism: onset, progression and mortality." Neurology. 17 (5): 427–42. Available: http://n.neurology.org/content/17/5/427

Customer Product	Medical Management Requirements*		
New York Products			
НМО	Potential for Retrospective Review		
PPO in Plan	Potential for Retrospective Review		
PPO OOP	Potential for Retrospective Review		
POS in Plan	Potential for Retrospective Review		
POS OOP	Potential for Retrospective Review		
Essential Plan	Potential for Retrospective Review		
MVP Medicaid Managed Care	Potential for Retrospective Review		
MVP Child Health Plus	Potential for Retrospective Review		
MVP Harmonious Health Care Plan	Potential for Retrospective Review		
MVP Medicare Complete	Potential for Retrospective Review		
MVP Medicare Preferred Gold HMO POS	Potential for Retrospective Review		
MVP Medicare Secure HMO POS	Potential for Retrospective Review		
MVP Medicare WellSelect PPO	Potential for Retrospective Review		
MVP Medicare WellSelect Plus PPO	Potential for Retrospective Review		
MVP Patriot Plan PPO	Potential for Retrospective Review		
MVP DualAccess D-SNP HMO	Potential for Retrospective Review		
MVP DualAccess Complete D-SNP HMO	Potential for Retrospective Review		
MVP DualAccess Plus D-SNP HMO	Potential for Retrospective Review		
UVM Health Advantage Select PPO	Potential for Retrospective Review		
USA Care PPO	Potential for Retrospective Review		
Healthy NY	Potential for Retrospective Review		
MVP Premier	Potential for Retrospective Review		
MVP Premier Plus	Potential for Retrospective Review		
MVP Premier Plus HDHP	Potential for Retrospective Review		
MVP Secure	Potential for Retrospective Review		
MVP EPO	Potential for Retrospective Review		
MVP EPO HDHP	Potential for Retrospective Review		
MVP PPO	Potential for Retrospective Review		
MVP PPO HDHP	Potential for Retrospective Review		
Student Health Plans	Potential for Retrospective Review		
ASO	See SPD		
Vermont Products	555 5. 5		
POS in Plan	Potential for Retrospective Review		
POS OOP	Potential for Retrospective Review		
MVP Medicare Preferred Gold HMO POS	Potential for Retrospective Review		
MVP Medicare Secure Plus HMO POS	Potential for Retrospective Review		
MVP VT HMO	Potential for Retrospective Review		
MVP VT HDHP HMO	Potential for Retrospective Review		
MVP VT Plus HMO	Potential for Retrospective Review		
MVP VT Plus HDHP HMO	Potential for Retrospective Review		
MVP Secure	Potential for Retrospective Review		
ASO	See SPD		
730	See SPD		

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g., HDHP HMO auth requirements are the same as listed for HMO).

*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

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Revision History

04/01/2021 – Annual review, updated to new format, removed prior authorization from pulse generator (61885, 61886, 61888).

04/01/2023 – Removed prior authorization. Policy title updated to reflect policy is related to movement disorders.

04/01/2025 – Annual review with no changes to the indications or criteria.

Deep Brain Stimulation Page 7 of 7



Dental Care Services
Accidental Injury to Sound Natural Teeth
Congenital Disease or Anomaly

Type of Policy: Medical

Prior Approval Date: 10/23/2023

Approval Date: 12/04/2023

Effective Date: 02/01/2024

Related Polices: Dental Care Services: Facility Services for Dental

Care

Dental Care Services: Prophylactic Dental

Extractions

Dental Care Services: Medical Care for Dental

Complications

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

N/A

Codes Subject to Retrospective Review

N/A

Experimental/Investigational

N/A

Common Diagnosis Codes

ICD-10-CM Diagnosis Codes: S02.5XXA, S02.5XXB

Common Procedure Codes

N/A

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy.

Dental Care Services
Accidental Injury to Sound and Natural Teeth

Page 1 of 6

Overview

An accidental injury is caused by an external force or element such as a blow or fall that requires immediate medical attention. Dental care for accidental injury is limited to dental treatment necessary to repair sound natural teeth. Injury to the teeth while eating is not considered an accidental injury.

A sound natural tooth is defined as one that has not been weakened by existing dental pathology such as decay or periodontal disease or has not been previously restored by a crown, inlay, onlay, porcelain restoration, or treatment by endodontics.

Contractual benefits for dental care or treatment will not be provided, except for such care or treatment due to accidental injury to sound natural teeth within twelve (12) months of the accident or when a claim is made within twelve (12) months of the accident establishing that it is medically necessary for the care to occur beyond twelve (12) months of the accident and except for dental care or treatment necessary due to congenital disease and anomaly.

Covered dental services may include procedures that will restore an injured tooth to its usual condition. Examples include, but are not limited to, emergency root canal, extraction if the tooth cannot be saved, and re-implantation of the injured tooth.

Indications/Criteria

Accidental Injury to Sound Natural Teeth Documentation Requirements

The following is required:

- documentation supporting the evidence of an accidental injury to a sound natural tooth within twelve (12) months from the date of the accidental injury stating that the customer requires dental care as a result of the accidental injury; or
- documentation from the customer's health care provider, within twelve (12) months
 from the date of the accidental injury, stating that the customer requires dental care
 as a result of the accidental injury and that it is not medically appropriate for such
 care or treatment to be provided within twelve (12) months from the date of such
 accidental injury; or
- Congenital disease or anomaly related to the teeth that have resulted in functional impairment.

Exclusions

- Not meeting contractual benefits under Indications/Criteria in this policy.
- Request for contractual benefits for dental services on teeth not damaged through an accidental injury and not meeting the definition of a sound natural tooth.

- Requests for contractual benefits for dental services to occur beyond the twelve (12) months of the accident without any documentation of medical necessity.
- Dental implants are not covered as there are other alternative treatments available and, therefore, are not considered to be medically necessary.
- Injury to the teeth while eating is not considered an accidental injury.

Medicare Variation

Dental Care services for accidental injury to sound natural teeth are not covered.

Dental Services for Medicare Advantage Products are limited to the instances listed below:

- reconstruction of a ridge if performed as a result of, and at the same time as, the surgical removal of a tumor (for other than dental purposes), the totality of surgical procedures is a covered service;
- the wiring of teeth when it is done in connection with the reduction of a jaw fracture;
- the extraction of teeth to prepare the jaw for radiation treatment of neoplastic disease is covered (refer to MVP's Dental Care Services: Prophylactic Dental Extraction policy);
- removal of a torus palatinus (a bony protuberance of the hard palate) if the procedure is not performed to prepare the mouth for dentures;
- dental splints used to treat a covered medical condition such as a dislocated upper/lower jaw joint are covered;
- outpatient facility services and observational level of care services in connection with the provision of dental services, such as the administration of anesthesia or diagnostic x-rays are only covered if the dental procedure is covered;
- inpatient hospital services in connection with dental services if the individual, because of the underlying medical conditions and clinical status or because the severity of the dental procedure, requires inpatient hospitalization,
- An oral or dental examination (not treatment) performed on an inpatient basis as part of comprehensive workup prior to renal transplant surgery or performed in a RHC/FQHC prior to a heart valve replacement.
- Routine and preventative dental services coverage is dependent on the specific plan contract.

A primary service (regardless of cause or complexity) provided for the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth (e.g.,

Dental Care Services Accidental Injury to Sound Natural Teeth

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preparation of the mouth for dentures, removal of diseased teeth in an infected jaw) are not covered, unless specifically noted above.

A secondary service that is related to the teeth or structures directly supporting the teeth unless it is incident to and an integral part of a covered primary service that is necessary to treat a non-dental condition (e.g., tumor removal) and it is performed at the same time as the covered primary service and by the same physician/dentist. In those cases in which these requirements are met and the secondary services are covered, Medicare does not make payment for the cost of dental appliances, such as dentures, even though the covered service resulted in the need for the teeth to be replaced, the cost of preparing the mouth for dentures, or the cost of directly repairing teeth or structures directly supporting teeth (e.g., alveolar process).

Medicaid Variation

As documented in the NYS Medicaid Program Dental Policy and Procedure Code Manual, Medicaid Managed Care (MMC) plan coverage now includes revisions for crowns, root canals, and dental implants and the purpose of these changes is to expand coverage of these dental services when such dental services are medically necessary. Root canals, crowns, replacement dentures and dental implants are now covered benefits. Prior authorization requests for these services may not be denied on the basis that they are not covered services.

"Medically necessary" is set forth as "medical, dental and remedial care, services and supplies..." which are necessary to prevent, diagnose, correct or cure conditions in the person that cause acute suffering, endanger life, result in illness or infirmity, interfere with such person's capacity for normal activity, or threaten some significant handicap..." - New York State Social Services Law § 365-a(2).

References (Reviewed 2023)

- 1. New York State Insurance Department. Regulation 26. 11 NYCRR Part 52. 2008.
- 2. New York State Department of Health. eMedNY. Provider Manuals: Dental. Available: https://www.emedny.org/ProviderManuals/index.aspx
- 3. Centers for Medicare and Medicaid Services. Medicare Dental Coverage Available at: https://www.cms.gov/Medicare/Coverage/MedicareDentalCoverage/index.html?redirect=/MedicareDentalCoverage/
- Centers for Medicare and Medicaid Services. Medicare Benefit Policy Manual. Chapter 15. Covered Medical and Other Health Services. Section 150 – Dental Services Effective 01/01/2023. Available at: www.cms.gov/manuals/Downloads/bp102c15.pdf

Customer Product	Medical Management Requirements*		
New York Products			
HMO	Retrospective Review		
PPO in Plan	Retrospective Review		
PPO OOP	Retrospective Review		
POS in Plan	Retrospective Review		
POS OOP	Retrospective Review		
Essential Plan	Retrospective Review		
MVP Medicaid Managed Care	Retrospective Review		
MVP Child Health Plus	Retrospective Review		
MVP Harmonious Health Care Plan	Retrospective Review		
MVP Medicare Complete Wellness	Retrospective Review		
MVP Medicare Preferred Gold HMO POS	Retrospective Review		
MVP Medicare Secure HMO POS	Retrospective Review		
MVP Medicare Secure Plus HMO POS	Retrospective Review		
MVP Medicare WellSelect PPO	Retrospective Review		
MVP Medicare WellSelect Plus PPO	Retrospective Review		
MVP Medicare Patriot Plan PPO	Retrospective Review		
MVP DualAccess D-SNP HMO	Retrospective Review		
MVP DualAccess Complete D-SNP HMO	Retrospective Review		
MVP DualAccess Plus D-SNP HMO	Retrospective Review		
UVM Health Advantage Select PPO	Retrospective Review		
USA Care PPO	Potential for Retrospective Review		
Healthy NY	Retrospective Review		
MVP Premier	Retrospective Review		
MVP Premier Plus	Retrospective Review		
MVP Premier Plus HDHP	Retrospective Review		
MVP Secure	Retrospective Review		
MVP EPO	Retrospective Review		
MVP EPO HDHP	Retrospective Review		
MVP PPO	Retrospective Review		
MVP PPO HDHP	Retrospective Review		
Student Health Plans	Retrospective Review		
ASO	See SPD		
Vermont Products			
POS in Plan	Retrospective Review		
POS OOP	Retrospective Review		
MVP Medicare Preferred Gold HMO POS	Retrospective Review		
MVP Medicare Secure Plus HMO POS	Retrospective Review		
MVP VT HMO	Retrospective Review		
MVP VT HDHP HMO	Retrospective Review		
MVP VT Plus HMO	Retrospective Review		
MVP VT Plus HDHP HMO	Retrospective Review		
MVP Secure	Retrospective Review		
ASO	See SPD		

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Revision History:

02/01/2022 – Annual Review with no changes to the indications or criteria.

10/02/2023 – Medicaid Managed Care (MMC) plan coverage now includes revisions for crowns, root canals, replacement dentures and dental implants.

Dental Care Services Accidental Injury to Sound Natural Teeth



Dental Care Services Facility Services for Dental Care

Type of Policy: Medical

Prior Approval Date: 10/23/2023

Approval Date: 12/04/2023

Effective Date: 02/01/2024

Related Polices: Dental Care Services: Accidental Injury to Sound and

Natural Teeth

Dental Care Services: Prophylactic Dental Extractions

Dental Care Services: Medical Care for Dental

Complications

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

N/A

Codes Subject to Retrospective Review

N/A

Experimental/Investigational

N/A

Common Diagnosis Codes

N/A

Common Procedure Codes

N/A

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are

Dental Care Services Facility Services for Dental Care Page 1 of 7

MVP Health Care Medical Policy subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy.

Overview

This policy addresses medical care rendered to a customer in the outpatient department or inpatient department of the hospital or ambulatory surgical center for dental services.

New York

Outpatient services for necessary dental procedures are covered only when a non-dental physical impairment or medical condition exists that makes outpatient facility services necessary to safeguard the health of the patient. This does not include outpatient facility services for anxiety or psychological reasons. MVP will cover medically necessary outpatient facility expenses but not dental professional charges.

Indications/Criteria

Documentation must be submitted for requests of medically necessary hospital or ambulatory surgical center care and administration of general anesthesia administered by a licensed anesthesiologist or certified nurse anesthetist for dental procedures performed on a covered person who is:

- a child under the age of seven years who is determined by a licensed dentist to be unable to receive needed dental treatment in an outpatient setting (in office), where the provider treating the patient certifies that due to the patient's age and the patient's condition or problem, hospitalization or general anesthesia in a hospital or ambulatory surgical center is required in order to perform significantly complex dental procedures safely and effectively; or
- a child 12 years of age or younger with documented phobias or documented mental illness, as determined by a licensed physician or a licensed mental health professional, whose dental needs are sufficiently complex and urgent that delaying or deferring treatment can be expected to result in infection, loss of teeth, or other increased oral or dental morbidity; for whom a successful result cannot be expected from dental care provided under local anesthesia; and for whom a superior result can be expected from dental care provided under general anesthesia; or
- a person who has exceptional medical circumstances or a developmental disability, as determined by a licensed physician that will place the person at serious risk.

MVP Medicaid Managed Care and Medicaid Child Health Plus

Documentation submitted for requests of medically necessary dental surgery performed in an ambulatory or inpatient setting must indicate one of the following:

 dental condition of significant dental complexity which requires certain dental procedures to be performed in a surgical day care facility or hospital setting;

Dental Care Services Facility Services for Dental Care

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- medical co-morbidity (e.g., asthma); or
- medical condition that would require use of the outpatient setting.

Exclusions

- In-plan coverage only for the New York HDHP PPO and PPO Select for accidental injury to sound natural teeth.
- Medical care rendered for dental services not meeting criteria for outpatient dental services.
- MVP Medicaid Managed Care: dental services in an emergency situation are only covered for those services performed in the emergency room.

Medicare Variation

Dental Services for Medicare Advantage Products are limited to the instances listed below:

- reconstruction of a ridge if performed as a result of, and at the same time as, the surgical removal of a tumor (for other than dental purposes), the totality of surgical procedures is a covered service;
- the wiring of teeth when it is done in connection with the reduction of a jaw fracture;
- the extraction of teeth to prepare the jaw for radiation treatment of neoplastic disease is covered (refer to MVP's Dental Care Services: Prophylactic Dental Extraction policy);
- removal of a torus palatinus (a bony protuberance of the hard palate) if the procedure is not performed to prepare the mouth for dentures;
- dental splints used to treat a covered medical condition such as a dislocated upper/lower jaw joint are covered;
- outpatient facility services and observational level of care services in connection
 with the provision of dental services, such as the administration of anesthesia or
 diagnostic x-rays are only covered if the dental procedure is covered;
- inpatient hospital services in connection with dental services if the individual, because of the underlying medical conditions and clinical status or because the severity of the dental procedure, requires inpatient hospitalization,
- An oral or dental examination (not treatment) performed on an inpatient basis as part of comprehensive workup prior to renal transplant surgery or performed in a RHC/FQHC prior to a heart valve replacement.

A primary service (regardless of cause or complexity) provided for the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth (e.g.,

Dental Care Services Facility Services for Dental Care

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preparation of the mouth for dentures, removal of diseased teeth in an infected jaw) are not covered, unless specifically noted above.

A secondary service that is related to the teeth or structures directly supporting the teeth unless it is incident to and an integral part of a covered primary service that is necessary to treat a non-dental condition (e.g., tumor removal) and it is performed at the same time as the covered primary service and by the same physician/dentist. In those cases in which these requirements are met and the secondary services are covered, Medicare does not make payment for the cost of dental appliances, such as dentures, even though the covered service resulted in the need for the teeth to be replaced, the cost of preparing the mouth for dentures, or the cost of directly repairing teeth or structures directly supporting teeth (e.g., alveolar process).

Routine and preventative dental services coverage is dependent on the specific plan contract.

MVP Medicaid Managed Care and Medicaid Child Health Plus Variation

Dental surgery performed in an ambulatory or inpatient setting is a plan benefit when due to the complexity of the procedure or when sedation is needed for customer management. Hospitalization charges for general anesthesia services is a plan benefit when due to the complexity of the procedure or when sedation is needed for customer management. Dental anesthesia services rendered must adhere to the dental anesthesia definitions, practice requirements, record keeping standards, certifications, training and education requirements required by New York State Education Department.

As documented in the NYS Medicaid Program Dental Policy and Procedure Code Manual, Medicaid Managed Care (MMC) plan coverage now includes revisions for crowns, root canals, and dental implants and the purpose of these changes is to expand coverage of these dental services when such dental services are medically necessary. Root canals, crowns, replacement dentures and dental implants are now covered benefits. Prior authorization requests for these services may not be denied on the basis that they are not covered services.

"Medically necessary" is set forth as "medical, dental and remedial care, services and supplies..." which are necessary to prevent, diagnose, correct or cure conditions in the person that cause acute suffering, endanger life, result in illness or infirmity, interfere with such person's capacity for normal activity, or threaten some significant handicap..." - New York State Social Services Law § 365-a(2).

References (Reviewed 2023)

Centers for Medicare and Medicaid Services. Medicare Dental Coverage (2013).
 Available:

Dental Care Services Facility Services for Dental Care

- https://www.cms.gov/Medicare/Coverage/MedicareDentalCoverage/index.html?redirect=/MedicareDentalCoverage/
- 2. Centers for Medicare and Medicaid Services. Medicare Benefit Policy Manual Chapter 15- Covered Medical and Other Health Services 150-Dental Services https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-loms-Items/Cms012673.html
- 3. New York State Department of Health Provider Manuals. Dental Manual. Available: https://www.emedny.org/ProviderManuals/Dental/index.aspx

Customer Product	Medical Management Requirements*	
New York Products		
HMO	Potential for Retrospective Review	
PPO in Plan	Potential for Retrospective Review	
PPO OOP	Potential for Retrospective Review	
POS in Plan	Potential for Retrospective Review	
POS OOP	Potential for Retrospective Review	
Essential Plan	Potential for Retrospective Review	
MVP Medicaid Managed Care	Potential for Retrospective Review	
MVP Child Health Plus	Potential for Retrospective Review	
MVP Harmonious Health Care Plan	Potential for Retrospective Review	
MVP Medicare Complete Wellness	Prior Auth	
MVP Preferred Gold HMO POS	Prior Auth	
MVP Medicare Secure HMO POS	Prior Auth	
MVP Medicare Secure Plus HMO POS	Prior Auth	
MVP Medicare WellSelect PPO	Prior Auth	
MVP Medicare WellSelect Plus PPO	Prior Auth	
MVP Medicare Patriot Plan PPO	Prior Auth	
MVP DualAccess D-SNP HMO	Prior Auth	
MVP DualAccess Complete D-SNP HMO	Prior Auth	
MVP DualAccess Plus D-SNP HMO	Prior Auth	
UVM Health Advantage Select PPO	Prior Auth	
USA Care PPO	Potential for Retrospective Review	
Healthy NY	Potential for Retrospective Review	
MVP Premier	Potential for Retrospective Review	
MVP Premier Plus	Potential for Retrospective Review	
MVP Premier Plus HDHP	Potential for Retrospective Review	
MVP Secure	Potential for Retrospective Review	
MVP EPO	Potential for Retrospective Review	
MVP EPO HDHP	Potential for Retrospective Review	
MVP PPO	Potential for Retrospective Review	
MVP PPO HDHP	Potential for Retrospective Review	
Student Health Plans	Potential for Retrospective Review	
ASO	See SPD	
Vermont Products	See SFD	
POS in Plan	Potential for Retrospective Review	
POS OOP	Potential for Retrospective Review	
MVP Medicare Preferred Gold HMO POS	Potential for Retrospective Review	
MVP Medicare Secure Plus HMO POS	Potential for Retrospective Review	
MVP VT HMO	Potential for Retrospective Review	
MVP VT HIMO	Potential for Retrospective Review Potential for Retrospective Review	
MVP VT Plus HMO	Potential for Retrospective Review Potential for Retrospective Review	
MVP VT Plus HDHP HMO	Potential for Retrospective Review	
MVP Secure	Potential for Retrospective Review	
ASO	See SPD	
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[♦] Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

*Medical Management Requirements

Prior Auth
Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

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MVP Health Care Medical Policy Revision History:

02/01/2022 – Annual Review with no changes to the indications or criteria.

06/01/2023 - 41899 - Unlisted procedure, dentoalveolar structures is no longer going to be reviewed for Commercial, Medicaid and ASO plans with coverage being added to medically necessary administration of general anesthesia and dental procedures.

10/02/2023 – Medicaid Managed Care (MMC) plan coverage now includes revisions for crowns, root canals, replacement dentures and dental implants. Removed exclusions for ASO groups and plans that are no longer available.



Dental Care Services
Medical Services for Complications
of Dental Problems

Type of Policy: Medical

Prior Approval Date: 03/06/2023

Approval Date: 03/28/2025

Effective Date: 06/01/2025

Related Polices: Dental Care Services: Accidental Injury to Sound and

Natural Teeth

Dental Care Services: Prophylactic Dental Extractions Dental Care Services: Facility Services for Dental Care

Emergency Department Services

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

N/A

Codes Subject to Retrospective Review

N/A

Experimental/Investigational

N/A

Common Diagnosis Codes

N/A

Common Procedure Codes

N/A

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy.

Overview

Dental Care Services Page 1 of 6
Medical Services for Complications of Dental Problems

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MVP does not provide benefits for any services related to dental care or treatment except under the limited circumstances described within this policy.

Medical complications related to dental problems or treatment may require medical care. Medical services for dental problems typically are treated by a dentist. However, on occasion, when the etiology of the medical complication is not clear and the onset of the medical condition is sudden, acute or severe, treatment may be rendered in an emergency room or in the primary care physician's (PCP) office. The PCP may refer to the appropriate in-plan specialist.

For accidental injury or trauma to teeth, refer to the MVP Dental Care Services: Accidental Injury to Sound and Natural Teeth medical policy.

Documentation Requirements

Documentation of the medical problem must include:

- nature, acuity of symptoms, date of onset, and oral examination; and
- treatment of the problems must be rendered by a qualified provider.

Indications/Criteria

Medical complications related to dental problems treated in the emergency room are covered when a prudent layperson considers the symptom(s) would result in serious impairment, dysfunction, disfigurement, or serious health consequences. Examples of medical complications that are related to dental problems may include facial cellulitis, fever, or the sudden onset of severe jaw pain of unclear etiology.

Exclusions

- Any requests not meeting the above criteria.
- Coverage is limited to the treatment of the medical complication only.
- The following dental related circumstances are not covered:
 - definite dental problem appropriate for a dental office in which care could have been provided in a dental office or in which care would have been practical for a dental office are not covered; or
 - the causes of the symptoms are dental in origin and have been present for greater than one week.

Medicare Variation

Dental Services for Medicare Advantage Products:

 reconstruction of a ridge if performed as a result of, and at the same time as, the surgical removal of a tumor (for other than dental purposes), the totality of surgical procedures is a covered service;

- the wiring of teeth when it is done in connection with the reduction of a jaw fracture:
- the extraction of teeth to prepare the jaw for radiation treatment of neoplastic disease is covered (refer to MVP's Dental Care Services: Prophylactic Dental Extraction policy);
- removal of a torus palatinus (a bony protuberance of the hard palate) if the procedure is not performed to prepare the mouth for dentures;
- dental splints used to treat a covered medical condition such as a dislocated upper/lower jaw joint are covered;
- outpatient facility services and observational level of care services in connection
 with the provision of dental services, such as the administration of anesthesia or
 diagnostic x-rays are only covered if the dental procedure is covered;
- inpatient hospital services in connection with the provision of dental services if the individual, because of his/her underlying medical conditions and clinical status, or because the severity of the dental procedure, requires hospitalization in connection with the provision of dental services;
- dental examinations and treatments performed to eliminate infection preceding an organ transplant surgery or when performed prior to a heart valve replacement.
- Routine and preventative dental services coverage is dependent on the specific plan contract.

The following two categories of services are excluded from Medicare coverage:

A primary service (regardless of cause or complexity) provided for the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth (e.g., preparation of the mouth for dentures, removal of diseased teeth in an infected jaw) are not covered, unless specifically noted above.

A secondary service that is related to the teeth or structures directly supporting the teeth unless it is incident to and an integral part of a covered primary service that is necessary to treat a non-dental condition (e.g., tumor removal) and it is performed at the same time as the covered primary service and by the same physician/dentist. In those cases in which these requirements are met and the secondary services are covered, Medicare does not make payment for the cost of dental appliances, such as dentures, even though the covered service resulted in the need for the teeth to be replaced, the cost of preparing the mouth for dentures, or the cost of directly repairing teeth or structures directly supporting teeth (e.g., alveolar process).

References (Reviewed 2025)

Centers for Medicare and Medicaid Services. Medicare Dental Coverage (2013).
 Available:

Dental Care Services
Medical Services for Complications of Dental Care

https://www.cms.gov/Medicare/Coverage/MedicareDentalCoverage/index.html?redirect=/MedicareDentalCoverage/

- Centers for Medicare and Medicaid Services. Medicare Benefit Policy Manual Chapter 15- Covered Medical and Other Health Services 150-Dental Serviceshttps:https://www.cms.gov/Regulations-and-guidance/Manuals/downloads/bp102c15.pdf
- Centers for Medicare and Medicaid Services, Medicare National Coverage
 Determinations. Pub 100-01, the Medicare General Information, Eligibility, and
 Entitlement Manual, Chapter 5, Definitions and Pub 3. Available:
 https://www.cms.gov/Regulations-and-Guidance/Manuals/downloads/ge101c05.pdf
- 4. Centers for Medicare and Medicaid Services (CMS) Press Release: HHS Finalizes Physician Payment Rule Strengthening Access to Behavioral Health Services and Whole-Person Care November 1, 2022 Available: <u>Finalizing Payment for Dental Services that are Integral to Covered Medical Services</u>

Customer Product	Medical Management Requirements*
New York Products	
HMO	Retrospective Review
PPO in Plan	Retrospective Review
PPO OOP	Retrospective Review
POS in Plan	Retrospective Review
POS OOP	Retrospective Review
Essential Plan	Retrospective Review
MVP Medicaid Managed Care	Retrospective Review
MVP Child Health Plus	Retrospective Review
MVP Harmonious Health Care Plan	Retrospective Review
MVP Medicare Complete Wellness	Retrospective Review
MVP Medicare Preferred Gold HMO POS	Retrospective Review
MVP Medicare Secure HMO POS	Retrospective Review
MVP Medicare Secure Plus HMO POS	Retrospective Review
MVP Medicare WellSelect PPO	Retrospective Review
MVP Medicare WellSelect Plus PPO	Retrospective Review
MVP Medicare Patriot Plan PPO	Retrospective Review
MVP DualAccess D-SNP HMO	Retrospective Review
MVP DualAccess Complete D-SNP HMO	Retrospective Review
MVP DualAccess Plus D-SNP HMO	Retrospective Review
UVM Health Advantage Select PPO	Retrospective Review
USA Care PPO	Potential for Retrospective Review
Healthy NY	Retrospective Review
MVP Premier	Retrospective Review
MVP Premier Plus	Retrospective Review
MVP Premier Plus HDHP	Retrospective Review
MVP Secure	Retrospective Review
MVP EPO	Retrospective Review
MVP EPO HDHP	Retrospective Review
MVP PPO	Retrospective Review
MVP PPO HDHP	Retrospective Review
Student Health Plans	Retrospective Review
ASO	See SPD
Vermont Products	
POS in Plan	Retrospective Review
POS OOP	Retrospective Review
MVP Medicare Preferred Gold HMO POS	Retrospective Review
MVP Medicare Secure Plus HMO POS	Retrospective Review
MVP VT HMO	Retrospective Review
MVP VT HDHP HMO	Retrospective Review
MVP VT Plus HMO	Retrospective Review
MVP VT Plus HDHP HMO	Retrospective Review
MVP Secure	Retrospective Review
ASO	See SPD

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Revision History:

02/01/2022 – Annual Review with no changes to the indications or criteria.

04/01/2023 – Added coverage to Medicare variation for coverage of dental examinations and treatments to eliminate infection preceding an organ transplant and for certain cardiac procedures.

06/01/2025 – Annual review no changes to indications or criteria.



Dental Care Services Prophylactic Dental Extractions

Type of Policy: Medical

Prior Approval Date: 12/06/2021

Approval Date: 11/06/2023

Effective Date: 02/01/2024

Related Polices: Dental Care Services: Accidental Injury to Sound and Natural

Teeth

Dental Care Services: Medical Services for Complications of

Dental Care

Dental Care Services: Facility Services for Dental Care

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

N/A

Codes Subject to Retrospective Review

N/A

Experimental/Investigational

N/A

Common Diagnosis Codes

N/A

Common Procedure Codes

N/A

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy.

Overview

Dental services performed by a dentist or other physician may be required for the extraction of teeth to prepare the mandible and maxilla for radiation treatments. The long-term effects of radiation therapy of the mouth and neck result in altering the quality and quantity of salivary flow. This alteration increases the formation of dental caries, which increases the risk of osteonecrosis. It is recommended that all dental therapies, including extractions, are completed two to three weeks in advance of radiation therapy.

Medical Record Documentation

The medical record must document the following:

- pre-dental examination to identify potential problems;
- diagnosis of the patient;
- the sole reason for seeking this service is to comply with the medical treatment plan;
 and
- start date for radiation therapy

Indications/Criteria

Coverage will be considered for the extraction of teeth when the services are a prerequisite of radiation therapy.

Exclusions

Not meeting criteria under Indications/Criteria in this policy.

Oral examinations are covered prior to kidney transplantation or heart valve replacement but treatment for dental issues is not covered.

Medicare Variation

Dental Services for MVP Medicare Advantage Products are limited to the instances listed below:

- reconstruction of a dental ridge if performed as a result of, and at the same time
 as, the surgical removal of a tumor (for other than dental purposes), the totality
 of surgical procedures is a covered service;
- the wiring of teeth when it is done in connection with the reduction of a jaw fracture;
- the extraction of teeth to prepare the jaw for radiation treatment for cancer is covered;

- removal of a torus palatinus (a bony protuberance of the hard palate) if the procedure is not performed to prepare the mouth for dentures;
- dental splints used to treat a covered medical condition such as a dislocated upper/lower jaw joint are covered;
- outpatient facility services and observational level of care services in connection with the provision of dental services, such as the administration of anesthesia or diagnostic x-rays are only covered if the dental procedure is covered;
- inpatient hospital services in connection with the provision of dental services if the individual, because of his/her underlying medical conditions and clinical status, or because the severity of the dental procedure, requires hospitalization in connection with the provision of dental services, or
- An oral or dental examination (not treatment) performed on an inpatient basis as part of comprehensive workup prior to renal transplant surgery or performed in a RHC/FQHC prior to a heart valve replacement.
- Routine and preventative dental services coverage is dependent on the specific plan contract.

A primary service (regardless of cause or complexity) provided for the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth (e.g., preparation of the mouth for dentures, removal of diseased teeth in an infected jaw) are not covered, unless specifically noted above.

A secondary service that is related to the teeth or structures directly supporting the teeth unless it is incident to and an integral part of a covered primary service that is necessary to treat a non-dental condition (e.g., tumor removal) and it is performed at the same time as the covered primary service and by the same physician/dentist. In those cases in which these requirements are met and the secondary services are covered, Medicare does not make payment for the cost of dental appliances, such as dentures, even though the covered service resulted in the need for the teeth to be replaced, the cost of preparing the mouth for dentures, or the cost of directly repairing teeth or structures directly supporting teeth (e.g., alveolar process).

References (Reviewed 2023)

- Centers for Medicare and Medicaid Services. Medicare Dental Coverage Available at: https://www.cms.gov/Medicare/Coverage/MedicareDentalCoverage/index.html?redirect=/MedicareDentalCoverage/
- Centers for Medicare and Medicaid Services. Medicare Benefit Policy Manual. Chapter 15. Covered Medical and Other Health Services. Section 150 – Dental Services Rev. Effective 01/01/2023 Available at: www.cms.gov/manuals/Downloads/bp102c15.pdf

Customer Product	Medical Management Requirements*
New York Products	
HMO	Retrospective Review
PPO in Plan	Retrospective Review
PPO OOP	Retrospective Review
POS in Plan	Retrospective Review
POS OOP	Retrospective Review
Essential Plan	Retrospective Review
MVP Medicaid Managed Care	Retrospective Review
MVP Child Health Plus	Retrospective Review
MVP Harmonious Health Care Plan	Retrospective Review
MVP Medicare Complete Wellness	Retrospective Review
MVP Medicare Preferred Gold HMO POS Plus	Retrospective Review
MVP Medicare Secure HMO POS	Retrospective Review
MVP Medicare Secure Plus HMO POS	Retrospective Review
MVP Medicare WellSelect PPO	Retrospective Review
MVP Medicare WellSelect Plus PPO	Retrospective Review
MVP Medicare Patriot Plan PPO	Retrospective Review
MVP DualAccess D-SNP HMO	Retrospective Review
MVP DualAccess Complete D-SNP HMO	Retrospective Review
MVP DualAccess Plus D-SNP HMO	Retrospective Review
UVM Health Advantage Select PPO	Retrospective Review
USA Care PPO	Potential for Retrospective Review
Healthy NY	Retrospective Review
MVP Premier	Retrospective Review
MVP Premier Plus	Retrospective Review
MVP Premier Plus HDHP	Retrospective Review
MVP Secure	Retrospective Review
MVP EPO	Retrospective Review
MVP EPO HDHP	Retrospective Review
MVP PPO	Retrospective Review
MVP PPO HDHP	Retrospective Review
Student Health Plans	Retrospective Review
ASO	See SPD
Vermont Products	
POS in Plan	Retrospective Review
POS OOP	Retrospective Review
MVP Medicare Preferred Gold HMO POS	Retrospective Review
MVP Medicare Secure Plus HMO POS	Retrospective Review
MVP VT HMO	Retrospective Review
MVP VT HDHP HMO	Retrospective Review
MVP VT Plus HMO	Retrospective Review
MVP VT Plus HDHP HMO	Retrospective Review
MVP Secure	Retrospective Review

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

*Medical Management Requirements

Prior Auth

Potential for Retrospective Review No Prior Authorization Required. Maybe subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

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MVP Health Care Medical Policy Revision History:

02/01/2022 – Annual Review with no changes to the indications or criteria.

02/01/2024 – Annual review with no changes to the indications or criteria. Medicare variation and references reviewed.



Dermabrasion

Type of Policy: Surgical

Prior Approval Date: 10/03/2022

Approval Date: 10/07/2024

Effective Date: 12/01/2024

Related Polices: Cosmetic and

Reconstructive Services

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

N/A

Codes Requiring Retrospective Review

N/A

Experimental/Investigational/Cosmetic

15780 - Dermabrasion; total face (eg, for acne scarring, fine wrinkling, rhytids, general keratosis)

15781 - Dermabrasion; segmental, face

15782 – Dermabrasion; regional, other than face

15783 - Dermabrasion; superficial, any site (eg, tattoo removal)

Common Diagnosis Codes

ICD-10 code: L57.0

Common Procedure Codes

CPT Codes: N/A

Dermabrasion Page 1 of 4

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

Dermabrasion is a surgical procedure to remove superficial scars from the face and neck caused by cystic acne, other dermatological conditions (e.g., selected growths) as well as injury or trauma (e.g., automobile accident or other traumatic event).

Indications/Criteria

Dermabrasion is a commonly used method to treat the surface of the skin in order to improve its appearance. Any procedure that is solely utilized to enhance the skin's appearance is considered to be cosmetic in nature and is not medically necessary.

Medical literature does not support the use of dermabrasion for restoration of a functional deficit since more effective alternative treatments with far fewer potential side effects are currently available.

Exclusions

N/A

Medicare Variation

Dermabrasion as a treatment for actinic keratosis is covered without restrictions based on lesion or patient characteristics.

15781 - Dermabrasion; segmental, face, 15782 – Dermabrasion; regional, other than face, 15783 - Dermabrasion; superficial, any site (eg, tattoo removal) are covered for Medicare plans when billed with a diagnosis of L57.0.

This determination is based on the Medicare National Coverage Determination (NCD) Treatment of Actinic Keratosis (250.4) for coverage conditions available at: https://www.cms.gov/medicare-coverage-database/search.aspx

References (Reviewed 2024)

- 1. American Society of Plastic Surgeons (ASPS). Dermabrasion. Available: www.plasticsurgery.org
- 2. Centers for Medicare & Medicaid Services (CMS). National Coverage Determination. Treatment of actinic keratosis (250.4). https://www.cms.gov. Published November 26, 2001.

Customer Product	Medical Management Requirements*
New York Products	-
НМО	Potential for Retrospective Review
PPO in Plan	Potential for Retrospective Review
PPO OOP	Potential for Retrospective Review
POS in Plan	Potential for Retrospective Review
POS OOP	Potential for Retrospective Review
Essential Plan	Potential for Retrospective Review
MVP Medicaid Managed Care	Potential for Retrospective Review
MVP Child Health Plus	Potential for Retrospective Review
MVP Harmonious Health Care Plan	Potential for Retrospective Review
MVP Medicare Complete Wellness	Potential for Retrospective Review
MVP Medicare Preferred Gold HMO POS	Potential for Retrospective Review
MVP Medicare Secure HMO POS	Potential for Retrospective Review
MVP Medicare Secure Plus HMO POS	Potential for Retrospective Review
MVP Medicare WellSelect PPO	Potential for Retrospective Review
MVP Medicare WellSelect Plus PPO	Potential for Retrospective Review
MVP Medicare Patriot Plan PPO	Potential for Retrospective Review
MVP DualAccess D-SNP HMO	Potential for Retrospective Review
MVP DualAccess Complete D-SNP HMO	Potential for Retrospective Review
MVP DualAccess Plus D-SNP HMO	Potential for Retrospective Review
UVM Health Advantage Select PPO	Potential for Retrospective Review
USA Care PPO	Potential for Retrospective Review
Healthy NY	Potential for Retrospective Review
MVP Premier	Potential for Retrospective Review
MVP Premier Plus	Potential for Retrospective Review
MVP Premier Plus HDHP	Potential for Retrospective Review
MVP Secure	Potential for Retrospective Review
MVP EPO	Potential for Retrospective Review
MVP EPO HDHP	Potential for Retrospective Review
MVP PPO	Potential for Retrospective Review
MVP PPO HDHP	Potential for Retrospective Review
Student Health Plans	Potential for Retrospective Review
ASO	See SPD
Vermont Products	
POS in Plan	Potential for Retrospective Review
POS OOP	Potential for Retrospective Review
MVP Medicare Preferred Gold HMO POS	Potential for Retrospective Review
MVP Medicare Secure Plus HMO POS	Potential for Retrospective Review
MVP VT HMO	Potential for Retrospective Review
MVP VT HDHP HMO	Potential for Retrospective Review
MVP VT Plus HMO	Potential for Retrospective Review
MVP VT Plus HDHP HMO	Potential for Retrospective Review
MVP Secure	Potential for Retrospective Review
ASO	See SPD

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Revision History:

12/01/2022 – updated annual policy, corrected typographical error by moving codes from Common Procedure Codes section to under experimental, investigational, cosmetic review, added Medicare NCD.

12/01/2024 – Annual review with no changes to policy indications or criteria. Updated links in policy references.

Dermabrasion Page 4 of 4



Digital Therapeutics

Type of Policy: Medical/Behavioral Health

Prior Approval Date: n/a

Approval Date: 07/03/2023

Effective Date: 12/01/2023

Related Polices: Biofeedback Therapy

Durable Medical Equipment

(Includes Prosthetics & Orthotics)

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

HCPCS/CPT codes	Code Description
A9291	Prescription digital behavioral therapy, per course of treatment
E1905	Virtual reality cognitive behavioral therapy device (CBT), including pre-programmed therapy software

Codes Requiring Retrospective Review

Experimental/Investigational

HCPCS/CPT codes	Code Description
A9291	Prescription digital behavioral therapy, per course of treatment
Virtual reality cognitive behavioral therapy device (CBT), including pre-programmed therapy software	

Digital Therapeutics Page 1 of 7

0710T	Motor-cognitive, semi-immersive virtual reality facilitated gait	
0719T	training, each 15 minutes	
0740T	Remote autonomous algorithm-based recommendation system for	
	insulin dose calculation and titration; initial set-up and patient	
	education	
	Remote autonomous algorithm-based recommendation system for	
0741T	insulin dose calculation and titration; provision of software, data	
	collection, transmission, and storage, each 30 days	
0770T	Virtual reality technology to assist therapy (List separately in	
07701	addition to code for primary procedure)	
	Virtual reality (VR) procedural dissociation services provided by the	
	same physician or other qualified health care professional	
	performing the diagnostic or therapeutic service that the VR	
0771T	procedural dissociation supports, requiring the presence of an	
07711	independent, trained observer to assist in the monitoring of the	
	patient's level of dissociation or consciousness and physiological	
	status; initial 15 minutes of intraservice time, patient age 5 years or	
	older	
	Virtual reality (VR) procedural dissociation services provided by the	
	same physician or other qualified health care professional	
	performing the diagnostic or therapeutic service that the VR	
0772T	procedural dissociation supports, requiring the presence of an	
07721	independent, trained observer to assist in the monitoring of the	
	patient's level of dissociation or consciousness and physiological	
	status; each additional 15 minutes intraservice time (List separately	
	in addition to code for primary service)	
	Virtual reality (VR) procedural dissociation services provided by a	
	physician or other qualified health care professional other than the	
0773T	physician or other qualified health care professional performing the	
07731	diagnostic or therapeutic service that the VR procedural	
	dissociation supports; initial 15 minutes of intraservice time, patient	
	age 5 years or older	
0774T	Virtual reality (VR) procedural dissociation services provided by a	
	physician or other qualified health care professional other than the	
	physician or other qualified health care professional performing the	
	diagnostic or therapeutic service that the VR procedural	
	dissociation supports; each additional 15 minutes intraservice time	
	(List separately in addition to code for primary service	
0791T	Motor-cognitive, semi-immersive virtual reality-facilitated gait	
	training, each 15 minutes	

Digital Therapeutics Page 2 of 7

Common Diagnosis Codes

N/A

Common Diagnosis Codes associated with this policy have been provided for informational purposes only. The list of codes may not be all-inclusive and may be updated to reflect any applicable revisions to the ICD-10 code set and/or medical necessity quidelines applied in this policy.

Common Procedure Codes

CPT Codes: N/A

HCPCS Codes: N/A

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

Digital therapeutics is a growing industry that uses prescription or nonprescription interventions that can be delivered via software used alone or in conjunction with medications of medical devices.

Digital therapeutics include artificial intelligence (AI), augmented (AR) and virtual reality (VR) and mobile health applications (MMA).

Artificial intelligence uses computer systems, databases and algorithms to problem solve and make decisions by imitating human abilities.

Augmented (AR) and virtual reality (VR) uses computer simulation and modeling to provide an artificial three-dimensional environment that can be interacted with.

Mobile health applications are programs developed for the use on mobile devices.

Indications/Criteria

The following digital therapeutics will be considered to be experimental and investigational because there is insufficient evidence in published peer-reviewed literature, please note this list is not inclusive:

- BlueStar Rx
- Canvas Dx
- CureSight
- D-Nav
- Drowzle Pro
- Endeavor Rx
- Freespira

- Halo AF Detection System
- Insulia
- leva Pelvic Health System
- Mahana IBS
- MindMotion GO
- My Dose Coach

Digital Therapeutics Page 3 of 7

- myVisionTrack (Home Vision Monitor- HVM)
- Nerivio
- NightWare
- Parallel

- Regulora
- RelieVRx
- reSet
- reSet-O
- Somryst

Exclusions

No specific exclusions noted.

References (2023)

- 1. Hayes, Inc. Evidence Analysis Research Brief. RelieVRx (AppliedVR Inc) for management of low back pain. Published April 11, 2022.
- 2. Hayes, Inc. Evidence Analysis Research Brief. Outpatient Virtual Reality-Based Rehabilitation of the Lower Extremities After Stroke. Published March 2, 2022.
- 3. Hayes, Inc. Health Technology Assessment. Prescription Digital Therapeutics for Management of Type 2 Diabetes Mellitus. Published March 14, 2022.
- 4. Hayes, Inc. Health Technology Assessment. Prescription Digital Therapeutics for Management of Type 1 Diabetes Mellitus. Published March 1, 2022.
- 5. Hayes, Inc. Evolving Evidence Review. Freespira Digital Therapeutic (Freespira Inc.) for Treatment of Panic Disorder. Published May 3, 2022.
- 6. Hayes, Inc. Evidence Analysis Research Brief. Freespira Digital Therapeutic (Freespira Inc.) for Treatment of Posttraumatic Stress Disorder. Published August 4, 2022.
- 7. Hayes, Inc. Evidence Analysis Research Brief. Regulora (metaMe Health Inc.) for Treatment of Irritable Bowel Syndrome. Published January 23,2023.
- 8. Hayes, Inc. Evolving Evidence Review. EndeavorRx (Akili Interactive Labs Inc.) for Treatment of Attention-Deficit/Hyperactivity Disorder in Children. Published May 3, 2022.
- 9. Hayes, Inc. Evolving Evidence Review. EndeavorRx (Akili Interactive Labs Inc.) for Treatment of Attention-Deficit/Hyperactivity Disorder in Children. Published May 3, 2022.
- 10. Hayes, Inc. Evidence Analysis Research Brief. CureSight for Treatment of Amblyopia in Children. Published November 8, 2022.
- 11. Hayes, Inc. Evolving Evidence Review. Mahana IBS (Mahana Therapeutics Inc.) for Treatment of Irritable Bowel Syndrome. Published June 23, 2022.
- 12. Hayes, Inc. Evolving Evidence Review. leva Pelvic Health System (Renovia Inc.) for Treatment of Urinary Incontinence. Published January 13, 2023.

Digital Therapeutics Page 4 of 7

- 13. Hayes, Inc. Health Technology Assessment. Mobile Medical Applications for Substance Use Disorder. Published May 7, 2021.
- 14. US Food & Drug Administration (FDA). Augmented Reality and Virtual Reality in Medical Devices. https://www.fda.gov. Published September 28, 2022.
- 15. US Food & Drug Administration (FDA). Policy for device software functions and mobile medical applications: guidance for industry and Food and Drug Administration staff. https://www.fda.gov. Published September 28, 2022.

Digital Therapeutics Page 5 of 7

Member Product	Medical Management Requirements*
New York Products	-
HMO	Retrospective Review E&I
PPO in Plan	Retrospective Review E&I
PPO OOP	Retrospective Review E&I
POS in Plan	Retrospective Review E&I
POS OOP	Retrospective Review E&I
Essential Plan	Retrospective Review E&I
MVP Medicaid Managed Care	Retrospective Review E&I
MVP Child Health Plus	Retrospective Review E&I
MVP Harmonious Health Care Plan	Retrospective Review E&I
MVP Medicare Complete Wellness	Retrospective Review E&I
MVP Medicare Preferred Gold HMO POS	Retrospective Review E&I
	<u> </u>
MVP Medicare Secure HMO POS	Retrospective Review E&I
MVP Medicare Secure Plus HMO POS	Retrospective Review E&I
MVP Medicare WellSelect PPO	Retrospective Review E&I
MVP Medicare WellSelect Plus PPO	Retrospective Review E&I
MVP Medicare Patriot Plan (PPO)	Retrospective Review E&I
MVP DualAccess D-SNP HMO	Retrospective Review E&I
MVP DualAccess Complete D-SNP HMO	Retrospective Review E&I
MVP DualAccess Plus D-SNP HMO	Retrospective Review E&I
UVM Health Advantage Select PPO	Retrospective Review E&I
USA Care PPO	Potential for Retrospective Review
Healthy NY	Retrospective Review E&I
MVP Premier	Retrospective Review E&I
MVP Premier Plus	Retrospective Review E&I
MVP Premier Plus HDHP	Retrospective Review E&I
MVP Secure	Retrospective Review E&I
MVP EPO	Retrospective Review E&I
MVP EPO HDHP	Retrospective Review E&I
MVP PPO	Retrospective Review E&I
MVP PPO HDHP	Retrospective Review E&I
Student Health Plans	Retrospective Review E&I
ASO	•
	Retrospective Review E&I Retrospective Review E&I
Vermont Products	·
POS in Plan	Retrospective Review E&I
POS OOP	Retrospective Review E&I
MVP Medicare Preferred Gold HMO POS POS MVP Medicare Secure Plus HMO POS	Retrospective Review E&I
MVP Medicare Secure Plus HMO POS MVP VT HMO	Retrospective Review E&I Retrospective Review E&I
MVP VT HMO MVP VT HDHP HMO	Retrospective Review E&I
MVP VT Plus HMO	Retrospective Review E&I
MVP VT Plus HDHP HMO	Retrospective Review E&I
MVP Secure	Retrospective Review E&I
ASO	Retrospective Review E&I

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review.

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Digital Therapeutics Page 6 of 7

Revision History:

12/01/2023 – New policy adopted.

Digital Therapeutics Page 7 of 7



Durable Medical Equipment (Includes Prosthetics & Orthotics)

Type of Policy: DME

Prior Approval Date: 04/03/2023

Approval Date: 01/06/2025

Effective Date: 04/01/2025

Related Polices: N/A

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

See MVP Durable Medical Equipment (DME) Prior Authorization List

https://www.mvphealthcare.com/utilization

Codes Requiring Retrospective Review

N/A

Experimental/Investigational

E0715 - Intravaginal device for Kegel exercises

E0716 - Supplies and accessories for intravaginal device for Kegel exercises

E2001 - Suction pump, home model, portable or stationary, electric, any type, for use with external urine management system

A9268 – Programmer for transient, orally ingested capsule

A9269 – Programable, transient, orally ingested capsule, for use with external programmer, per month

Common Diagnosis Codes

N/A

Common Procedure Codes

N/A

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

Durable Medical Equipment (DME) is defined as equipment which can withstand repeated use; is primarily and customarily used to serve a medical purpose rather than convenience or comfort; is generally not useful to a person in the absence of illness or injury; is appropriate for use in the patient's home and could be brought to a physician's office or facility for treatment.

Home is defined as a place of residence other than an institution meeting the definition of a hospital or skilled nursing facility. DME includes, but is not limited to, items such as oxygen delivery systems, hospital beds, wheelchairs, walkers, intermittent positive pressure machines, and crutches. Diabetic management DME includes, but is not limited to, blood glucose monitors, insulin infusion pumps and continuous glucose monitors.

Replacement refers to a new item that takes the place of an essentially identical item that is no longer satisfactory for use. Substitution of a somewhat different item that is required by a change in medical condition, fit, or function is considered an initial provision, not a replacement.

Routine maintenance refers to upkeep and servicing of a DME item that is presently in working condition.

Repair refers to the restoration of equipment to sound condition by replacing a part or fixing what is broken.

Indications/Criteria

<u>Documentation</u>, <u>Process and Quality Standard Requirements</u>

MVP Health Care follows MVP medical policy and benefit coverage guidelines. In the absence of policy, MVP follows Medicare Affiliated Contractors' (MAC) rules in the following order:

- CMS Centers for Medicare and Medicaid www.cms.hhs.gov/center/dme.asp
- Noridian Healthcare Solutions LLC Medicare's DME administrative contractor for
 Jurisdiction Region A (includes NY and VT), which maintains supplier manuals, DME
 list serves, outreach and education.
 - https://med.noridianmedicare.com/web/jadme/policies/lcd/active

- Medicaid MVP follows the Medicaid DME Procedure Codes and Coverage Guidelines Manual for MVP Managed Medicaid customers. https://www.emedny.org/ProviderManuals/DME/index.aspx
- PDAC MVP follows the Pricing, Data, Analysis and Coding (PDAC) Contractor for assignment of HCPCS codes and product classification: https://www4.palmettogba.com/pdac_dmecs/

Requests for durable medical equipment must meet the following criteria:

- the definition of DME noted above in Overview must be met including that the item/service is appropriate for home use;
- the service/item must meet applicable MVP DME policy criteria, Medicare policy criteria or Medicaid criteria; [1, 2, 3]
- equipment may be purchased or rented at MVP's discretion; coverage is limited to standard equipment only.
- indicate whether other less costly alternatives have been tried and failed to meet the customer's medical necessity requirements.
- if a participating physician orders a product for a condition that is typically not covered under MVP Medical Policy, Medicare or DMERC's coverage criteria, the supplier is responsible to provide MVP all documentation of the request for final medical review and decision prior to rendering the service;
- routine maintenance is not covered. Routine periodic servicing, such as testing, cleaning, regulating, and checking of the equipment is not covered; [1, 2]
- applicable DME co-payment or deductibles apply per contract or certificate of coverage or specific benefit design. Co-payments for diabetic management DME may differ.

Repairs and Replacement

- Coverage includes replacement or repair as defined above. MVP shall determine
 whether to repair or replace the particular piece of equipment. Repair or
 replacement of equipment due to wear or damage is covered;
- Replacement and repair are covered only when medically necessary and if it is not covered under a manufacturer's warranty or purchase agreement:
- Repair or replacement of a DME item which becomes unusable or non-functioning because of individual misuse, abuse, or neglect is not covered.
- The repair policies will apply to the repair or replacement of a DME items which had been in use prior to the user enrolling with MVP Health Care.

Repairs

- Repairs are covered for medically necessary equipment.
- Prior authorization for labor (K0739) and repair must include narrative information itemizing:
 - o the nature and medical necessity for each repair;
 - o the anticipated time each repair will take;
 - date of purchase (month/year);
 - product name;
 - make/model;
 - o for common repairs, MVP Health Care follows the allowed units of service published by Medicare.

Replacement DME

- Replacement of DME and supplies specify that the reasonable useful lifetime cannot be less than five (5) years.
- Replacement during the first five years of use, during the "reasonable useful lifetime," is covered if the item is lost, irreparably damaged, or the patient's medical condition changes such that the current equipment no longer meets the patient's needs;
- There must be a new physician order that documents the reason for replacement, if the customer continues to use and are benefiting from the equipment;
- Replacement after five years would require that the item is irreparably damaged, and replacement is more cost effective than repair;
- Replacement of lost, stolen, or irreparably damaged items requires a new physician order documenting the medical necessity of the item. Proof of loss or damage through documentation such as a police report, picture, or corroborating statement should be submitted.
- Requests for replacement equipment must include the following:
 - o the description of the owned equipment that is being replaced;
 - o the HCPCS code of the original piece of equipment;
 - o the date of purchase of the original piece of equipment;
 - o reason for replacement; and
 - o new orders and face to face evaluation from physician.
 - an evaluation by a licensed medical professional (PT/OT/SLP) as needed (e.g. Power Mobility Devices).

Supplies

Coverage for disposable supplies (e.g., bandages, catheter kits) depends on the customer's contract or rider or specific plan design.

The following diabetic management supplies must be purchased at a participating pharmacy and billed through the pharmacy benefit manager. Customers will be responsible for their applicable pharmacy or diabetic management co-payment depending on their benefit design, quantity limits may apply.

- standard blood glucose meters, test strips, lancets, etc.;
- insulin;
- infusion sets and reservoirs for an insulin pump; or

Medications

Some medications administered through a nebulizer require prior authorization. Refer to the MVP formulary which identifies medications that require prior authorization. Medications administered through a nebulizer must be purchased at a participating pharmacy. The prescription drug benefit is required for coverage.

<u>Custom Fabricated Durable Medical Equipment</u>

K0900, custom fabricated durable medical equipment other than wheelchairs.

Requirements for custom fabricated DME item, a covered item must be:

- 1. Uniquely constructed or substantially modified for a specific customer according to a physician's description and orders; and,
- 2. So different from another item used for the same purpose that the two items cannot be grouped together for pricing purposes.

Custom fabricated does not include:

- 1. Items that are measured, assembled, fitted, or adapted in consideration of a patient's body size, weight, disability, period of need, or intended use (these are custom fitted items); or,
- 2. Items that have been assembled by a supplier, or ordered from a manufacturer, who makes available customized features, modification or components intended for an individual patient's use in accordance with instructions from the patient's physician. These items are not uniquely constructed or substantially modified and can be grouped with other items for pricing purposes. The use of customized options or accessories or custom fitting of certain parts does not result in equipment being considered as customized.

In the absence of MVP Medical Policy, MVP follows Medicare Affiliated
Contractors' (MAC) or the NYS Medicaid Criteria for DME for the following:

Patient Lifts:

MVP Commercial and Medicare Products refer to the Medicare Local Coverage Determination (LCD) for Patient Lifts. Available:

https://med.noridianmedicare.com/web/jadme/policies/lcd/active

MVP Medicaid Managed Care Products refer to the NYS Medicaid DME manual.

Available: https://www.emedny.org/ProviderManuals/index.aspx

Pressure Reducing Support Surfaces (Group I, II, III):

MVP Commercial and Medicare Products refer to the Medicare Local Coverage Determination (LCD) for Pressure Reducing Support Surfaces (Group I, II, III). Available: https://med.noridianmedicare.com/web/jadme/policies/lcd/active

MVP Medicaid Managed Care Products refer to the NYS Medicaid DME manual. Available: https://www.emedny.org/ProviderManuals/index.aspx

Exclusions:

The following may be exclusions to the customer's contract (always refer to the specific Customer's contract when determining benefits):

- structural changes to a patient's home (e.g., ramps, stair lifts, elevators) or vehicle accessories (e.g., wheelchair lifts, ramps, or special seats);
- routine maintenance;
- items specifically excluded in the contract or items that can be purchased over the counter;
- replacement of equipment to improve appearance, for convenience or comfort; duplicate items, (e.g., for use in more than one location; one at home and one at school to participate in sports);
- air conditioners, air filters or exercise equipment and other items that are excluded under most contracts;
- battery backups and generators for any DME items are considered a convenience item;
- repair or replacement of durable medical equipment which becomes unusable or nonfunctioning because of individual misuse, abuse or neglect is not covered under most MVP contracts;
- Replacement desired due to advanced technology is considered not medically necessary.

Crutch substitute (E0118) is not medically necessary as there is insufficient published clinical literature demonstrating safety and effectiveness in the population.

Female external catheter system (Purewick, Primafit – K1006, supplies billed with unlisted code) is not medically necessary as there is insufficient published clinical literature demonstrating that it is an equally effective alternative in the management of urinary incontinence.

There is a lack of evidence to support that ingestible vibrating capsules (HCPCS Code A9268, A9269) are a safe and effective treatment of chronic constipation. There are no published studies with long-term follow-up data which demonstrates durable and safe outcomes associated with vibrating ingestible device use over time, therefore, ingestible devices for the treatment of constipation are considered experimental and investigational.

Intravaginal treatment device for stress incontinence (including but not limited to the Flyte system [HCSPCS codes E0715, E0716]) is not medically necessary as there is insufficient published clinical literature demonstrating that it is effective in the management of urinary stress incontinence.

Vibration based devices for treatment of osteoporosis (for example, Osteoboost Belt) are experimental and investigational because of insufficient evidence that they improve bone strength, density or have impact on health outcomes or patient management.

Medicare Variation:

- Replacement of DME and supplies specify that the reasonable useful lifetime cannot be less than five (5) years. Replacement during the first five years of use, during the "reasonable useful lifetime," is covered if the item is lost, irreparably damaged, or the patient's medical condition changes such that the current equipment no longer meets the patient's needs;
- If a PAP device is replaced following the 5-year Reasonable Useful Lifetime (RUL), there must be a face-to-face evaluation by their treating practitioner that documents that the beneficiary continues to use and benefit from the PAP device. There is no requirement for a new sleep test or trial period.
- The following supplies must be purchased at a participating pharmacy and billed through the pharmacy benefit manager. (A prescription drug benefit **is not** required.) The customer will be responsible for the applicable Medicare Part B coinsurance.
 - diabetic management supplies, including glucometers, strips, lancets, and related supplies; and
 - o insulin when administered using an external insulin pump.
- Insulin and supplies related to the intermittent administration of insulin are covered under the Medicare Part D prescription benefit. (A prescription drug benefit **is** required.)

- Medications administered through a nebulizer must be purchased at a participating pharmacy and billed through the pharmacy benefit manager. These medications require prior authorization to determine the applicable benefit (Medicare Part B vs. Medicare Part D) and/or medical necessity. Customers will be responsible for their applicable co-payments or co-insurance depending on the benefit. A prescription drug benefit is not required for these medications if deemed Part B.
- Disposable medical supplies are covered in accordance with Medicare coverage criteria.

MVP Medicaid Managed Care Variation:

- Providers are no longer able to bill MVP Managed Medicaid or HARP members for pharmacy and pharmacy related durable medical equipment and supplies because NYS Medicaid covers these items. This includes certain durable medical equipment (DME), enteral and parenteral nutrition, family planning supplies, medical/surgical supplies, miscellaneous supplies and hearing aid batteries as designated by the New York State Department of Health. The full list of codes that must be billed to Medicaid Fee-For-Service is located at https://www.emedny.org/ProviderManuals/Pharmacy/index.aspx See the OTC and Supply Fee Schedule.
- Providers should bill these directly to New York State Medicaid Fee-For-Service using the Medicaid member client identification number (CIN) after 04/01/2023. Claims submitted directly to MVP for items that are carved out to Fee-For-Service will deny as not a covered benefit.
- Select medical supplies, can be billed through the pharmacy benefit manager under the customer's pharmacy benefit.
- A provider may not make a private pay agreement with an MVP Medicaid Managed
 Care customer to accept an MVP Medicaid fee for a particular covered service then
 provide a different upgraded service and agree to charge the MVP Medicaid
 Managed Care customer only the difference in fee between two services, in addition
 to billing MVP for the covered service.
- Gait Trainers: (E8000, E8001, E8002) are covered when the NYS Medicaid coverage criteria are met at https://www.emedny.org/ProviderManuals/DME/index.aspx
- Standing Systems E0637, E0638, E0641, E0642 are covered when the NYS Medicaid coverage criteria are met at https://www.emedny.org/ProviderManuals/DME/index.aspx

Durable Medical Equipment Not Covered List:

MVP maintains a list of durable medical equipment that is not covered. An item or service may be non-covered and not medically necessary if the criteria are not met in a

medical policy. Other items may be contractual exclusions that are not recognized as a benefit in a customer contract or certificate of coverage. Items that are not covered will be denied when the claim is submitted.

See the MVP non-covered items list for specific variations by each line of business: <u>Provider Reference Library Home (mvphealthcare.com)</u>

<u>Durable Medical Equipment Prior Authorization Requirements:</u>

Please refer to the appropriate MVP Medical Policy (listed below) for specific priorauthorization requirements for each line of MVP business:

- Bone Growth Stimulator
- Breast Pumps
- Burn Garments and Lymphedema Sleeves
- Cochlear Implants
- Cold Therapy Devices
- Compression Stockings
- Continuous Glucose Monitoring
- Continuous Passive Motion Devices
- Electrical Stimulation Devices
- Erectile Dysfunction
- External Breast Prosthesis
- High Frequency Chest Wall Oscillation Devices
- Hospital Beds
- Hyperhidrosis Treatments
- Insulin Infusion Pumps
- Light Therapy for Seasonal Affective Disorder
- Mechanical Stretching Devices
- Needle-Free Insulin Injectors
- Negative Pressure Wound Therapy Pumps
- Obstructive Sleep Apnea Devices
- Orthotic Devices
- Oxygen & Oxygen Equipment
- Oxygen Therapy for Cluster Headaches

- Prosthetic Devices, External Eye & Facial Prosthesis
- Prosthetic Devices, External Upper and Lower Limb
- Phototherapy, Photochemotherapy, and Excimer Laser Therapy for Dermatologic Conditions
- Sacral Nerve Stimulation
- Scoliosis Bracing
- Speech Generating Devices
- Therapeutic Footwear for Diabetics
- Wheelchairs (Electric) and Power Scooters
- Wheelchairs (Manual)

References (Reviewed 2025)

- Centers for Medicare & Medicaid Services Durable Medical Equipment. (DME Center. Available: https://www.cms.gov/Center/Provider-Type/Durable-Medical-Equipment-DME-Center.html
- 2. New York State Department of Health. eMedNY. Provider Manuals. DME. Available: https://www.emedny.org/ProviderManuals/index.aspx
- 3. New York State Medicaid Update. February 2014. Volume 30. Number 2. Available: http://www.health.ny.gov/health_care/medicaid/program/update/2014/feb14_mu.pdf
- 4. Centers for Medicare & Medicaid Services. Department of Health and Human Services. MNL Matters. MLN Matters ® Number: MM8158 Revised. Effective Date: July 1, 2013. Available: https://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnmattersarticles/downloads/MM8158.pdf
- 5. Nordian Healthcare Solutions- National Heritage Insurance Company Medicare's DME administrative contractor for Medicare Region A (DMERC) Available. https://med.noridianmedicare.com/web/jadme/policies/lcd/active
- Becton, Dickinson and Company (BD). PureWick Urine Collection System [website]. Franklin Lakes, NJ: BD; 2020. Available at: https://www.purewickathome.com/purewick-how-it-works/. Accessed October 6, 2020.
- 7. Hayes Health Evolving Evidence Review. External Female Catheters. HAYES, Inc.; © 2022 Hayes, a symplr company. May 9, 2022.
- 8. American Gastroenterological Association, Bharucha AE, Dorn SD, Lembo A, Pressman A. American Gastroenterological Association medical position statement on constipation. Gastroenterology. 2013; 144(1):211-217.

- 9. American Gastroenterological Association, Bharucha AE, Dorn SD, Lembo A, Pressman A. American Gastroenterological Association medical position statement on constipation. Gastroenterology. 2013; 144(1):211-217.
- 10. Włodarczyk J, Waśniewska A, Fichna J, et al. Current overview on clinical management of chronic constipation. J Clin Med. 2021; 10(8):1738.
- 11. Bharucha AE, Lacy BE. Mechanisms, evaluation, and management of chronic constipation. Gastroenterology. 2020; 158(5):1232-1249.e3. Noridian Healthcare Solutions, LLC DME Jurisdiction A E0118 Crutch Substitute posted on May 4, 2017 Available: Search Result JA DME Noridian (noridianmedicare.com)

Customer Product	Medical Management Requirements*
New York Products	
HMO	Prior Auth
PPO in Plan	Prior Auth
PPO OOP	Prior Auth
POS in Plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Prior Auth
MVP Child Health Plus	Prior Auth
MVP Harmonious Health Care Plan	Prior Auth
MVP Medicare Complete Wellness	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP Medicare WellSelect PPO	Prior Auth
MVP Medicare WellSelect Plus PPO	Prior Auth
MVP Medicare Patriot Plan PPO	Prior Auth
MVP DualAccess D-SNP HMO	Prior Auth
MVP DualAccess Complete D-SNP HMO	Prior Auth
MVP DualAccess Plus D-SNP HMO	Prior Auth
UVM Health Advantage Select PPO	Prior Auth
USA Care	Potential for Retrospective Review
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	
POS In Plan	Prior Auth
POS OOP	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP VT HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD
	300 3. 2

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Revision History:

12/01/2021 – Annual review with no changes to the indications or criteria; updated to new format; added exclusion for replacement DME that is desired due to advanced technology is considered not medically necessary; added section for the MVP DME Not Covered List with links to find the list.

04/01/2023 - Updated to reflect NYS Medicaid Carve-in.

06/01/2023 - Purewick added as an exclusion.

04/01/2025 – Added HCPCS Code A9268, A9269 to prior authorization. Added Intravaginal treatment device for stress incontinence and vibration-based devices for treatment of osteoporosis to exclusions section (HCPCS Code E0715 and E0716).



Early Childhood Developmental Disorders Vermont

Type of Policy: Behavioral Health

Prior Approval Date: 11/07/2022

Approval Date: 11/04/2024

Effective Date: 02/01/2025

Related Polices: Applied Behavior Analysis

Autism Spectrum Disorders New

York State

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

For customers without a prescription drug benefit, prior authorization may be required for drug coverage. See Applied Behavior Analysis for behavioral health procedures that require prior authorization. MVP Health Care may require prior authorization for the services that are covered in this policy. See those policies for specific medical management requirements.

Codes Requiring Retrospective Review

N/A

Experimental/Investigational

N/A

Common Diagnosis Codes

The following diagnosis codes will be considered medically necessary when applicable criteria have been met:

ICD-10- CM Diagnosis Codes: F20.0, F20.1, F20.2, F20.3, F20.5, F20.8, F20.81, F20.89, F20.9, F30, F31, F32, F33, F34, F39, F50.0, F50.00, F50.01, F50.02, F50.2, F50.8, F50.9, F60.2, F71, F72, F80.0, F80.1, F80.2, F80.4, F80.8, F80.81, F80.89, F80.9, F84.0, F84.2, F88, F89, F90.0, F90.1, F90.2, F90.8, F90.9, Z72.81, Z72.810

Common Diagnosis Codes associated with this policy have been provided for informational purposes only. The list of codes may not be all-inclusive and may be updated to reflect any applicable revisions to the ICD-10 code set and/or medical necessity quidelines applied in this policy.

Common Procedure Codes

N/A

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

This medical policy applies only to MVP plans in the State of Vermont that are required to follow the Vermont Health Insurance Law for early childhood developmental disorders including applied behavior analysis for autism spectrum disorder treatment.

The definition of early childhood developmental disorders means a childhood mental or physical impairment or combination of mental and physical impairments that results in functional limitations in major life activities, accompanied by a diagnosis defined by the Diagnostic and Statistical Manual of Mental Disorders (DSM) or the International Classification of Diseases (ICD). The term includes autism spectrum disorders but does not include a learning disability.

The term Autism Spectrum Disorder (ASD) is listed as a diagnostic category in the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, American Psychiatric Association*. The primary goals of treatment are to maximize the child's ultimate functional independence and quality of life by minimizing the core autism spectrum disorder features, facilitating development and learning, promoting socialization, reducing maladaptive behaviors, and educating and supporting families.

Indications/Criteria

The diagnosis and treatment of early childhood developmental disorders is covered in accordance with the Vermont state mandate, including applied behavior analysis supervised by a nationally board-certified behavior analyst.

Treatment for early childhood developmental disorders means evidence-based care (medical and behavioral) and related equipment prescribed or ordered for an individual by a licensed health care provider or a licensed psychologist who determines the care to be medically necessary, including:

- behavioral health treatment;
- pharmacy care;
- psychiatric and psychological care; and

• therapeutic care, e.g., services provided by a licensed or certified speech language pathologist, occupational therapist, or physical therapist.

Exclusions

- Complementary and alternative medicine is not supported in the American Academy
 of Pediatrics Guidelines for the Identification, Evaluation, and Management of
 Children with Autism Spectrum Disorders because there is not enough scientific
 evidence to support their use as treatments for ASDs. The following therapies are
 considered not medically necessary. This list is not considered to be all inclusive:
 - auditory integration training;
 - behavioral optometry;
 - craniosacral manipulation;
 - o detoxification therapies (e.g., chelation therapy);
 - holding therapy;
 - dolphin therapy;
 - equine therapy (hippotherapy).
- Drugs not meeting MVP's Experimental and Investigational policy criteria are excluded from coverage.
- Services that are considered primarily educational or training in nature to improve academic or work performance or to correct a learning disability are considered to be not medically necessary.

References (Reviewed 2024)

- 1. Diagnostic and Statistical Manual of Mental Disorders, 5th Edition, Arlington, VA, American Psychiatric Association, 2013.
- 2. Johnson CP, Myers SM; American Academy of Pediatrics, Council on Children With Disabilities. Identification and evaluation of children with autism spectrum disorders. *Pediatrics*. 2007; 120:1183–1215.
- 3. The Vermont Statutes Online. Title 8: Banking and Insurance, Chapter 107: HEALTH INSURANCE 8 V.S.A. § 4088i. Coverage for diagnosis and treatment of autism spectrum disorders. Available: http://legislature.vermont.gov/statutes/title/08
- 4. The Vermont Statutes Online. Title 8: Banking and Insurance, Chapter 107: HEALTH INSURANCE 8 V.S.A. § 4088i (Amended). Coverage for diagnosis and treatment of early childhood developmental disorders. No. 158. S.223. Available: http://legislature.vermont.gov/statutes/title/08
- 5. MVP Health Care customer Certificate of Coverage (COC); Section A. Coverage for Diagnosis and Treatment of Early Childhood Developmental Disorders.

Customer Product	Medical Management Requirements*
Vermont Products	
POS in Plan	Covered
POS OOP	Covered
MVP Medicare Preferred Gold HMO POS	Covered
MVP Medicare Secure Plus HMO POS	Covered
MVP VT HMO	Covered
MVP VT HDHP HMO	Covered
MVP VT Plus HMO	Covered
MVP VT Plus HDHP HMO	Covered
MVP Secure	Covered
ASO	See SPD

[♦] Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Revision History

01/01/2023 – Annual review; updated policy to align with Applied Behavior Analysis policy and NY Autism Spectrum Disorders policy.

01/01/2025 – Annual Review with removal of age restrictions according to VT Department of Financial Regulation (DFR).

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MVP Health Care Medical Policy

Electrical Stimulation Devices and Therapies

Type of Policy: DME/Medical

Prior Approval Date: 01/06/2025

Approval Date: 03/28/2025

Effective Date: 06/01/2025

Related Polices:Bone Growth Stimulator

Deep Brain Stimulation

Durable Medical Equipment (DME)

Sacral Nerve Stimulation

Spinal Cord Stimulator for Intractable Pain

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

HCPCS Codes for all MVP Products: A4540, A4541, A4542, A4543, A4544, E0490, E0491, E0492, E0493, E0721, E0731, E0732, E0733, E0734, E0735, E0740, E0743, E0744, E0745, E0762, E0764, E0765, E0766, E0769, E0770,

HCPCS Codes for MVP Medicaid Products and MVP Medicare Products Only: A4555,

Codes Requiring Retrospective Review

N/A

Experimental/Investigational

HCPCS Codes: A4540, A4541, A4542, E0490, E0491, E0492, E0493, E0732, E0733, E0734,

E0735, E0744, E0746, E0762, E0765

CPT Codes: 64555, 64596, 64597, 64598

Common Diagnosis Codes

ICD-10- CM Diagnosis Codes:

G12.2, G12.20, G12.21, G12.22, G12.29, G12.8, G12.9, G21.9, G35, G36, G37, G44.201, G54.0, G54.1, G54.2, G54.3, G54.4, G54.5, G54.6, G54.7, G54.8, G54.9, G83.9, R11.0, R11.1, R11.10, R11.11, R11.12, R11.13, R11.14, R11.2, M15.0, M15.1, M15.2, M15.3, M15.4, M15.8, M15.9, M16.0, M16.1, M16.10, M16.11, M16.12, M16.2, M16.3, M16.30, M16.31, M16.32, M16.4, M16.5, M16.50, M16.51, M16.52, M16.6, M16.7, M16.9, M17.0, M17.1, M17.10, M17.11, M17.12, M17.2, M17.3, M17.30, M17.31, M17.32, M17.4, M17.5, M17.9, M18.0, M18.1, M18.10, M18.11, M18.12, M18.2, M18.3, M18.30, M18.31, M18.32, M18.4, M18.5, M18.50, M18.51, M18.52, M18.9, M19.01, M19.011, M19.012, M19.019, M19.021, M19.022, M19.029, M19.031, M19.032, M19.039, M19.041, M19.042, M19.049, M19.071, M19.072, M19.079, M19.11, M19.111, M19.112, M19.119, M19.121, M19.122, M19.129, M19.131, M19.132, M19.139, M19.141, M19.142, M19.149, M19.171, M19.172, M19.179, M19.211, M19.212, M19,219, M19.221, M19.222, M19.229, M19.231, M19.232, M19.239, M19.241, M19.242, M19.249, M19.271, M19.272, M19.279, M19.90, M19.91, M19.92, M19.93, M53.2x1, M53.2x2, M53.2x4, M53.2x5, M53.2x6, M53.2x7, S53.2x8, M53.2x9, R30.0, R30.1, R30.9, S32.0, S32.9, S53.80, S53.81, S53.82, S53.83, S53.84, S53.85, S53.86, S53.87, S53.88, S53.9

Common Diagnosis Codes associated with this policy have been provided for informational purposes only. The list of codes may not be all-inclusive and may be updated to reflect any applicable revisions to the ICD-10 code sets and/or medical necessity guidelines applied in this policy.

Common Procedure Codes

N/A

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

Electrical stimulators provide direct, alternating, pulsating and/or pulsed wave energy to accelerate healing of chronic wounds, facilitate functional restoration, treat muscle atrophy and diminish pain. Neuromuscular Electrical Stimulation (NMES), Transcutaneous Electrical Nerve Stimulation (TENS), and Electromagnetic Therapy (ET) are some of the many forms of electrical stimulation that may be provided by indwelling transcutaneous needles or by surface electrodes.

Various devices and treatments are available for patients in an outpatient clinic, a physician's office, or in the patient's home. Some treatments may require surgical implantation of leads and a trial period to insure efficacy. Electrical stimulation for some conditions may be tried as a last resort when the customer has failed a trial of conservative therapies.

Indications/Criteria

Documentation

Medical record documentation must include all of the following:

- the exact nature of the customer's impairments and functional limitations to be treated;
- medical necessity for the type, frequency and duration of therapy to treat the customer's condition;
- appropriate conservative therapies that have been tried and failed e.g., pharmacological, surgical, physical, or psychological therapies;
- the expected goals for medically necessary therapy(s); and
- when regression or plateaus occur, the reasons for the lack of progress should be noted to justify continued treatment.

Neuromuscular Electrical Stimulation (NMES) (E0745)

Neuromuscular electrical stimulation (NMES) will be covered when used as one component of a comprehensive rehabilitation program for the treatment of disuse atrophy where the nerve supply to the muscle is intact, including brain, spinal cord and peripheral nerves, and other non-neurological reasons for disuse atrophy such as casting or splinting of limb, contracture due to scarring of soft tissue as in burn lesions, major knee surgery (e.g., ACL, TKR), or total hip replacement (THR) surgery (until orthotic training begins).

- Coverage of an NMES for more than two months is determined by individual consideration based upon supportive documentation (including current muscle testing) provided by the therapist and/or attending physician.
- An NMES unit will be covered as a rental only.

<u>Functional Electrical Stimulation in Patients with Spinal Cord Injury (SCI) (E0770, E0764)</u>

The type of NMES that is used to enhance the ability to walk of spinal cord injury (SCI) patients is commonly referred to as functional electrical stimulation (FES).

Coverage for the use of NMES/FES is limited to spinal cord injury (SCI) patients for walking who have completed a training program which consists of at least 32 physical therapy sessions with the device over a period of three (3) months. Physical therapy necessary to perform this training must be directly performed by the physical therapist as part of a one-on-one training program.

The goal of physical therapy must be to train SCI patients on the use of FES devices to achieve walking, not to reverse or retard muscle atrophy.

Coverage for functional electrical stimulation (FES) for walking will be covered in spinal cord injury patients with all of the following characteristics:

- persons with intact lower motor units (L1 and below) (both muscle and peripheral nerve);
- persons with muscle and joint stability for weight bearing at upper and lower extremities that can demonstrate balance and control to maintain an upright support posture independently;
- persons that demonstrate brisk muscle contraction to FES and have sensory perception electrical stimulation sufficient for muscle contraction;
- persons that possess high motivation, commitment and cognitive ability to use such devices for walking;
- persons that can transfer independently and can demonstrate independent standing tolerance for at least 3 minutes;
- persons that can demonstrate hand and finger function to manipulate controls;
- persons with at least six-month post recovery spinal cord injury and restorative surgery;
- persons without hip and knee degenerative disease and no history of long bone fracture secondary to osteoporosis; and
- persons who have demonstrated a willingness to use the device long-term.

Functional electrical stimulation for walking will not be covered in SCI patients with any of the following:

- persons with cardiac pacemakers;
- severe scoliosis or severe osteoporosis;
- skin disease or cancer at area of stimulation;
- irreversible contracture; or
- autonomic dysflexia.

<u>Transcutaneous Electrical Nerve Stimulation (TENS) for Acute Post-operative Pain (E0720, E0730)</u>

A transcutaneous electrical nerve stimulator (TENS) is covered for the treatment of patients with acute post-operative pain who meet the following criteria:

- medical necessity is limited to 30 days from the day of surgery;
- coverage for more than 30 days is determined by individual consideration based upon supportive documentation provided by the attending physician.

Transcutaneous Electrical Nerve Stimulation (TENS) for Chronic Pain (E0720, E0730)

A transcutaneous electrical nerve stimulator (TENS) is covered for the treatment of patients with chronic pain who meet all of the following criteria:

- the medical record must document the location of the pain, the duration of time the patient has had the pain, and the etiology of the pain;
- the pain must have been present for at least 90 days;
- the etiology of the pain must be a type that is accepted as responding to TENS therapy. Examples of conditions for which a TENS unit is not considered to be reasonable and necessary are: headache, visceral abdominal pain, pelvic pain, and temporomandibular joint (TMJ) pain (not all inclusive);
- the TENS unit must be used by the patient on a trial basis for a minimum of 30 days, but not to exceed 60 days. The trial period must be monitored by the physician to determine the effectiveness of the TENS unit in modulating the pain;
- the physician must determine that the patient is likely to derive significant therapeutic benefit from continuous use of the unit over a long period of time. The physician's records must document a re-evaluation of the patient at the end of the trial period, must indicate how often the patient used the TENS unit, the typical duration of use each time, and the results;
- a four lead TENS unit may be used with either two leads or four leads, depending on the characteristics of the patient's pain. If it is ordered for use with four leads, the medical record must document why two leads are insufficient to meet the patient's needs; and
- if two TENS leads are reasonable and necessary, then a maximum of one unit of Code A4595 would be allowed per month; if four TENS leads are necessary, a maximum of two units per month would be allowed. If the use of the TENS unit is less than daily, the frequency of billing for the TENS supply code should be reduced proportionally.

The physician ordering the TENS unit must be the attending physician or a consulting physician for the disease or condition resulting in the need for the TENS unit.

Transcutaneous Electrical Nerve Stimulation (TENS) for Chronic Low Back Pain (CLBP)

TENS therapy for CLBP is only covered when all of the following criteria are met:

- the customer has one of the following diagnoses:
 - o lumbosacral root lesions, not elsewhere classified; or
 - o sacroiliitis, not elsewhere classified; or
 - o lumbosacral spondylosis without myelopathy; or
 - o thoracic or lumbar spondylosis with myelopathy lumbar region; or

- o lumbar intervertebral disc without myelopathy; or
- lumbosacral intervertebral disc; or
- o intervertebral disc disorder myelopathy lumbar region; or
- o post laminectomy syndrome lumbar region; or
- o other and unspecified disc disorders, lumbar region; or
- o spinal stenosis, lumbar region without neurogenic claudication; or
- o spinal stenosis, lumbar region with neurogenic claudication; or
- o lumbago; or
- o sciatica; or
- o thoracic or lumbosacral neuritis or radiculitis, unspecified, radicular
- o syndrome of lower extremities; or
- acquired spondylolisthesis; or
- o non-allopathic lesions NEC (not elsewhere classified) lumbar region; or
- o spondylosis, lumbosacral region; or
- o spondylolisthesis; or
- fracture of vertebral column without mention of spinal cord injury, lumbar, closed; or
- fracture of vertebral column with mention of spinal cord injury, lumbar, closed; or
- o sprains and strains of sacroiliac region lumbosacral (joint) (ligament); or
- o sprains and strains of sacroiliac ligament; or
- o sprains and strains of other and unspecified parts of back, lumbar; or
- o injury to nerve roots and spinal plexus, lumbar root; and
- the customer is enrolled in an approved clinical study that meets all of the requirements set out in National Coverage Determination (NCD) for Transcutaneous Electrical Nerve Stimulation (TENS) for Chronic Low Back Pain (CLBP) (160.27).^[3] (CMS Internet Only Manual 100-3, Chapter 1); and
- the TENS unit must be used by the patient on a trial basis for a minimum of 30 days, but not to exceed 60 days. The trial period must be monitored by the physician to determine the effectiveness of the TENS unit in modulating the pain; and
- the physician must determine that the patient is likely to derive significant therapeutic benefit from continuous use of the unit over a long period of time. The physician's records must document a re-evaluation of the patient at the end of the

trial period, must indicate how often the patient used the TENS unit, the typical duration of use each time, and the results; and

- a four lead TENS unit may be used with either two leads or four leads, depending on the characteristics of the patient's pain. If it is ordered for use with four leads, the medical record must document why two leads are insufficient to meet the patient's needs; and
- if two TENS leads are reasonable and necessary, then a maximum of one unit of Code A4595 would be allowed per month; if four TENS leads are necessary, a maximum of two units per month would be allowed. If the use of the TENS unit is less than daily, the frequency of billing for the TENS supply code should be reduced proportionally.

NOTE: TENS units requiring just two leads are not covered for MVP Medicaid Managed Care customers.

The physician ordering the TENS unit must be the attending physician or a consulting physician for the disease or condition resulting in the need for the TENS unit.

TENS therapy for CLBP that does not meet these criteria will be denied as not reasonable and necessary.

Conductive Garment for Use with TENS (E0731)

A conductive garment used with a TENS unit may be covered when all of the following conditions are met:

- it has been prescribed by a physician for use in delivering covered TENS treatment; and
- one of the medical indications outlined below is met:
 - the patient cannot manage without the conductive garment because there
 is such a large area or so many sites to be stimulated and the stimulation
 would have to be delivered so frequently that it is not feasible to use
 conventional electrodes, adhesive tapes, and lead wires; or
 - the patient cannot manage without the conductive garment for the treatment of chronic intractable pain because the areas or sites to be stimulated are inaccessible with the use of conventional electrodes, adhesive tapes, and lead wires; or
 - the patient has a documented medical condition, such as skin problems, that preclude the application of conventional electrodes, adhesive tapes, and lead wires; or
 - the patient requires electrical stimulation beneath a cast to treat chronic intractable pain, and

• a conductive garment may be covered with a neuromuscular electrical stimulator (NMES) if there is a skin disease or a cancer at the area of stimulation.

A conductive garment is not covered for use with a TENS or an NMES device during the trial period unless:

- the patient has a documented skin problem prior to the start of the trial period; or
- the TENS or NMES is reasonable and necessary for the patient.

Non-Implantable Pelvic Floor Electrical Stimulator (E0740)

- Pelvic floor electrical stimulation with a non-implantable stimulator is covered for the treatment of stress and/or urge urinary incontinence in cognitively intact patients who have failed a documented trial of pelvic muscle exercise (PME) training.
- A failed trial of PME training is defined as no clinically significant improvement in urinary continence after completing four weeks of an ordered plan of pelvic muscle exercises designed to increase periurethral muscle strength.

<u>Electrical Stimulation (ES) and Electromagnetic Therapy for the Treatment of Wounds</u> (E0769)

The use of ES and electromagnetic therapy for the treatment of wounds are considered adjunctive therapies and will only be covered when all of the following criteria have been met:

- ES and electromagnetic therapy will be covered for chronic Stage III or Stage IV pressure ulcers, arterial ulcers, diabetic ulcers, and venous stasis ulcers;
- chronic ulcers are defined as ulcers that have not healed within 30 days of occurrence. ES or electromagnetic therapy will be covered only after appropriate standard wound therapy has been tried for at least 30 days and there are no measurable signs of improved healing. This 30-day period may begin while the wound is acute;
- standard wound care includes: optimization of nutritional status, debridement by any means to remove devitalized tissue, maintenance of a clean, moist bed of granulation tissue with appropriate moist dressings, and necessary treatment to resolve any infection that may be present. Standard wound care based on the specific type of wound includes: frequent repositioning of a patient with pressure ulcers (usually every 2 hours), offloading of pressure and good glucose control for diabetic ulcers, establishment of adequate circulation for arterial ulcers, and the use of a compression system for patients with venous ulcers;
- measurable signs of improved healing include: a decrease in wound size (either surface area or volume), decrease in amount of exudates, and decrease in amount of necrotic tissue;

- ES or electromagnetic therapy must be discontinued when the wound demonstrates 100% epitheliliazed wound bed;
- continued treatment with ES or electromagnetic therapy is not covered if measurable signs of healing have not been demonstrated within any 30-day period of treatment;
- ES and electromagnetic therapy services can only be covered when performed by a physician, physical therapist, or a clinician incident to a physician service; and
- unsupervised use of ES or electromagnetic therapy for wound therapy will not be covered, as this use has not been found to be medically reasonable and necessary.

Electrical Tumor Treatment Field Therapy (E0766)

Coverage for Electrical Tumor Treatment Field Therapy may be considered when used for adjuvant therapy with temozolomide or when used as monotherapy.

- Electrical Tumor Treatment Field Therapy (E0766) used with adjuvant temozolomide may be considered for coverage when all the following criteria are met:
 - Customer is ≥ 22 years old;
 - Customer has newly diagnosed supratentorial glioblastoma;
 - Good performance status (KPS ≥ 60);
 - Customer underwent maximal tumor debulking, if possible;
 - Customer completed radiation therapy with concurrent temozolomide.
- Electrical Tumor Treatment Field Therapy (E0766) used as monotherapy may be considered for coverage on a case-by-case basis when all the following criteria are met:
 - Customer is ≥ 22 years old;
 - Customer has recurrent supratentorial glioblastoma;
 - o Customer completed radiation therapy with concurrent temozolomide

Exclusions

- Not meeting criteria listed under Indications/Criteria of this policy.
- A4556 (electrodes), A4630 (replacement batteries), and A4595 (leads) are covered only if the customer's plan has coverage for disposable supplies.
- There is insufficient evidence from well-designed prospective clinical trials that the following devices or therapies have been proven to be medically safe and/or effective for their indicated use compared to current standard interventions and are, therefore, considered investigational.

- o Functional electrical stimulation devices (E0770, E0764) for use in patients without spinal cord injury (see Indications/Criteria of this policy).
- Functional electrical stimulation exercise devices (i.e., RT300 Electrical Stimulation Bike).
- Percutaneous electrical nerve stimulation (PENS) and percutaneous neuromodulation therapy (PNT) for the treatment of chronic low back pain, including, but not limited to, diabetic neuropathy, headache, and osteoarthritis of the knee. The evidence in the peer-reviewed literature did not demonstrate Percutaneous electrical nerve stimulation (PENS) and percutaneous neuromodulation therapy (PNT) is effective in the long term and therefore is considered investigational.
- Transcutaneous Electrical Nerve Stimulation (TENS) (E0765) for the treatment of post-operative nausea and vomiting, chemotherapy induced nausea, nausea and vomiting of pregnancy, motion sickness and all other indications are not covered.
- Threshold electrical stimulation (TES) as a treatment for motor disorders, including, but not limited to, cerebral palsy, scoliosis, or spina bifida.
- Interferential stimulators for the treatment of circulation disorders, range of motion, edema, muscle spasms, bone healing, and pain and to promote soft tissue healing.
- o Gastric electrical stimulation for the treatment of obesity.
- Currently no implantable pulse generator, radiofrequency device, or leads are approved by the FDA for peripheral occipital nerve stimulation to treat occipital neuralgia or headaches.
- Transcutaneous electrical joint stimulation devices (E0762) are considered investigational for any indication.
- Electrosleep therapy for the treatment of chronic insomnia, anxiety, depression, psychosomatic disorders, such as asthma, spastic colitis, or tension headache, and for organic disorders including essential hypertension.
- Electrical aversion (electroversion) therapy for the treatment of alcoholism.
- Electrical continence aids which stimulate anal musculature to allow the patient to ambulate without incontinence.
- Electrical stimulation used in the treatment of Bell's palsy, multiple sclerosis and strokes (when there is no potential for restoration of function).
- Scrambler therapy MC-5A CALMARE® (Transcutaneous Electrical Modulation Pain Reprocessing Device) for chronic, intractable pain, post-surgical pain, post-

traumatic acute pain, cancer related pain, and reducing peripheral neuropathy caused by chemotherapy.

- Electrical stimulation of muscles for treatment of scoliosis (E0744).
- Electrical Tumor Treatment Field Therapy (E0766) is not covered for any other indication not listed in the Indication/Criteria section.
- Cefaly device for prevention, treatment and other indications for migraine headaches is not covered. There is insufficient evidence in the peer-reviewed literature to support the use of the Cefaly transcutaneous electrical stimulator (TENS) headband for the treatment of migraine headaches, therefore the Cefaly device is considered investigational and not covered.
- GammaCore non-implantable transcutaneous vagus nerve stimulation (tVNS)(E0735) is considered investigational because the long-term outcomes in the published peer-reviewed scientific literature do not support the safety and effectiveness for the acute or chronic treatment of pain associated with episodic cluster headache or migraines in adult patients.
- Cranial Electrotherapy Systems (CES) (E0732) deliver low level electrical stimulation (microcurrent) to the brain through electrodes that are attached to the ear lobes or behind the ears. CES has been proposed for the treatment of anxiety, depression, insomnia, substance abuse, depression, tension headaches, cluster headaches and migraines. CES devices are investigational and not covered for any indication because there is insufficient evidence regarding the safety and effectiveness of Cranial Electrotherapy Systems (CES) for the reduction of pain or improvement in function.
- Remote electrical neuromodulation (REN) (e.g. Nerivio) device proposed as a treatment for episodic or chronic migraine headaches is considered investigational and not covered for all indications because there is insufficient evidence regarding the safety and effectiveness of REN.
- Cala Trio nerve stimulating device (E0734, A4542) proposed as a treatment of essential tremors is considered experimental and investigational because there is insufficient evidence regarding the safety and effectiveness has not been established.
- Percutaneous electrical nerve stimulation (PENS)(CPT Code: 64555), percutaneous electrical nerve field stimulation (PENFS) (CPT Code: 64596, 64597, 64598), percutaneous neuromodulation therapy (PNT) or auricular electrostimulation devices (including all permanent and temporary) are considered experimental, investigational or unproven for any indication, including but not limited to the treatment of acute or chronic pain conditions. Examples of implantable peripheral nerve stimulators for pain relief include: Sprint PNS System, StimQ Peripheral Nerve Stimulator (PNS) System, and StimRouter Neuromodulation System.

- Restorative Neurostimulation Therapy (e.g., ReActiv8 64555) are considered experimental, investigational or unproven for any indication, including but not limited to the treatment of acute or chronic pain conditions.
- Monarch external trigeminal nerve stimulation (eTNS) (E0733, A4541) proposed for treatment of pediatric ADHD is considered experimental and investigational because there is insufficient evidence regarding the safety and effectiveness has not been established.
- Electrical stimulation of muscles for treatment of scoliosis (HCPCS E0744) is considered experimental and investigational because there is insufficient evidence regarding the safety of and effectiveness for this treatment has not been established.
- Biofeedback devices (HCPCS E0746) are not covered for home use because they are considered experimental and investigational as there is insufficient evidence in peer-reviewed medical literature regarding effectiveness or proof the technology improves outcomes.
- eXciteOSA Daytime Therapy Device (E0490, E0491, E0492, E0493) for the treatment of obstructive sleep apnea is considered to be experimental and investigational as there is insufficient evidence in peer-reviewed medical literature regarding safety, effectiveness and/or proof the technology improves outcomes.
- The NTX100 Tonic Motor Activation (TOMAC) System (E0743, A4544) for the treatment of restless leg syndrome is considered to be experimental and investigational as there is insufficient evidence in peer-reviewed medical literature regarding safety, effectiveness and/or proof the technology improves outcomes.
- The use of auricular stimulation (E0721, A4543) for, but not limited to, the treatment of opioid withdrawal (e.g., Sparrow Ascent) is considered to be experimental and investigational as there is insufficient evidence in peer-reviewed literature regarding the safety, effectiveness, and/or proof that the technology improves outcomes.

MVP Medicaid Managed Care Variation

Coverage for transcutaneous electrical nerve stimulation (TENS) is limited to customers with a diagnosis of knee pain due to osteoarthritis (ICD-10- Codes: M17.10, M17.9, M17.5, M25.169, M25.869, M25.9). If at least one of these diagnostic codes is not billed with the claim for TENS, the TENS will be denied administratively.

Functional Electrical Stimulation (FES) via transcutaneous, percutaneous, and implanted devices are considered not medically necessary for treatment of spinal cord injury, head injury, cerebral palsy, and upper motor neuron disease and is, therefore, not covered (ICD-10 Codes: B91, G12.0, G12.1, G12.8, G12.21, G12.22, G12.29, G12.8, G12.9, G14, G20,

G21.11, G21.19, G21.8, G35, G36.0, G37.0, G37.1, G37.2, G37.3, G37.5, G37.8, G37.9, G80.0, G80.1, G80.2, G80.8, G80.9, P11.5, S04.9XXS, S06.0X1A, S06.0X2A, S06.0X3A, S06.0X4A, S06.0X5A, S06.0X6A, S06.0X9A, S06.9X9S, S14.109S, S24.109S, S34.139S). If at least one of the diagnostic codes is not billed with the claims for FES, the FES will be denied administratively.

TENS and FES units that are billed with a covered diagnosis must also meet the applicable medical necessity criteria within this policy for that diagnosis.

For MVP Medicaid products, tumor treatment field therapy (E0766) is not covered.

MVP Medicare Variation

<u>Tumor Treatment Field Therapy (E0766)</u>

Initial coverage for newly diagnosed glioblastoma multiforme:

Tumor treatment field therapy (E0766) is covered for the treatment of newly diagnosed Glioblastoma Multiforme (GBM) only when <u>all</u> the following criteria are met:

- There is a confirmed (World Health Organization (WHO) grade IV astrocytoma), newly diagnosed, supratentorial GBM; and,
- The customer has received initial treatment with maximal debulking surgery (when feasible), followed by chemotherapy and radiotherapy; and,
- Tumor treatment field therapy is initiated within 7 weeks from the last dose of concomitant chemotherapy or radiotherapy, whichever is later; and,
- The beneficiary has no evidence of progression by Response Assessment in Neuro-Oncology (RANO) criteria; and,
- The beneficiary has a Karnofsky Performance Score (KPS) of at least 70; and,
- The beneficiary will use TTFT for an average of 18 hours per day.

Continued coverage for newly diagnosed GBM beyond the first three months of therapy:

Continued coverage of TTFT (E0766) beyond the first three months of therapy requires that the treating practitioner must conduct a clinical re-evaluation and document that the beneficiary is continuing to use and is benefiting from TTFT.

Documentation of clinical benefit is demonstrated by:

- Face-to-face clinical re-evaluation by the treating practitioner; and,
- Objective evidence of adherence to therapy, reviewed by the treating practitioner.

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Adherence to therapy is defined as the use of TTFT for an average of 18 hours per day (excluding days the treating practitioner has documented a medical need to limit or interrupt treatment).

If the above criteria are not met, continued coverage of TTFT will be denied as not medically necessary.

Recurrent GMB:

Tumor treatment field therapy (E0766) is not medically necessary for the treatment of recurrent GBM.

Other uses:

The use of TTFT for any indications other than newly diagnosed GBM is not medically necessary.

For full coverage details refer to the following Medicare Local Coverage Determination (LCD): Noridian Healthcare Solutions (Medicare) Local Coverage Determination (LCD) for Tumor Treatment field Therapy (TTFT)(L34730). Effective Date: 09/01/19 Available: https://med.noridianmedicare.com/web/jddme/policies/lcd/active

Transcutaneous Electrical Nerve Stimulators (TENS) (E0720, E0730)

A TENS is covered for the treatment of beneficiaries with chronic, intractable pain or acute post-operative pain when one of the following coverage criteria, I-III, are met.

I. Acute Post-operative Pain

TENS is covered for acute post-operative pain. Coverage is limited to 30 days (one month's rental) from the day of surgery. Payment will be made only as a rental.

A TENS unit will be denied as not reasonable and necessary for acute pain (less than three months duration) other than for post-operative pain.

II. Chronic Pain Other than Low Back Pain

TENS is covered for chronic, intractable pain other than chronic low back pain when all of the following criteria must be met:

- The presumed etiology of the pain must be a type that is accepted as responding to TENS therapy. Examples of conditions for which TENS therapy is not considered to be reasonable and necessary are (not all-inclusive):
 - o headache
 - visceral abdominal pain
 - o pelvic pain
 - o temporomandibular joint (TMJ) pain
- The pain must have been present for at least three months

Other appropriate treatment modalities must have been tried and failed

TENS therapy for chronic pain that does not meet these criteria will be denied as not reasonable and necessary.

III. Chronic Low Back Pain (CLBP) TENS therapy for CLBP is only covered when all of the following criteria are met:

- The Medicare customer has one of the diagnosis codes listed in the Diagnosis Codes that Support Medical Necessity section in the Noridian Healthcare Solutions. Local Coverage Determination (LCD) for Transcutaneous Electrical Nerve Stimulators (TENS) (L33802). Revision Effective Date 10/01/2015.
 Available: https://med.noridianmedicare.com/web/jddme/policies/lcd/active
- The beneficiary is enrolled in an approved clinical study that meets all of the requirements set out in National Coverage Determination (NCD) for Transcutaneous Electrical Nerve Stimulation (TENS) for Chronic Low Back Pain (CLBP) (160.27) Available: Available: www.cms.gov/

For Medicare full coverage details of Transcutaneous Electrical Nerve Stimulators (TENS) National Coverage Determination (NCD) and Local Coverage Determination (LCD) refer to the links above.

For Medicare products, TENS (E0730) used to treat Chronic Low Back Pain is provided under limited coverage. Reimbursement is only available for beneficiaries who are enrolled in an approved clinical trial. *

*Currently there is no Medicare approved clinical trial for TENS therapy for chronic low back pain, therefore the TENS is not covered by MVP Health Care.

Refer to the following links for full Medicare coverage of chronic low back pain:

Noridian Healthcare Solutions. Local Coverage Determination (LCD) for Transcutaneous Electrical Nerve Stimulators (TENS) (L33802). Revision Effective Date 10/01/2019. Available: https://med.noridianmedicare.com/web/jddme/policies/lcd/active

Peripheral Nerve Stimulation (CPT Code: 64555, 64596, 64597, 64598)

For full Medicare coverage details about peripheral nerve stimulation please refer to the following NCD for Medicare Customers: National Coverage Determination (NCD) Electrical Nerve Stimulators (160.7) Effective Date: 08/07/1995 and Medicare LCD: Peripheral Nerve Stimulation A55531 and L37360. Available: MCD Search (cms.gov)

References (Updated 2025)

1. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for Neuromuscular Electrical Stimulation (NMES) (160.12). Effective Date 10/1/2006. Available: www.cms.gov/.

- 2. Noridian Healthcare Solutions. Local Coverage Determination (LCD) for Transcutaneous Electrical Nerve Stimulators (TENS) (L33802). Revision Effective Date 01/01/2020. Available:
- https://med.noridianmedicare.com/web/jddme/policies/lcd/active.
- 3. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for Transcutaneous Electrical Nerve Stimulation (TENS) for Chronic Low Back Pain (CLBP) (160.27). Effective Date 6/8/2012. Available: www.cms.gov/.
- 4. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for Non-Implantable Pelvic Floor Electrical Stimulator (230.8). Effective Date 6/19/2006. Available: www.cms.gov/.
- 5. Chou R. MD, Qaseem A. MD, Snow V. MD et al. Diagnosis and Treatment of Low Back Pain: A Joint Clinical Practice Guideline from the American College of Physicians and the American Pain Society. Ann Intern Med 2007; 147:478-491. Available: www.annals.org.
- 6. American College of Obstetrics and Gynecology. ACOG (American College of Obstetrics and Gynecology) Practice Bulletin: nausea and vomiting of pregnancy. Obstet Gynecol. 2004 Apr;103(4):803-14.
- 7. Allen, TK, Habib, AS. P6 stimulation for the prevention of nausea and vomiting associated with cesarean delivery under neuraxial anesthesia: a systematic review of randomized controlled trials. Anesth Analg. 2008;107(4):1308-1312.
- 8. Walker, J.L., MD, Ryan S.R., PT, Coburn T.R., PA-C. Does Threshold Nighttime Electrical Stimulation Benefit Children with Spina Bifida? A Pilot Study. The Association of Bone and Joint Surgeons1 2010. 29 September 2010. Clin Orthop Relat Res (2011) 469:1297–1301.
- 9. Dali C, Hansen FJ, Pedersen SA et al. Threshold electrical stimulation (TES) in ambulant children with CP: a randomized double-blind placebo-controlled clinical trial. Dev Med Child Neurol 2002; 44(6):364-369.
- 10. American Society of Anesthesiologists (ASA). Practice guidelines for chronic pain management. A report by the American Society of Anesthesiologists Task Force on Pain Management, Chronic PainSection. Anesthesiology. 1997;86(4):995-1004.
- 11. Shikora, SA., Bergenstal., R., Bessler, M., Brody, F., et al. Implantable gastric stimulation for the treatment of clinically severe obesity: results of the SHAPE trial. Surg Obes Relat Dis. 2009; 5(1): 31-7.
- 12. Hayes Directory. Occipital Nerve Stimulation for Chronic Cluster Headache and Chronic Migraine Headache. May 30, 2012. Available: www.hayesinc.com.
- 13. Fary RE, Carroll GJ, Briffa TG, Briffa NK. The effectiveness of pulsed electrical stimulation in the management of osteoarthritis of the knee: results of a double-blind,

- randomized, placebo-controlled, repeated-measures trial. Arthritis Rheum. 2011 May;63(5):1333-42. doi: 10.1002/art.3025.
- 14. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for Electrosleep Therapy (30.4). Available: www.cms.gov/.
- 15. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for Electrical Aversion Therapy for the Treatment of Alcoholism (130.4). Available: www.cms.gov/.
- 16. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for Electrical Continence Aid (230.15). Available: www.cms.gov/.
- 17. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for Electrical Stimulation (ES) and Electromagnetic Therapy for the Treatment of Wounds (270.1). Effective Date 7/1/2004. Available: www.cms.gov/.
- 18. Centers for Medicare & Medicaid Services (CMS). Department of Health & Human Services (DHHS). CMS Manual System. Pub. 100-03 Medicare National Coverage Determinations, Apr 6, 2004.
- 19. Food and Drug Administration (FDA) 510K Summary for the Competitive Technologies, Inc. Scrambler Therapy MC-5A TENS Device (per 21CFR 807.92). Feb 20, 2009.
- 20. Ricci M., Pirotti S., Scarpi E., Burgio M., Maltoni M., Sansoni E., Amadori D. Managing chronic pain: Results from an open-label study using MC5-A Calmare device. Supportive Care in Cancer. 20 (2) (pp 405-412) [Abstract], 2012.
- 21. U.S. National Institutes of Health. MC5-A Scrambler Therapy in Reducing Peripheral Neuropathy Caused by Chemotherapy. NCT01290224. Available: www.clinicaltrials.gov.
- 22. Mayo Clinic. Scoliosis. Alternative Medicine. Feb 3, 2012. Available: www.mayoclinic.com/health/scoliosis/DS00194/DSECTION=alternative-medicine.
- 23. New York State Medicaid Update. Medicaid Coverage Guidelines for Transcutaneous Electrical Nerve Stimulation (TENS) and Functional Electrical Stimulation (FES). Vol 29. No 10. September 2013. Available:
- https://www.health.ny.gov/health_care/medicaid/program/update/2013/sept13_mu.pdf.
- 24. Noridian Healthcare Solutions. Local Coverage Determination (LCD) for Tumor Treatment Field Therapy (TTFT) (L34823). Revised Effective Date 01/01/2020. Available: https://med.noridianmedicare.com/web/jddme/policies/lcd/active.
- 25. The National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Central Nervous System Cancers. Version 1. 2016. Available: www.nccn.org.

- 26. Turner SG; et al. The effect of field strength on glioblastoma multiforme response in patients treated with the NovoTTF-100A system. World Journal of Surgical Oncology. 12 (p 162), 2014.
- 27. Kanner A.A., et al. Post hoc analyses of intention-to-treat population in phase III comparison of NovoTTF-100A system versus best physician's choice chemotherapy. Seminars in Oncology. 41 (S6) (pp S25-S34), 2014.
- 28. Mrugala M.M., et al. Clinical practice experience with NovoTTF-100A system for glioblastoma: The patient registry dataset (PRiDe). Seminars in Oncology. 41 (S6) (pp S4-S13), 2014.
- 29. Vymazal J., et al. Response patterns of recurrent glioblastomas treated with tumor-treating fields. Seminars in Oncology. 41 (S6) (pp S14-S24), 2014.
- 30. Stupp R., et al. NovoTTF-100A versus physician's choice chemotherapy in recurrent glioblastoma: A randomised phase III trial of a novel treatment modality. European Journal of Cancer. 48 (14) (pp 2192-2202), 2012.
- 31. Schoenen J1, Vandersmissen B, Jeangette S, Herroelen L, Vandenheede M, Gérard P, Magis D. Migraine prevention with a supraorbital transcutaneous stimulator: a randomized controlled trial. Neurology. 2013 Feb 19;80(8):697-704.
- 32. Weiner DK, Perera S, Rudy TE, et al. Efficacy of percutaneous electrical nerve stimulation and therapeutic exercise for older adults with chronic low back pain: a randomized controlled trial. Pain. Nov 30, 2008; 140(2):344-357.
- 33. Yokoyama M, Sun X, Oku S, et al. Comparison of percutaneous electrical nerve stimulation with transcutaneous electrical nerve stimulation for long-term pain relief in patients with chronic low back pain. Anesth Analg. Jun 2004; 98(6):1552-1556.
- 34. Ghoname EA, White PF, Ahmed HE, et al. Percutaneous electrical nerve stimulation: an alternative to TENS in the management of sciatica. Pain. Nov 1999; 83(2):193-199.
- 35. Ghoname EA, Craig WF, White PF, et al. Percutaneous electrical nerve stimulation for low back pain: arandomized crossover study. JAMA. Mar 3 1999; 281(9):818-823.
- 36. National Institute for Health and Care Excellence (NICE). IPG 450. Percutaneous electrical nerve stimulation for refractory neuropathic pain. 2013. Available: http://www.nice.org.uk/guidance/ipg450.
- 37. Stupp R, Wong ET, Kanner AA, et al. NovoTTF-100A versus physician's choice chemotherapy in recurrent glioblastoma: a randomised phase III trial of a novel treatment modality. Eur J Cancer 2012; 48:2192.
- 38. Sampson JH. Alternating Electric Fields for the Treatment of Glioblastoma. JAMA 2015; 314:2511.

- 39. Montori VM, Devereaux PJ, Adhikari NK, et al. Randomized trials stopped early for benefit: a systematic review. JAMA 2005; 294:2203.
- 40. Batchelor, Tracey, MD, MPH, et al. Initial postoperative therapy for glioblastoma and anaplastic astrocytoma. UpToDate®. Dec 08, 2016.
- 41. Centers for Medicare & Medicaid Services (CMS). National coverage determination (NCD) for vagus nerve stimulation (VNS) (160.18). https://www.cms.gov. Published May 4, 2007.
- 42. Hayes, Inc. Prognosis Overview. GammaCore transcutaneous nerve stimulator. http://www.hayesinc.com. Published September 6, 2018.
- 43. Chou DE, Gross GJ, Casadei CH, Yugrakh MS. External Trigeminal Nerve Stimulation for the Acute Treatment of Migraine: Open-Label Trial on Safety and Efficacy. Neuromodulation. 2017 Oct;20(7):678-683.
- 44. Di Fiore P, Bussone G, Galli A, Didier H, Peccarisi C, D'Amico D, Frediani F. Trancutaneous supraorbital neurostimulation for the prevention of chronic migraine: a prospective, open-label preliminary trial. Neurol Sci. 2017 May;38(Suppl 1):201-206.
- 45. Przeklasa-Muszynska A, Skrzypiec K, Kocot-Kepska M, Dobrogowski J, Wiatr M, Mika J. Non-invasive transcutaneous Supraorbital Neurostimulation (tSNS) using Cefaly® device in prevention of primary headaches. Neurol Neurochir Pol. 2017 Mar Apr;51(2):127-134.
- 46. HAYES Health Technology Assessment: Cranial Electrical Stimulation For The Treatment Of Fibromyalgia; Lansdale, PA: HAYES, Inc.; ©Hayes, a TractManager Company September 25, 2018 Annual Review: November 21, 2019; Reviewed January 14, 2020.
- 47. HAYES Evolving Evidence Review: Nerivio Migra (Theranica Bio-Electronics Ltd.) for Treatment of Acute Migraine Episodes. ©2021 Hayes, Inc, a sympir company. July 23, 2021.
- 48. Rapoport AM, Bonner JH, Lin T Harris D, Gruper Y, Ironi, A, Cowan RP. Remote electrical neuromodulation (REN) in the acute treatment of migraine: a comparison with usual care and acute migraine medications. J Headache Pain. 2019;20(1):83. Published 2019 Jul 22.
- 49. Yarnitsky D, Dodick DW, Grosberg BM, Burstein R, Ironi A, Harris D, Lin T, Silberstein SD. Remote electrical neuromodulation (REN) relieves acute migraine: a randomized, double-blind, placebo-controlled, multicenter trial. Headache. Sep 2019;59(8):1240-1252.
- 50. Isaacson S, Peckham E, Tse W, et al. Prospective home-use study on noninvasive neuromodulation therapy for essential tremor. Tremor and Other Hyperkinetic Movements.2020;10(1):1-16. https://digitalcommons.psjhealth.org.

- 51. Kim J, Wichmann T, Inan O, et al. A wearable system for attenuating essential tremor based on peripheral nerve stimulation. IEEE J Transl Eng Health Med.2020;8:1-11. https://www.embs.org.
- 52. UpToDate, Inc. Essential tremor: treatment and prognosis. http://www.uptodate.com. Updated February 2021.
- 53. HAYES Evolving Evidence Review: Cala Trio (Cala Health, Inc.) for Treatment of Essential Tremor. ©2021 Hayes, Inc, a sympir company. January 5, 2022.
- 54. HAYES Evolving Evidence Review: IB-Stim (Innovative Health Solutions) for Treatment of Pain Associated with Irritable Bowel Syndrome. ©2021 Hayes, Inc, a sympir company. March 5, 2021.
- 55. HAYES Evolving Evidence Review eXciteOSA Device (Signifier Medical Technologies LLC) for Treatment of Snoring in Patients With Primary Snoring or Mild Obstructive Sleep Apnea. ©2021 Hayes, Inc, a sympir company. December 12, 2022.
- 56. Hayes, Inc. Evidence Analysis Research Brief. Peripheral nerve stimulation with the SPRINT PNS System for chronic knee pain. Published January 8, 2021.
- 57. Hayes, Inc. Evidence Analysis Research Brief. SPRINT PNS System (SPR Therapeutics) for chronic pain. Published May 14, 2020.
- 58. Hayes, Inc. Evidence Analysis Research Brief. StimRouter Neuromodulation System (Bioness Inc.) for treatment of chronic pain. Published June 19, 2020.
- 59. Hayes, Inc. Evolving Evidence Review Nidra (Noctrix Health Inc) for Treatment of Restless Legs Syndrome. Hayes, Inc. August 13, 2024.
- 60. Hayes, Inc. Evolving Analysis Research Brief Sparrow Ascent (Spark Biomedical) for Management of Opioid Withdrawal Symptoms. Hayes, Inc. March 13, 2024.
- 61. Gilligan C, et al. Long-term outcomes of restorative neurostimulation in patients with refractory chronic low back pain secondary to multifidus dysfunction: two-year results of the ReActiv8-B pivotal trial. Neuromodulation 2023 Jan; 26(1): 87-97
- 62. Hayes, Inc.Evolving Evidence Review. ReActiv8 Implantable Neurostimulation System (Mainstay Medical Ltd.) for Chronic Low Back Pain. Hayes, Inc. August 5, 2024.

Customer Product	Medical Management Requirements*
New York Products	
HMO	Prior Auth
PPO in Plan	Prior Auth
PPO OOP	Potential for Retrospective Review
POS in Plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Prior Auth
MVP Child Health Plus	Prior Auth
MVP Harmonious Health Care Plan	Prior Auth
MVP Medicare Complete Wellness	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP Medicare WellSelect PPO	Prior Auth
MVP Medicare WellSelect Plus PPO	Prior Auth
MVP Medicare Patriot Plan PPO	Prior Auth
MVP DualAccess D-SNP HMO	Prior Auth
MVP DualAccess Complete D-SNP HMO	Prior Auth
MVP DualAccess Plus D-SNP HMO	Prior Auth
UVM Health Advantage Select PPO	Prior Auth
USA Care	Prior Auth
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	933 5. 2
POS In Plan	Prior Auth
POS OOP	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP VT HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
IVI JCCUIC	See SPD

[♦] Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro ReviewRetrospective Review RequiredNot CoveredService is not a covered benefit.See SPDSee Specific Plan Design

MVP Health Care Medical Policy

Revision History:

12/01/2021 - remote electrical neuromodulation (REN) electrical stimulation devices (e.g. Neverio) to the list of devices that are investigational for migraine headache treatment.

08/01/2022 – Added Cala Trio device (K1018, K1019), Percutaneous electrical nerve stimulation (PENS), percutaneous electrical nerve field stimulation (PENFS) (0720T), percutaneous neuromodulation therapy (PNT) or auricular electrostimulation devices (e.g., IB-Stim Device) to exclusions.

02/01/2023 – Adding prior authorization to K1018 and K1019.

06/01/2023 – Exclusions for electrical stimulation of muscles for treatment of scoliosis and biofeedback were removed from another medical policy and moved to this policy. No changes in policy position.

12/01/2023 -Added exclusion for eXciteOSA Daytime Therapy Device (E0490, E0491, K1028, K1029)

01/01/2024- Added new codes A4540, A4541, A4542, E0492, E0493, E0732, E0733, E0734, E0735 to prior authorization. Removed invalid codes K1002, K1016, K1017, K1018, K1019, K1020, K1023, K1028, K1029.

06/01/2024 – Moved Peripheral Nerve Stimulators and CPT Codes: 64555, 64596, 64597, 64598 and references to Hayes from Experimental Investigational Policy.

10/01/2024 - Removed prior authorization from HCPCS Codes: A4556, A4557, A4630, E0720, E0730.

12/01/2024 - Completed formal review of fast-track updates effective 10/01/2024.

2/1/2025 – added NTX100 Tonic Motor Activation (TOMAC) System (E0743, A4544) and auricular stimulation (E0721, A4543) Sparrow Ascent to exclusions as experimental and investigational.

06/01/2025 - ReActiv8 added to exclusions as experimental and investigational.



MVP Health Care Behavioral Health Medical Necessity Criteria

Electroconvulsive Therapy (ECT)

Type of Policy: Behavioral Health

Prior Approval Date: 12/05/2022

Approval Date: 11/04/2024

Effective Date: 02/01/2025

Related Polices: Mental Health Services

Electroconvulsive Therapy (ECT)

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

CPT Codes: N/A

Codes Requiring Retrospective Review

N/A

Experimental/Investigational

N/A

Common Diagnosis Codes associated with this policy have been provided for informational purposes only. The list of codes may not be all-inclusive and may be updated to reflect any applicable revisions to the ICD-10 code set and/or medical necessity guidelines applied in this policy.

Common Procedure Codes

00104 - Anesthesia for electroconvulsive therapy

90870 - Electroconvulsive therapy (includes necessary monitoring)

for all MVP plans.

Common Diagnosis Codes

F06.1, F20.0 – F20.9, F25.0 – F25.9, F30.10 – F30.9, F31.0 – F31.9, F32.0 – F33.9

InterQual Criteria Behavioral Health Policies

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Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP

Overview

Electroconvulsive Therapy (ECT) is a procedure during which brief electrical stimulation is applied to the brain while the patient is under anesthesia for the purpose of inducing a seizure. Acute or short–term ECT is used in adolescent, adult, and geriatric patients to treat unipolar or bipolar depression, acute mania, schizophrenia, schizoaffective disorder, schizophreniform disorder, post–partum psychosis, catatonia and neuroleptic malignant syndrome.

An ECT-privileged psychiatrist, an anesthesia provider, and any specialists who have provided consultation should all clear the patient for ECT before ECT is administered.

Historically, there have been racial and gender inequities in availability and utilization of ECT throughout the United States. MVP encourages clinicians to consider ECT in the management of the above conditions. See also MVP Treatment Guidelines for Depression, Bipolar Disorder, and Schizophrenia.

Indications/Criteria

Electroconvulsive Therapy (ECT) is covered for the following indications when coverage criteria are met:

- A. An ECT-privileged psychiatrist, an anesthesia provider, and any specialists who have provided consultation should all clear the patient for ECT before ECT is administered.
 - a. documents history, current symptoms, and rationale for treatment, etc.
- B. One of the following diagnoses must be present:
 - a. Major Depressive Episode
 - i. Major Depression, unipolar
 - ii. Major Depression, Recurrent
 - iii. Bipolar Disorder, depressed
 - iv. Bipolar Disorder, mixed
 - v. Bipolar Disorder, NOS
 - b. Manic Episode
 - i. Bipolar I Disorder, manic
 - ii. Bipolar I Disorder, mixed
 - iii. Bipolar I Disorder, NOS
 - iv. Bipolar I or II Disorder with rapid cycling

- c. Schizophrenia, any subtype, Schizoaffective Disorder, Schizophreniform Disorder
- d. Catatonia
 - i. Due to another mental disorder
 - ii. Due to another medical condition
 - iii. Unspecified
- e. Neuroleptic Malignant Syndrome
- f. Major Depressive Episode (with or without psychotic features) with peripartum onset
- g. Brief Psychotic Disorder with peripartum onset
- C. Indications for use of ECT *prior* to trial of other treatments including psychotropic medication include (but are not limited to):
 - Need for rapid, definitive response on either medical or psychiatric grounds for any of the following:
 - i. Severe agitation or aggression
 - ii. Delusions
 - iii. Hallucinations
 - iv. Socially withdrawn (e.g., delusions, paranoia, hallucinations, or depression)
 - v. Significant functional impairment
 - vi. Refusal of foods or fluids that presents a medical risk
 - vii. Unremitting self-injury and injuries requiring professional medical attention and not due to a personality disorder
 - b. High immanent risk for suicide or homicide
 - c. Neuroleptic Malignant Syndrome
 - d. Previous positive response to ECT
 - e. Risks of other treatments outweighs the risk of ECT
 - f. Patient preference
- D. Indications for use of ECT after a trial of treatment based on one of the following:
 - a. Adequate medication trial for the primary diagnosis:
 - i. Bipolar depression and trials of ≥ 2 different medications with established effectiveness for bipolar depression and at adequate doses and duration or stopped due to intolerable adverse effects
 - ii. Unipolar depression and trials of ≥ 2 different antidepressants from ≥ 2 different classes and at adequate doses and duration or stopped due to intolerable adverse effects
 - iii. For Catatonia: trial of benzodiazepine that is ineffective or not tolerated because of sedation
 - iv. For psychosis: at least one trial of antipsychotic at adequate doses and duration or stopped because of intolerance

- v. For NMS: no medication trials required, though alternative management is recommended.
- Medications contraindicated due to comorbid medical condition or potential for dangerous interaction with medications needed for comorbid medical condition(s)
- c. Substantial morbidity or mortality associated with delay in pharmacotherapeutic response
- d. Previous positive response to electroconvulsive therapy

The average course of treatment is 6 to 12 treatments, but some patients may require as many as 20 treatments. More than 20 sessions of ECT in a treatment series is rarely medically necessary to achieve remission; however additional, less frequent sessions may continue as prophylaxis, sometimes indefinitely. Continuation or maintenance ECT may be utilized after the initial course of acute ECT treatment to prevent relapse or recurrence of symptoms, respectively, based on the clinical assessment of the ECT provider.

Contraindications:

Although there are no absolute medical contraindications to ECT, there are specific conditions that may be associated with substantially increased risk and therefore may exclude a specific individual from this level of care. Such conditions include but are not limited to:

- a. unstable or severe cardiovascular conditions such as recent myocardial infarction, congestive heart failure, and severe valvular cardiac disease;
- b. aneurysm or vascular malformation that might be susceptible to rupture with increased blood pressure;
- increased intracranial pressure, as may occur with some brain tumors or other space-occupying lesions;
- d. recent cerebral infarction;
- e. pulmonary conditions such as severe chronic obstructive pulmonary disease, asthma, or pneumonia; and
- f. anesthetic risk rated as American Society of Anesthesiologists level 4 or 5

Exclusions

Combined ECT and other neuro-stimulation techniques (e.g., transcranial direct current stimulation, and repetitive transcranial magnetic stimulation) for the treatment of psychiatric disorders.

Electroconvulsive Therapy (ECT) is considered experimental and investigational for the treatment of the following indications because its effectiveness for these indications has not been established (not an all-inclusive list):

Autism Spectrum Disorder (ASD)

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Parkinson's Disease

Eating disorders Age < 13

Obsessive-compulsive disorder

Post-traumatic stress disorder

References (Reviewed 2024)

- 1. American Psychiatric Association, Practice guideline for the treatment of patients with major depressive disorder, third edition. 2010
- 2. American Psychiatric Association. Practice guideline for the treatment of patients with bipolar disorder, second edition. 2006; p. 851-944.
- 3. American Psychiatric Association Committee on Electroconvulsive Therapy, The practice of electroconvulsive therapy: Recommendations for treatment, training, and privileging, 2nd ed. 2001.
- 4. American Psychiatric Association, Practice Guideline for the Treatment of Patients with Schizophrenia, Third Edition. 2020
- 5. American Academy of Child and Adolescent Psychiatry, Electroconvulsive Therapy in Children and Adolescent: Brief Overview and Ethical Issues. 2012
- 6. Ali et al., Mol Neuropsychiatry 2019, 5: 75-83
- 7. Bahji et al., Acta Psychiatr Scand 2019, 139: 214-26
- 8. Benson and Seiner, Harv Rev Psychiatry 2019, 27: 354-8
- 9. Bodicherla et al., Cureus 2020, 12: e8832
- 10. Ghaziuddin et al., J Am Acad Child Adolesc Psychiatry 2004, 43: 1521-39
- 11. Isserles et al., J ECT 2020, 36: 42-6
- 12. Kuhlwilm et al., Acta Psychiatr Scand 2020, 142: 233-41
- 13. Meshkat S, Alnefeesi Y, Jawad MY, et al. Brain-derived neurotrophic factor (BDNF) as a biomarker of treatment response in patients with treatment resistant depression (TRD): A systematic review & meta-analysis. Psychiatry Res. 2022;317:114857.
- 14. McLoughlin DM, Mogg A, Eranti S, et al. The clinical effectiveness and cost of repetitive transcranial magnetic stimulation versus electroconvulsive therapy in severe depression: A multicentre pragmatic randomised controlled trial and economic analysis. Health Technol Assess. 2007;11(24):1-54.
- 15. Van den Berg et al., Am J Geriatr Psychiatry 2018, 26: 419-34
- 16. Wachtel et al., Curr Opin Psychiatry 2018, 31: 116-22
- 17. Sajith et al., J ECT 2017, 33: 63-7

- 18. Fontenelle et al., J Clin Psychiatry 2015,76: 949-57)
- 19. Case BG, et al. Racial differences in the availability and use of electroconvulsive therapy for recurrent major depression. J Affective Disorders 136(2012) 359-365.

Customer Product	Behavioral Health Management Requirements*
New York Products	
НМО	Potential for Retrospective Review
PPO in Plan	Potential for Retrospective Review
PPO OOP	Potential for Retrospective Review
POS in Plan	Potential for Retrospective Review
POS OOP	Potential for Retrospective Review
Essential Plan	Potential for Retrospective Review
MVP Medicaid Managed Care	Potential for Retrospective Review
MVP Child Health Plus	Potential for Retrospective Review
MVP Harmonious Health Care Plan	Potential for Retrospective Review
MVP Medicare Complete Wellness	Potential for Retrospective Review
MVP Medicare Preferred Gold HMO POS	Potential for Retrospective Review
MVP Medicare Secure HMO POS	Potential for Retrospective Review
MVP Medicare Secure Plus HMO POS	Potential for Retrospective Review
MVP Medicare WellSelect PPO	Potential for Retrospective Review
MVP Medicare WellSelect Plus PPO	Potential for Retrospective Review
MVP Medicare Patriot Plan PPO	Potential for Retrospective Review
MVP DualAccess D-SNP HMO	Potential for Retrospective Review
MVP DualAccess Complete D-SNP HMO	Potential for Retrospective Review
MVP DualAccess Plus D-SNP HMO	Potential for Retrospective Review
UVM Health Advantage Select PPO	Potential for Retrospective Review
USA Care	Potential for Retrospective Review
Healthy NY	Potential for Retrospective Review
MVP Premier	Potential for Retrospective Review
MVP Premier Plus	Potential for Retrospective Review
MVP Premier Plus HDHP	Potential for Retrospective Review
MVP Secure	Potential for Retrospective Review
MVP EPO	Potential for Retrospective Review
MVP EPO HDHP	Potential for Retrospective Review
MVP PPO	Potential for Retrospective Review
MVP PPO HDHP	Potential for Retrospective Review
Student Health Plans	Potential for Retrospective Review
ASO	See SPD
Vermont Products	
POS in Plan	Potential for Retrospective Review
POS OOP	Potential for Retrospective Review
MVP Medicare Preferred Gold HMO POS	Potential for Retrospective Review
MVP Medicare Secure Plus HMO POS	Potential for Retrospective Review
MVP VT HMO	Potential for Retrospective Review
MVP VT HDHP HMO	Potential for Retrospective Review
MVP VT Plus HMO	Potential for Retrospective Review
MVP VT Plus HDHP HMO	Potential for Retrospective Review
MVP Secure	Potential for Retrospective Review
ASO	See SPD

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Auth
Prior Authorization Required
Potential for Retrospective Review
No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Revision History

12/01/2021 – Transcranial Magnetic Stimulation is no longer reviewed with InterQual. See the Transcranial Magnetic Stimulation Behavioral Health Policy for current indications and criteria.

02/01/2023 – Title changed to Electroconvulsive Therapy because no authorization is required and InterQual is no longer used to review for medical necessity. Added diagnosis that are covered, indications for use of ECT prior to trail of other treatments and after a trial of treatments. Added exclusions to coverage.

02/01/2025 – Annual review; added exclusions for TMS, OCD and PTSD, updated references.



MVP Health Care Medical Policy

Emergency Department Services

Type of Policy: Medical

Prior Approval Date: 05/02/2022

Approval Date: 06/03/2024

Effective Date: 08/01/2024

Related Polices: N/A

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

N/A

Codes Requiring Retrospective Review

N/A

Experimental/Investigational

N/A

Common Diagnosis Codes

N/A

Common Procedure Codes

CPT Codes: 99281, 99282, 99283, 99284, 99285, 99291, 99292

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

MVP Health Care Medical Policy

An emergency medical condition or symptom may be due to a change in a person's physical or mental state that can potentially result in a serious and/or life-threatening event. Falls, burns, motor vehicle accidents and chest pain often require emergency medical services.

Emergency medical services in an Emergency Department setting may be provided by medical doctors (MD) and doctors of osteopathy (DO), physician assistants and nurse practitioners. Emergency Services rendered to a member shall not be subject to prior authorization, and reimbursement for Emergency Services shall not be denied retrospectively, if determined to be medically necessary to stabilize or treat an emergency condition.

Indications/Criteria

Emergency medical services may be indicated for the treatment of an emergency medical condition that is defined as follows: The term "emergency" is defined as the sudden onset of a medical condition (including emergency labor and delivery) manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possess an average knowledge of health and medicine, could reasonably expect that absence of immediate medical attention could result in any one of the following:

- placing the patient's health in serious jeopardy; or, in the case of a pregnant individual, the health of the individual or their unborn child; or
- · serious impairment to bodily functions; or
- serious dysfunction of any bodily organ or part; or
- serious disfigurement of such person.

This definition must be met at the time medical service is provided or it will not be considered to be an emergency medical condition. Not all services that are medically necessary meet the Federal definition of emergency medical condition.

Symptoms that a prudent layperson would not consider to result in serious impairment, dysfunction, disfigurement or serious health consequences are considered non-emergent. Emergency room services are not medically necessary for non-emergent care.

Court Ordered Services

Generally, court ordered services are not ordered to evaluate or treat a condition that requires immediate medical attention due to the risk of injury to bodily functions. Therefore, court ordered services do not meet the criteria of emergency services and are considered not medically necessary.

Exclusions

Not meeting criteria listed under Indications/Criteria of this policy.

Medicare

Emergency Care Service is not addressed in National or Local Coverage Determinations or policies (NCD or LCD).

Medicaid Managed Care Variation

Court ordered services are covered for MVP Medicaid Managed Care.

References (Updated 2024)

- 1. United States Federal law [42 USC 1396b(v)(3), SSA 1903(v)(3) and 42 CFR 440.255].
- 2. Emergency Medical Treatment and Active Labor Act (EMTALA) (1986).
- 3. New York State Insurance Laws. §4900 (c) and §4902 (a) (8).
- Centers for Medicare and Medicaid Services (CMS). Medicare managed care manual. Ch 4 - Benefits and Beneficiary Protections. 20.2 Definitions of emergency and urgently needed services. Jan 1, 2015. Available at URL address: https://www.cms.gov/Regulations-and-Guidance/Manuals/downloads/mc86c04.pdf

Customer Product	Medical Management Requirements*
New York Products	
HMO	Potential for Retrospective Review
PPO in Plan	Potential for Retrospective Review
PPO OOP	Potential for Retrospective Review
POS In plan	Potential for Retrospective Review
POS OOP	Potential for Retrospective Review
Essential Plan	Potential for Retrospective Review
MVP Medicaid Managed Care	Potential for Retrospective Review
MVP Child Health Plus	Potential for Retrospective Review
MVP Harmonious Health Care Plan	Potential for Retrospective Review
MVP Medicare Complete Wellness	Potential for Retrospective Review
MVP Medicare Preferred Gold HMO POS	Potential for Retrospective Review
MVP Medicare Secure HMO POS	Potential for Retrospective Review
MVP Medicare Secure Plus HMO POS	Potential for Retrospective Review
MVP Medicare WellSelect PPO	Potential for Retrospective Review
MVP Medicare WellSelect Plus PPO	Potential for Retrospective Review
MVP Medicare Patriot Plan PPO	Potential for Retrospective Review
MVP DualAccess D-SNP HMO	Potential for Retrospective Review
MVP DualAccess Complete D-SNP HMO	Potential for Retrospective Review
MVP DualAccess Plus D-SNP HMO	Potential for Retrospective Review
UVM Health Advantage Select PPO	Potential for Retrospective Review
USA Care	Potential for Retrospective Review
Healthy NY	Potential for Retrospective Review
MVP Premier	Potential for Retrospective Review
MVP Premier Plus	Potential for Retrospective Review
MVP Premier Plus HDHP	Potential for Retrospective Review
MVP Secure	Potential for Retrospective Review
MVP EPO	Potential for Retrospective Review
MVP EPO HDHP	Potential for Retrospective Review
MVP PPO	Potential for Retrospective Review
MVP PPO HDHP	Potential for Retrospective Review
Student Health Plans	Potential for Retrospective Review
ASO	See SPD
Vermont Products	
POS in Plan	Potential for Retrospective Review
POS OOP	Potential for Retrospective Review
MVP Medicare Preferred Gold HMO POS	Potential for Retrospective Review
MVP Medicare Secure Plus HMO POS	Potential for Retrospective Review
MVP VT HMO	Potential for Retrospective Review
MVP VT HDHP HMO	Potential for Retrospective Review
MVP VT Plus HMO	Potential for Retrospective Review
MVP VT Plus HDHP HMO	Potential for Retrospective Review
MVP Secure	Potential for Retrospective Review
ASO	See SPD

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review.

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Revision History:

08/01/2022 – Annual review. No changes made.

08/01/2024 - Annual Review; updated overview to reflect no prior authorization, added pregnant individuals and unborn children to indications, added references for Medicare and New York State.



Endobronchial Valve Devices

Type of Policy: Medical

Prior Approval Date: 07/11/2022

Approval Date: 07/01/2024

Effective Date: 10/01/2024

Related Polices:

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

31647 – Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with balloon occlusion, when performed, assessment of air leak, airway sizing, and insertion of bronchial valve(s), initial lobe

31648 – Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with removal of bronchial valve(s), initial lobe

31649 – Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with removal of bronchial valve(s), each additional lobe

31651 - Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with balloon occlusion, when performed, assessment of air leak, airway sizing, and insertion of bronchial valve(s), each additional lobe

Codes Requiring Retrospective Review

N/A

Experimental/Investigational

N/A

Common Diagnosis Codes

J43.0-J43.9 - Emphysema

Common Diagnosis Codes associated with this policy have been provided for informational purposes only. The list of codes may not be all-inclusive and may be updated to reflect any applicable revisions to the ICD-10 code set and/or medical necessity quidelines applied in this policy.

Common Procedure Codes

CPT Codes: N/A

HCPCS Codes: N/A

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

In individuals with severe emphysema, diseased tissues progressively lose their elasticity and fail to expand and contract properly leading to hyperinflation that results in poor gas exchange and difficulty breathing.

Endobronchial valves (EBV) have been proposed as a less invasive alternative to lung volume reduction surgery (LVRS) in emphysema, where damaged tissue is surgically removed to make the lungs smaller allowing them to function better. Endobronchial valve placement is a minimally invasive procedure that can be used to treat emphysema while avoiding surgery. The technique addresses one-way valves which allow air to exit during expiration but stop it from entering during inspiration, by reducing volume in the occluded lobe (Eberhardt, 2015). Based on the condition of the individual's lungs, multiple valves may be implanted.

The Zephyr EBV (Pulmonx) is an example of a device used in this procedure that was approved through the US Food & Drug Administration (FDA). Also, The Spiration valve system (Olympus) has been US Food & Drug Administration (FDA) approved for use in endobronchial valve treatment for severe emphysema.

Endobronchial coils are metal wires that are straight when loaded in a catheter for placement in an airway, and once deployed in the airway return to their predetermined shape to compress diseased tissue and achieve tension in the diseased airway network. This is intended to increase elastic recoil of the lungs and decrease trapped air and hyperinflation.

Indications/Criteria

The use of endobronchial valve devices (EBV) is considered medically necessary for the treatment of individuals with severe emphysema when all of the following criteria are met:

1. Customer diagnosed with severe heterogeneous lung emphysema;

AND

- 2. Pulmonary function test that as demonstrated by all of the following:
 - Forced expiratory volume (FEV1) is less than 45% predicted; and
 - Total lung capacity (TLC) is greater than or equal to 100% predicted; and
 - Residual volume (RV) is greater than or equal to 180% predicted;
 AND
- 3. Functional and health parameters suggest likely to benefit from EBV as demonstrated by all of the following:
 - 6-minute walk distance greater than 140 meters; and
 - Nonsmoking for greater than 4 consecutive months; and
 - Body mass index (BMI) less than 35 kg/m².

Exclusions

The use of endobronchial valve devices is considered not medically necessary when the above criteria are not met and for all other indications including when the lung disease is not heterogenous.

Endobronchial coils for use in adult patient with homogenous or heterogeneous lung emphysema.

Medicare

Based on a review there is no Medicare National Coverage Determination (NCD) or Local Coverage Determinations (LCD).

References (Reviewed 2024)

- 1. Anile M, Venuta F, De Giacomo T, et al. Treatment of persistent air leakage with endobronchial one-way valves. J Thorac Cardiovasc Surg. 2006; 132(3):711-712.
- 2. Choi M, Lee WS, Lee M, et al. Effectiveness of bronchoscopic lung volume reduction using unilateral endobronchial valve: a systematic review and meta-analysis. Int J Chron Obstruct Pulmon Dis. 2015;10:703-710.
- 3. Criner GJ, Delage A, Voelker K, et al. Improving Lung Function in Severe Heterogeneous Emphysema with the Spiration(R) Valve System (EMPROVE): a multicenter, open-label, randomized, controlled trial. Am J Respir Crit Care Med. 2019; 200(11):1354-1362.
- 4. Criner, GJ, Sue, R, Wright, S, et al.; LIBERATE Study Group. A multicenter RCT of Zephyr Endobronchial Valve treatment in heterogeneous emphysema (LIBERATE). Am J Respir Crit Care Med. 2018; 198(9):1151-1164.

- 5. De Giacomo T, Venuta F, Diso D, Coloni GF. Successful treatment with one-way endobronchial valve of large air-leakage complicating narrow-bore enteral feeding tube malposition. Eur J Cardiothorac Surg. 2006; 30(5):811-812.
- 6. Dransfield MT, Garner JL, Bhatt SP, et al. Effect of Zephyr endobronchial valves on dyspnea, activity levels, and quality of life at one year. Results from a randomized clinical trial. AnnAm Thorac Soc. 2020; 17(7):829-838.
- 7. Fiorelli A, Santoriello C, De Felice A, et al. Bronchoscopic lung volume reduction with endobronchial valves for heterogeneous emphysema: long-term results. J Vis Surg. 2017; 3:170.
- 8. Flora A, Aragaki-Nakahodo A, Benzaquen S. Endobronchial valve placement for persistent air leaks secondary to pulmonary infections. J Bronchology Interv Pulmonol. 2021; 28(1):47-52.
- 9. Gompelmann D, Benjamin N, Bischoff E, et al. Survival after endoscopic valve therapy in patients with severe emphysema. Respiration. 2019a; 97(2):145-152.
- 10. Hayes, Inc. Medical Technology Directory. Comparative Effectiveness Review. Bronchoscopically placed coils or valves for lung emphysema: a review of reviews. Published February 25, 2019. Updated January 18, 2022. Available: https://evidence.hayesinc.com/.
- 11. Hayes, Inc. Search & Summary (ARCHIVED). Zephyr endobronchial valve (Pulmonx) for treatment of emphysema. Published October 23, 2018.
- 12. Huang X, Ding L, Xu H. Bronchoscopic valve placement for the treatment of persistent air leaks. Medicine (Baltimore). 2018; 97(13):e0183.
- 13. Klooster K, Hartman JE, Ten Hacken NH, Slebos DJ. One-year follow-up after endobronchial valve treatment in patients with emphysema without collateral ventilation treated in the STELVIO trial. Respiration. 2017; 93(2):112-121.
- 14. Klooster K, Ten Hacken NH, Hartman JE, et al. Endobronchial valves for emphysema without interlobar collateral ventilation. N Engl J Med. 2015; 373(24):2325-2335.
- 15. Labarca G, Uribe JP, Pacheco C, et al. Bronchoscopic lung volume reduction with endobronchial Zephyr valves for severe emphysema: a systematic review and meta-analysis. Respiration. 2019; 98(3):268-278.
- 16. Marchetti N, Kaufman T, Chandra D, et al. Endobronchial coils versus lung volume reduction surgery or medical therapy for treatment of advanced homogenous emphysema. Chronic Obstr Pulm Dis. 2018;5(2):87-96.
- 17. Schweigert M, Kraus D, Ficker JH, Stein HJ. Closure of persisting air leaks in patients with severe pleural empyema use of endoscopic one-way endobronchial valve. Eur J Cardiothorac Surg. 2011; 39(3):401-403.

- 18. Sciurba FC, Ernst A, Herth FJ, et al.; VENT Study Research Group. A randomized study of endobronchial valves for advanced emphysema. N Engl J Med. 2010; 363(13):1233-1244.
- 19. Toma TP, Hopkinson NS, Hillier J, et al. Bronchoscopic volume reduction with valve implants in patients with severe emphysema. Lancet. 2003; 361(9361):931-933.
- 20. Trudzinski FC, Höink AJ, Leppert D, et al. Endoscopic lung volume reduction using endobronchial valves in patients with severe emphysema and very low FEV1. Respiration. 2016; 92(4):258-265.
- 21. Valipour A, Slebos DJ, Herth F, et al. Endobronchial valve therapy in patients with homogeneous emphysema. Results from the IMPACT study. Am J Respir Crit Care Med 2016; 194(9): 1073-1082.
- 22. van Dijk M, Hartman JE, Klooster K, et al. Endobronchial valve treatment in emphysema patients with a very low DLCO. Respiration. 2020; 99(2):163-170.
- 23. Wood DE, McKenna RJ Jr, Yusen RD, et al. A multicenter trial of an intrabronchial valve for treatment of severe emphysema. J Thorac Cardiovasc Surg. 2007; 133(1):65-73.
- 24. Zoumot Z, Davey C, Jordan S, et al. Endobronchial valves for patients with heterogeneous emphysema and without interlobar collateral ventilation: open label treatment following the BeLieVeR-HIFi study. Thorax. 2017; 72(3):277-279.

Customer Product	Medical Management Requirements*
New York Products	
HMO	Prior Auth
PPO in Plan	Prior Auth
PPO OOP	Prior Auth
POS in Plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Prior Auth
MVP Child Health Plus	Prior Auth
MVP Harmonious Health Care Plan	Prior Auth
MVP Medicare Complete Wellness	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP Medicare WellSelect PPO	Prior Auth
MVP Medicare WellSelect Plus PPO	Prior Auth
MVP Medicare Patriot Plan PPO	Prior Auth
MVP DualAccess D-SNP HMO	Prior Auth
MVP DualAccess Complete D-SNP HMO	Prior Auth
MVP DualAccess Plus D-SNP HMO	Prior Auth
UVM Health Advantage Select PPO	Prior Auth
USA Care	Potential for Retrospective Review
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	Prior Auth
Vermont Products	
POS in Plan	Prior Auth
POS OOP	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP VT HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	Prior Auth

[♦] Note: Prior authorization requirements for HDHP products are the same as the base product (e.g., HDHP HMO auth requirements are the same as listed for HMO).

*Medical Management Requirements

Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review.

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

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MVP Health Care Medical Policy Revision History:

10/01/2022 – new policy effective

10/01/2024 – Annual review, no changes to criteria.



Endometrial Ablation

Type of Policy: Surgical

Prior Approval Date: 10/07/2024 **Provisional Approval** 05/30/2025

Date:

Provisional Effective

Date:

06/06/2025

Related Polices: Gender Affirming Treatment

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

58353 - Endometrial ablation, thermal, without hysteroscopic guidance

58356 - Endometrial cryoablation with ultrasonic guidance, including endometrial curettage, when performed

58563 - Hysteroscopy, surgical; with endometrial ablation (e.g., endometrial resection, electrosurgical ablation, thermoablation)

Codes Requiring Retrospective Review

None

Experimental/Investigational

None

Common Diagnosis Codes

Medically appropriate codes for when criteria are met in the policy:

Code:	Description:
F64.0-F64.9	Gender identity disorder (code range)
N92.0	Excessive and frequent menstruation with regular cycle
N92.1	Excessive and frequent menstruation with irregular cycle
N92.4	Excessive bleeding in the premenopausal period
N93.8	Other specified abnormal uterine and vaginal bleeding

Endometrial Ablation Page 1 of 5

N93.9	Abnormal uterine and vaginal bleeding, unspecified
Z87.890	Personal history of sex reassignment

Common Procedure Codes

CPT Codes: None

HCPCS Codes: None

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

Endometrial ablation is a medical procedure used to destroy the lining of the uterus (endometrium). It is typically performed to treat heavy menstrual bleeding that has not responded to other treatments and as an alternative to hysterectomy. The goal of the procedure is to reduce or stop menstrual flow. The procedure can be done using various methods, including radiofrequency, cryoablation, heated saline, or thermal fluid-filled balloon. Endometrial ablation is minimally invasive and can often be performed on an outpatient basis without general anesthesia. It is not recommended for persons who wish to become pregnant in the future, as it can significantly reduce or eliminate the possibility of pregnancy.

Indications/Criteria

Endometrial Ablation is covered when all of the following criteria are met:

- A. Is premenopausal, not pregnant, and has no desire for future childbearing; and
- B. Has abnormal uterine bleeding for greater than three (3) menstrual cycles that interferes with activities of daily living (ADLs); and
- C. Current Pap smear is within normal limits; and
- D. Diagnostic evaluation of the endometrium within the past 12 months by endometrial biopsy, or dilatation and curettage (D&C) failed to show evidence of remediable pathology; and
- E. Imaging within the last year that was negative for endometrial lesion (e.g., ultrasound, sonohysterogram); and
- F. Other bleeding disorders excluded or treated (e.g., thyroid disease); and
- G. Failed to respond to hormone therapy (contraceptives, progestin) or there is a contraindication to hormone therapy.

Endometrial ablation is considered covered for treatment of residual menstrual bleeding resulting from medically necessary gender affirming androgen therapy.

Endometrial Ablation Page 2 of 5

Exclusions

Endometrial ablation is not medically necessary for any other indication.

References (2024)

- 1. American College of Obstetricians and Gynecologists. Practice Bulletin #81: Endometrial ablation. Obstet Gynecol 2007 May;109(5):1233-48.
- 2. American Society for Reproductive Medicine. Indications and options for endometrial ablation. Fertil Steril 2008 Nov;90(5 Suppl):S236-40.
- 3. Bhattacharya S, et al. Hysterectomy, endometrial ablation and Mirena® for heavy menstrual bleeding: a systematic review of clinical effectiveness and cost-effectiveness analysis. Health Technol Assess 2011 Apr;15(19):iii-xvi,1-252.
- 4. Daniels JP, et al. International Heavy Menstrual Bleeding IPD Meta-analysis Collaborative Group. Second generation endometrial ablation techniques for heavy menstrual bleeding: network meta-analysis. BMJ 2012 Apr 23;344:e2564.
- 5. Dickerson, et al. Hyesterectomy compared with endometrial ablation for dysfunctional uterine bleeding, a randomized controlled trial. The American College of Obstetricians and Gynecologists 2007 Dec;110(6)1279-1289.
- 6. El-Nashar SA, et al. Global endometrial ablation for menorrhagia in women with bleeding disorders. Obstet Gynecol 2007 Jun;109(6):1381-7.
- Hoaglin DC, et al. Use of mixed-treatment-comparison methods in estimating efficacy of treatments for heavy menstrual bleeding. Eur J Med Res 2013 Jun 21;18:17.
- 8. World Professional Association for Transgender Health (WPATH). Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming people. 2022 8th version.

Endometrial Ablation Page 3 of 5

Member Product	Medical Management Requirements*
New York Products	
HMO	Prior Authorization
PPO in Plan	Prior Authorization
PPO OOP	Prior Authorization
POS in Plan	Prior Authorization
POS OOP	Prior Authorization
Essential Plan	Prior Authorization
MVP Medicaid Managed Care	Prior Authorization
MVP Child Health Plus	Prior Authorization
MVP Harmonious Health Care Plan	Prior Authorization
MVP Medicare Complete Wellness	Prior Authorization
MVP Medicare Preferred Gold HMO POS	Prior Authorization
MVP Medicare Secure HMO POS	Prior Authorization
MVP Medicare Secure Plus HMO POS	Prior Authorization
MVP Medicare WellSelect PPO	Prior Authorization
MVP Medicare WellSelect Plus PPO	Prior Authorization
MVP Medicare Patriot Plan PPO	Prior Authorization
MVP DualAccess D-SNP HMO	Prior Authorization
MVP DualAccess Complete D-SNP HMO	Prior Authorization
MVP DualAccess Plus D-SNP HMO	Prior Authorization
UVM Health Advantage Select PPO	Prior Authorization
USA Care PPO	Potential for Retrospective Review
Healthy NY	Prior Authorization
MVP Premier	Prior Authorization
MVP Premier Plus	Prior Authorization
MVP Premier Plus HDHP	Prior Authorization
MVP Secure	Prior Authorization
MVP EPO	Prior Authorization
MVP EPO HDHP	Prior Authorization
MVP PPO	Prior Authorization
MVP PPO HDHP	Prior Authorization
Student Health Plans	Prior Authorization
ASO	Prior Authorization
Vermont Products	
POS in Plan	Prior Authorization
POS OOP	Prior Authorization
MVP Medicare Preferred Gold HMO POS	Prior Authorization
MVP Medicare Secure Plus HMO POS	Prior Authorization
MVP VT HMO	Prior Authorization
MVP VT Plus HMO	Prior Authorization
MVP VT HDHP HMO	Prior Authorization
MVP VT Plus HDHP HMO	Prior Authorization
MVP Secure	Prior Authorization
ASO	Prior Authorization

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

*Medical Management Requirements

Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review.

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Endometrial Ablation Page 4 of 5

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Revision History:

12/01/2024 – New Policy; Added prior authorization to 58353, 58356, 58563.

06/06/2025 – Updated Pap testing to state "current" testing.

Endometrial Ablation Page 5 of 5



MVP Health Care

Endoscopy (Esophagogastroduodenoscopy and Colonoscopy)

Type of Policy: Medical

Prior Approval Date: 10/03/2023

Approval Date: 12/04/2023

Effective Date: 02/01/2024

Related Polices: Capsule Endoscopy

Botulinum Toxin Injection

Monitored Anesthesia Care

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

N/A

Codes Subject to Retrospective Review

N/A

Experimental/Investigational

0647T - Insertion of gastrostomy tube, percutaneous, with magnetic gastropexy, under ultrasound guidance, image documentation and report

43252 - Esophagogastroduodenoscopy, flexible, transoral; with optical endomicroscopy

Common Diagnosis Codes

ICD-10-CM Diagnosis Codes: C12, C13.0, C13.1, C13.2, C13.8, C13.9, C15.3, C15.4, C15.5, C15.8, C15.9, C30.1, C31.9, C32.0, C32.1, C32.2, C32.3, C32.8, C32.9, C33, C78.1, C78.39, C78.4, C81.01, C81.02, C81.03, C81.13, C81.12, C81.21, C81.22, C81.23, C81.31, C81.32, C81.33, C81.41, C81.42, C81.43, C81.71, C81.72, C81.73, C81.91, C81.92, C81.93, C82.91, C82.92, C82.93, C83.11, C83.12, C83.13, C83.31, C83.32, C83.33, C83.51, C83.52, C83.53,

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C83.71, C83.72, C83.73, C83.81, C83.82, C83.83, C84.01, C84.02, C84.03, C84.11, C84.12, C84.13, C84.43, C84.61, C84.62, C84.63, C84.71, C84.72, C84.73, C84.93, C85.83, C96.2, C96.A, D12.0, D12.1, D12.6, D13.0, D13.1, D13.2, D13.30, D13.39, D37.8, D37.9, D50.0, D50.1, D50.8, D50.9, D62, I69.991, I85.00, I85.01, I85.10, I85.11, J86.0, K20.0, K20.8, K20.9, K21.0, K21.9, K22.70, K22.10, K22.11, K22.2, K22.3, K22.4, K22.5, K22.6, K22.8, K25.0, K25.1,K25.2, K25.3, K25.4, K25.5, K25.7, K25.9, K26.0, K26.2, K26.3, K26.4, K26.5, K26.6, K26.7, K26.9, K27.0, K27.1, K27.2, K27.3, K27.4, K27.5, K27.6, K27.7, K27.9, K28.0, K28.1, K28.2, K28.3, K28.4, K28.5, K28.6, K28.7, K28.9, K30, K31.7, K50.00, K50.10, K50.80, K50.90, K51.00, K51.20, K51.30, K51.40, K51.50, K51.80 K51.90, K56.60, K58.9, K63.5, K70.30, K74.0, K74.60, K64.69, K76.6, K92.0, K92.1, K92.2, Q26.5, Q39.0, Q39.1, Q39.2, Q39.3, Q39.4, Q39.5, Q39.6, Q39.8, Q40.2, R10.11, R10.12, R10.13, R10.33, R11.10, R13.0. R13.10, R13.11, R13.12, R13.13, R13.14, R13.19, R93.3, R93.5, T18.100A, T18.108A, T18.110A, T18.120A, T18.128A, T18.190A, T18.198A, T18.2XXA, T18.8XXA, T18.9XXA, T28.1XXA, T28.6XXA, T54.0X1A, T54.0X2A, T54.0X3A, T54.0X4A, T54.1X1a, T54.1X2A, T54.1X3A, T54.1X4A, T54.92XA, T54.93XAT54.2X1A, T54.2X2A, T54.2X3A, T54.2X4A, T54.3X1A, T54.3X2A, T54.3X3A, T54.3X4A, Z12.10, Z12.11, Z12.12

Common Procedure Codes

CPT Codes: 43200, 43201, 43202, 43204, 43205, 43215, 43216, 43217, 43220, 43226, 43227, 43231, 43232, 43235, 43236, 43237, 43238, 43239, 43240, 43241, 43242, 43243, 43244, 43245, 43246, 43247, 43248, 43249, 43250, 43251, 43255, 43258, 43259, 43266, 44388, 44389, 44390, 44391, 44392, 44394, 45378, 45379, 45380, 45381, 45382, 43197, 43198, 43211, 43212, 43213, 43214, 43229, 43233, 43254, 43266, 43270, 44401, 44402, G0104, G0105, G0121

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive.

Overview

Esophagogastroduodenoscopy is a technique, utilizing an endoscope, which allows the visualization of the mucosal surfaces of the esophagus, stomach, and proximal duodenum. Standard diagnostic functions include inspection, biopsy, photography, and video recording. Esophagogastroduodenoscopy is also used to perform therapeutic procedures such as dilation of strictures, retrieval of foreign bodies, control of hemorrhage, etc.

Colonoscopy is a technique utilizing a colonoscope which allows the direct visual inspection of the entire colon and rectum. Standard diagnostic functions include inspection or biopsy. Colonoscopy is also used for therapeutic procedures such as excision of polyps or other abnormalities, control of hemorrhage, dilation of strictures, removal of foreign bodies, etc.

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Indications/Criteria

Esophagogastroduodenoscopy (EGD)

Screening Esophagogastroduodenoscopy (EGD)

- Potential Barrett's esophagus: Individuals with chronic (e.g., > 5 years of symptoms)
 gastroesophageal reflux disease (GERD) with multiple risk factors for Barrett's
 esophagus. Such risk factors for Barrett's esophagus include age older than 50 years,
 male gender, white race, hiatal hernia, elevated body mass index, and intraabdominal distribution of body fat.
- Potential cirrhosis and portal hypertension: Individuals with cirrhosis and portal hypertension but no prior variceal hemorrhage, especially those with platelet counts less than 140,000/mm3, or Child's class B or C disease.
- Potential pernicious anemia: Individuals with possible pernicious anemia (e.g., anemia, fatigue, tingling and numbness in the hands and feet, red tongue, shortness of breath) to identify prevalent lesions (e.g., carcinoid tumors, gastric cancer).

Diagnostic Esophagogastroduodenoscopy (EGD)

- Upper abdominal symptoms, including dyspepsia, that persist despite an adequate trial of proton pump inhibitor (PPI) therapy (at least daily ≥ 8 weeks).
- Upper abdominal symptoms associated with other symptoms or signs suggesting structural disease (e.g., anorexia and involuntary weight loss, bleeding, or dysphagia) or new onset symptoms in patients older than 50 years of age.
- Dysphagia or odynophagia.
- Esophageal reflux symptoms that persist or recur despite appropriate therapy, (anti-H. pylori treatment ≥ 10 days or acid suppression treatment ≥ 8 weeks).
- Evaluation of persistent vomiting of unknown cause.
- Other diseases in which the presence of upper GI pathology might modify other planned management (e.g., patients who have a history of ulcer or GI bleeding who are scheduled for organ transplantation, long-term anticoagulation or non-steroidal anti-inflammatory drug therapy for arthritis and those with cancer of the head and neck).
- Evaluation of familial adenomatous polyposis syndromes.
- Abnormal imaging studies suggestive of any of the following:
 - o suspected neoplastic lesion;
 - o gastric or esophageal ulcer; or
 - o upper GI tract stricture or obstruction.

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- GI bleeding:
 - o in patients with active or recent bleeding; or
 - o for presumed chronic blood loss and for iron deficiency anemia when the clinical situation suggests an upper GI source or when colonoscopy does not provide an explanation.
- When sampling of tissue or fluid from the upper GI tract is indicated.
- Evaluation of acute injury after caustic ingestion.
- To assess chronic diarrhea in patients suspected of having small-bowel disease (e.g., celiac disease) in the absence of significant findings on laboratory studies and lower endoscopy.
- Fecal Occult Blood Test (FOBT) positive with iron deficiency with one of the following:
 - o upper GI symptoms;
 - lower GI symptoms and lower GI tract evaluation non-diagnostic for FOBT positive; or
 - asymptomatic individual with one of the following:
 - <40 years old with continued FOBT positive after therapy (acid suppression therapy ≥ 4 weeks and no ASA/NSAID ≥4 weeks); or
 - ≥40 years old.
- Evaluation of esophageal masses and for directing biopsies for diagnosing esophageal cancer.
- Evaluation of persons with signs or symptoms of loco-regional recurrence after resection of esophageal cancer.

Therapeutic esophagogastroduodenoscopy (EGD)

- Manage and control esophagus or gastric variceal bleeding.
- Dilation of stenotic lesions (e.g., with trans-endoscopic balloon dilators or dilation systems using guide wires.
- Management of achalasia (e.g., botulinum toxin, balloon dilation).
- Palliative treatment of stenosing neoplasms (e.g., laser, multipolar electrocoagulation, stent placement).
- Placement of feeding or drainage tubes (trans-nasal, percutaneous endoscopic gastrostomy, percutaneous endoscopic jejunostomy).
- Removal of foreign bodies.

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- Treatment of bleeding lesions such as ulcers, tumors, vascular abnormalities (e.g., electrocoagulation, heater probe, laser photocoagulation, or injection therapy).
- Radiofrequency ablation (e.g., using a radiofrequency ablation catheter system) is covered for customers with Barrett's esophagus and low-grade dysplasia.
- Barrett's esophagus with high-grade dysplasia (HGD) may be treated with radiofrequency ablation (RFA), but only after endoscopic mucosal resection (EMR) of the intramucosal carcinoma (IMC) or visible lesion.

Sequential or periodic esophagogastroduodenoscopy (EGD)

- Surveillance of individuals with Barrett's esophagus without dysplasia: for individuals with Barrett's esophagus with no dysplasia, follow-up endoscopy every three to five years.
- Surveillance of individuals with Barrett's esophagus and low-grade dysplasia within six months. If low-grade dysplasia is confirmed, follow-up endoscopy at 12 months and yearly thereafter until no dysplasia is present on two consecutive annual endoscopies.
- Surveillance of individuals with Barrett's esophagus and high-grade dysplasia within three months, follow-up endoscopy every three months.
- Surveillance of individuals with caustic injury to the esophagus: every one to three years beginning 15 to 20 years after caustic ingestion.
- Surveillance of individuals with tylosis: every one to three years beginning at age 30 years.
- Surveillance of individuals with familial adenomatous polyposis around the time of colectomy or after age 30 years.
- Surveillance for recurrence of adenomatous polyposis in synchronous and metachronous sites at three to five-year intervals.
- Surveillance of individuals with symptomatic peptic ulcer disease refractory to appropriate medical therapy (anti-H pylori therapy or acid suppression therapy).

Colonoscopy

Screening Colonoscopy

- Screening of asymptomatic, average-risk individual age ≥ 45 years and ≤ 75 years. If negative/no polyps, repeat colonoscopy in 10 years.
- Screening of individuals with increased risk based on positive family history:
 - o personal history of adenoma or adenomatous polyps found on colonoscopy
 - familial history of adenoma or adenomatous polyp found at colonoscopy in a first-degree relative

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- personal or family history of colorectal cancer
- personal or inherited risk of a colorectal cancer (e.g., familial adenomatous polyposis [FAP], attenuated FAP, hereditary nonpolyposis colorectal cancer [HNPCC], MYH polyposis)
- o personal history of inflammatory bowel disease (e.g., ulcerative colitis, Crohn's disease)
- Examination to evaluate the entire colon for synchronous cancer or neoplastic polyps in a patient with treatable cancer or neoplastic polyp.
- Colonoscopy to remove synchronous neoplastic lesions at or around the time of curative resection of cancer followed by colonoscopy at one year and, if normal, then three years, and, if normal, then five years thereafter to detect metachronous cancer.
- Follow-up for removal of neoplastic polyp (follow-up at least three to six months to verify removal of large sessile adenoma [i.e., 2 cm in greatest dimension] after colonoscopic removal).
- Periodic colonoscopy post colon cancer surgery:
 - follow-up in one-year post colon resection;
 - o follow-up in three years post colon resection and surveillance colonoscopy at one year negative; and
 - follow-up in five years post colon resection and surveillance colonoscopy at three years negative.
- For individuals with Crohn's colitis and chronic ulcerative colitis: colonoscopy every one to two years with multiple biopsies for detection of cancer and dysplasia with one of the following:
 - o pancolitis of greater than seven years duration, or
 - left-sided colitis of over 15 years duration
- Follow-up for individuals positive for polyps: If the most advanced lesions at baseline colonoscopy are distal hyperplastic polyps <10 mm, the interval for colonoscopic follow-up should be 10 years.

Diagnostic Colonoscopy

- Evaluation of an abnormality discovered on barium enema and/or other imaging study that is likely to be clinically significant, such as a filling defect, or stricture, or an inadequate examination.
- Evaluation of unexplained gastrointestinal bleeding:
 - hematochezia;

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- o melena after an upper GI source has been excluded; and
- presence of fecal occult blood.
- Unexplained iron deficiency anemia.
- For evaluation of patients with chronic inflammatory bowel disease of the colon, if more precise diagnosis or determination of the extent of activity of disease will influence management.
- Evaluation of clinically significant diarrhea of unexplained origin (negative stool cultures, stool for ova and parasites negative x3, stool for C. difficile toxin titer negative).
- Evaluation of acute colonic ischemia/ischemic bowel disease (without signs of perforation).
- Evaluation of individual with Streptococcus bovis endocarditis.
- Evaluation of unexplained constipation (medical evaluation non-diagnostic for etiology of constipation) refractory to medical therapy (fiber supplementation, hyperosmotic agent, stool softener).
- Evaluation of anorectal polyp (adenomatous polyp only).
- Intraoperative identification of a lesion not apparent at surgery (e.g., polypectomy site, location of a bleeding site).
- Pre-operative tattooing of a lesion to facilitate intraoperative identification.
- Fecal Occult Blood Test (FOBT) positive without iron deficiency with one of the following:
 - o upper GI symptoms and EGD non-diagnostic for etiology of FOBT positive;
 - o lower GI symptoms; or
 - asymptomatic individual with one of the following:
 - <40 years old with continued FOBT positive after therapy (acid suppression therapy ≥ 4 weeks and no ASA/NSAID ≥4 weeks and EGD non-diagnostic for etiology of FOBT positive); or</p>
 - ≥40 years old.

Therapeutic Colonoscopy

- Treatment of bleeding from such lesions as vascular malformations, ulceration, neoplasia, and polypectomy site.
- Intraoperative evaluation of anastomotic reconstructions typical of surgery to treat diseases of the colon and rectum (e.g., evaluation for anastomotic leak and patency, bleeding, pouch formation).

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- As an adjunct to minimally invasive surgery for the treatment of diseases of the colon and rectum.
- Management or evaluation of operative complications (e.g., dilation of anastomotic strictures).
- Removal of foreign body.
- Excision of colonic polyps.
- Decompression of pseudo-obstruction of the colon (Olgilvie's syndrome).
- Treatment of sigmoid volvulus or stricture.
- Dilation of stenotic lesions (e.g., anastomotic strictures).
- Palliative treatment of stenosing or bleeding neoplasms (e.g., laser, electrocoagulation, stenting).

Bidirectional Endoscopy on the Same Day

Bidirectional endoscopy should be performed on the same day when both an esophagogastroduodenoscopy (EGD) and colonoscopy are required to minimize patient exposure to sedating agents and multiple bowel preparation.

Any bidirectional endoscopy not performed on the same day (when tests are separated by \leq 3 months) will require clinical rationale to support medical necessity of doing each procedure on a separate day.

Endoscopic submucosal dissection (ESD)

Endoscopic submucosal dissection (ESD) is a covered benefit for its indications.

Exclusions

Requests not meeting Indications/Criteria stated in this policy.

Esophagogastroduodenoscopy (EGD)

- For confirming placement of gastric band
- For diagnosing laryngopharyngeal reflux
- For routine screening
- Symptoms that are considered functional in origin.
- Metastatic adenocarcinoma of unknown primary site when the results will not alter management.
- Radiographic findings of:
 - o asymptomatic or uncomplicated sliding or hiatal hernia;
 - o uncomplicated duodenal ulcer that has responded to therapy; or

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- o deformed duodenal bulb when symptoms are absent or respond adequately to ulcer therapy.
- Surveillance for malignancy in individuals with gastric atrophy, pernicious anemia, fundic gland or hyperplastic polyps, gastric intestinal metaplasia, or previous gastric operations for benign disease.
- Surveillance of healed benign disease, such as esophagitis and gastric or duodenal ulcer.

Colonoscopy

Colonoscopy is generally not indicated in the following circumstances:

- chronic, stable, irritable bowel syndrome or chronic abdominal pain; there are unusual exceptions in which colonoscopy may be done once to rule out disease, especially if symptoms are unresponsive to therapy;
- acute non-bloody diarrhea;
- hemorrhoids;
- metastatic adenocarcinoma of unknown primary site in the absence of colonic signs or symptoms when it will not influence management;
- routine follow-up of inflammatory bowel disease (except for cancer surveillance in chronic ulcerative colitis and Crohn's colitis);
- GI bleeding or melena with a demonstrated upper GI source;
- bright red rectal bleeding with a convincing anorectal source on sigmoidoscopy and no other symptoms suggestive of a more proximal bleeding source;
- fulminant colitis;
- possible perforated vicus;
- acute severe diverticulitis; or
- diverticulosis. (This condition in not usually considered an indication for diagnostic or therapeutic colonoscopy but may be reported on the claim when the condition is found to be the final diagnosis).
- Magnetic Gastropexy (0647T) for the insertion of gastrostomy tube is considered to be investigational because there is a low-quality body of evidence regarding the safety and effectiveness of the procedure compared with other procedures.

Confocal laser endomicroscopy (including probe-based confocal laser endomicroscopy) (CPT Code: 43252) is experimental and investigational for all indications due to the lack of proven efficacy compared with other widely available advanced imaging or biopsy techniques and because the effectiveness of this service cannot be established by review of the available published peer-reviewed literature.

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Medicare Variation

MVP allows colorectal cancer screening tests of asymptomatic, average-risk individual age \geq 45 years and \leq 85 years for Medicare Customers.

There is a Medicare National Coverage Determination (NCD) for endoscopy. For full coverage details refer to: Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for Endoscopy (100.2). Effective Date N/A. Available: www.cms.gov/

There is a Medicare National Coverage Determination (NCD) for colorectal cancer screening. For full coverage details refer to: Centers for Medicare & Medicaid Services (CMS). Medicare Coverage Database. National Coverage Determination (NCD) for Colorectal Cancer Screening Tests (210.3).01/19/2021. Available: https://www.cms.gov/

There is a Medicare Article for colorectal cancer screening. For full coverage details refer to: Centers for Medicare & Medicaid Services (CMS). National Government Services, Inc. Article (A52378). Revision Effective date: 01/19/2021. Available: https://www.cms.gov/

References (Reviewed 2023)

- American Cancer Society (ACS) (a): Key Statistics for Colorectal Cancer 2020: American Cancer Society, Last Medical Review: June 29, 2020; Accessed October 5, 2021. Available:
 - http://www.cancer.org/cancer/colonandrectumcancer/detailedguide/colorectal-cancer-key-statistics.
- American Cancer Society (ACS) (b). Colorectal Cancer Early Detection, Diagnosis, and Staging. Last Medical Review: June 29, 2020 Last Revised: June 29, 2020. Accessed October 5, 2021. Available at URL address: https://www.cancer.org/cancer/colon-rectal-cancer/detection-diagnosis-staging.html.
- 3. American Society for Gastrointestinal Endoscopy (ASGE) Standards of Practice Committee, Shergill AK, Lightdale JR, et al. The role of endoscopy in inflammatory bowel disease. Gastrointest Endosc. 2015;81(5):1101-21.e213 (b).
- 4. American Society for Gastrointestinal Endoscopy (ASGE) Guideline. The role of endoscopy in the surveillance of pre-malignant and malignant conditions of the stomach. Gastrointestinal Endoscopy Journal. 2015. 81: 1-8. Available: http://www.asge.org/publications/publications.aspx?id=352.
- 5. American College Gastroenterology. Clinical Guidelines. Diagnosis and management of Barrett's esophagus. American Journal Gastroenterology. 2015: 322. Available: http://gi.org/clinical-guidelines/clinical-guidelines-sortable-list/.
- 6. American Gastroenterological Association (AGA). American Gastroenterological Association Clinical Guideline on the Diagnosis and Management of Gastroesophageal Reflux Disease. Gastroenterology. March 2013; 108:308–328.

Endoscopy Page 10 of 14

- Available: http://gi.org/guideline/diagnosis-and-managemen-of-gastroesophageal-reflux-disease/.
- 7. American Society for Gastrointestinal Endoscopy (ASGE) Guideline. ASGE Guideline: The role of endoscopy in the management of variceal hemorrhage. Gastrointestinal Endoscopy Journal. 2014. 80: 221-227. Available: http://www.asge.org/publications/publications.aspx?id=352.
- 8. American Society for Gastrointestinal Endoscopy (ASGE). Confocal laser endomicroscopy. Gastrointestinal Endoscopy Journal. 2014. 80: 928 938.
- 9. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for Endoscopy (100.2). Effective Date N/A. Available: www.cms.gov/.
- 10. American College of Radiology (ACR). ACR Appropriateness criteria: dysphasia. Last review date 2013. Available: https://acsearch.acr.org/list.
- 11. Centers for Medicare & Medicaid Services (CMS). Medicare Coverage Database. National Coverage Determination for Colorectal Cancer Screening Tests (210.3).09/08/2015. Available: www.cms.hhs.gov/.
- 12. Centers for Medicare & Medicaid Services (CMS). National Government Services, Inc. Billing and Coding: Colorectal Cancer Screening Article (A52378). Revision Effective date:01/19/2021. Available: www.cms.hhs.gov/.
- 13. National Comprehensive Cancer Network® (NCCN). Clinical Guidelines in Oncology™ Genetic/familial High-Risk Assessment: Colorectal. v.1.2020. Available: www.nccn.org/.
- 14. Gupta, M., et al. Constipation is not associated with an increased rate of findings on colonoscopy: results from a national endoscopy consortium. Endoscopy. 2010. Mar; 42(3); 208-212.
- 15. United States Preventive Services Task Force. Screening for Colorectal Cancer. Recommendation Statement. May 18, 2021. Available: https://www.uspreventiveservicestaskforce.org/uspstf/topic_search_results?topic_status=P
- 16. Lieberman DA, Rex DK, Winawer SJ, Giardiello FM, Johnson DA, Levin TR; United States MultiSociety Task Force on Colorectal Cancer. Guidelines for colonoscopy surveillance after screening and polypectomy: a consensus update by the US Multi-Society Task Force on Colorectal Cancer. Gastroenterology. 2012 Sep;143(3):844-57.
- 17. Rockey, DC, Occult and obscure gastrointestinal bleeding: causes and clinical management. Nat Rev Gastroenterol Hepatol. 2010 May; 7(5): 265-279.
- 18. Cohen, SH., et al. Clinical Practice Guideline for clostridium difficile infection in adults: 2010 update by the Society for Healthcare Epidemiology of America (SHEA)

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- and the Infectious Diseases Society of America (DESA). Infection Control and Hospital Epidemiology. May. 2010. 31(5).
- 19. de Saussure, P.H., Management of the returning traveler with diarrhea. Therapy Adv Gastroenterol. 2009 November; 2(6): 637-375.
- 20. Tolle, MA. Evaluating a sick child after travel to developing countries. J Am Board Fam Med. 2010; 23(6):704-713.
- 21. Hewiston, P., et al. Cochrane systematic review of colorectal cancer screening using the fecal occult blood test (hemocult): an update. American Journal Gastroenterology. 2008 Jun; 103(6):1541-1549.
- 22. American Society for Gastrointestinal Endoscopy (ASGE) Guideline. The role of endoscopy in the management of patients with diarrhea. Gastrointestinal Endoscopy Journal. 2010. 71 (6): 887-892. Reviewed and reapproved November 2014. Available: https://acsearch.acr.org/list
- 23. American Society for Gastrointestinal Endoscopy (ASGE) Guideline. The role of endoscopy in the assessment and treatment of esophageal cancer. Gastrointestinal Endoscopy Journal. 2013:77:328-344. Available: https://acsearch.acr.org/list
- 24. Rex DK, Boland CR, Dominitz JA, Giardiello FM, Johnson DA, Kaltenbach T, et al. Colorectal Cancer Screening: Recommendations for Physicians and Patients from the U.S. Multi-Society Task Force on Colorectal Cancer. Am J Gastroenterol. 2017 Jul;112(7):1016-1030.
- 25. Wilkerson G.R. Pustavoitau A. Carolan H. et al. Percutaneous ultrasound gastrostomy: a novel device and bedside procedure for gastrostomy tube insertion using magnetic and ultrasound guidance. J Med Dev. 2019; 13024501
- 26. American Society for Gastrointestinal Endoscopy (ASGE) Guideline. Technology Status Evaluation Report. Available: Endoscopic submucosal dissection (asge.org)

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Customer Product	Medical Management Requirements*
New York Products	
HMO	Potential for Retrospective Review
PPO in Plan	Potential for Retrospective Review
PPO OOP	Potential for Retrospective Review
POS in Plan	Potential for Retrospective Review
POS OOP	Potential for Retrospective Review
Essential Plan	Potential for Retrospective Review
MVP Medicaid Managed Care	Potential for Retrospective Review
MVP Child Health Plus	Potential for Retrospective Review
MVP Harmonious Health Care Plan	Potential for Retrospective Review
MVP Medicare Complete Wellness	Potential for Retrospective Review
MVP Medicare Preferred Gold HMO POS	Potential for Retrospective Review
MVP Medicare Secure HMO POS	Potential for Retrospective Review
MVP Medicare Secure Plus HMO POS	Potential for Retrospective Review
MVP Medicare WellSelect PPO	Potential for Retrospective Review
MVP Medicare WellSelect Plus PPO	Potential for Retrospective Review
MVP Medicare Patriot Plan PPO	Potential for Retrospective Review
MVP DualAccess D-SNP HMO	Potential for Retrospective Review
MVP DualAccess Complete D-SNP HMO	Potential for Retrospective Review
MVP DualAccess Plus D-SNP HMO	Potential for Retrospective Review
UVM Health Advantage Select PPO	Potential for Retrospective Review
USA Care	Potential for Retrospective Review
Healthy NY	Potential for Retrospective Review
MVP Premier	Potential for Retrospective Review
MVP Premier Plus	Potential for Retrospective Review
MVP Premier Plus HDHP	Potential for Retrospective Review
MVP EPO	Potential for Retrospective Review
MVP EPO HDHP	Potential for Retrospective Review
MVP PPO	Potential for Retrospective Review
MVP PPO HDHP	Potential for Retrospective Review
Student Health Plans	Potential for Retrospective Review
ASO	See SPD
Vermont Products	
POS in Plan	Potential for Retrospective Review
POS OOP	Potential for Retrospective Review
MVP Medicare Preferred Gold HMO POS	Potential for Retrospective Review
MVP Medicare Secure Plus HMO POS	Potential for Retrospective Review
MVP VT HMO	Potential for Retrospective Review
MVP VT HDHP HMO	Potential for Retrospective Review
MVP VT Plus HMO	Potential for Retrospective Review
MVP VT Plus HDHP HMO	Potential for Retrospective Review
ASO	See SPD

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

*Medical Management Requirements

Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

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Revision History:

02/01/2022- Annual review with Commercial/Medicaid screening colonoscopy age decrease for individuals age ≥ 45 years based on United States Preventative Services Task Force.

08/01/2022 – Reduced Medicare age for colonoscopy screening tests.

10/1/2022 – Added exclusion for magnetic gastropexy

12/01/2023 – Added exclusion for confocal laser endomicroscopy (CLE)

02/01/2024 - Added coverage to Endoscopic submucosal dissection (ESD).

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Endovascular Repair of Aortic Aneurysms and Percutaneous Transluminal Angioplasty

Type of Policy: Surgical

Prior Approval Date: 11/10/2023

Approval Date: 02/05/2024

Effective Date: 04/01/2024

Related Polices: N/A

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

N/A

Codes Subject to Retrospective Review

CPT Codes:

0075T	Transcatheter placement of extracranial vertebral artery stent(s), including radiologic supervision and interpretation, open or percutaneous; initial vessel
0076T	Transcatheter placement of extracranial vertebral artery stent(s), including radiologic supervision and interpretation, open or percutaneous; each additional vessel
37216	Transcatheter placement of intravascular stent(s), cervical carotid artery, open or percutaneous, including angioplasty, when performed, and radiological supervision and interpretation; without distal embolic protection

Experimental/Investigational

CPT Codes:

0075T	Transcatheter placement of extracranial vertebral artery stent(s), including radiologic supervision and interpretation, open or percutaneous; initial vessel
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0076T	Transcatheter placement of extracranial vertebral artery stent(s), including radiologic supervision and interpretation, open or percutaneous; each additional vessel
37216	Transcatheter placement of intravascular stent(s), cervical carotid artery, open or percutaneous, including angioplasty, when performed, and radiological supervision and interpretation; without distal embolic protection

Common CPT Codes

33880, 33881, 33883, 33884, 33886, 33889, 33891, 34701, 34702, 34703, 34704, 34705, 34706, 34708, 34709, 34710, 34711, 34717, 34718, 37215, 37218, 37252, 37253, 75957, 75958, 75959

Common Diagnosis Codes

ICD-10- CM Diagnosis Codes: A52.01, I12.0, I13.11, I13.2, I65.29, I70.0, I70.219, I70.229, I70.25, I70.269, I71.3, I70.399, I72.02, I71.4, Q27.8, S35.00XA

Please refer to the product grid for detailed authorization requirements for specific plans. Code lists may not be all inclusive. Codes requiring prior-authorization for some products may be retrospectively reviewed for plans that do not require prior-authorization. Common diagnosis and procedure codes are included for informational purposes. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

Endovascular aneurysm repair (or endovascular aortic repair) (EVAR) is a type of endovascular surgery used to treat an abdominal aortic aneurysm (AAA) or thoracic aortic aneurysm, the procedure then specifically termed TEVAR (thoracic endovascular aortic/aneurysm repair). Aortic aneurysms are bulges in the aorta, the main blood vessel that brings blood from the heart to the rest of the body.

Endovascular surgical procedures are minimally invasive procedures that use advanced technology and instrumentation to treat such disorders of the circulatory system as blockage or damage to blood vessels caused by the buildup of plaque (fatty deposits, calcium deposits, and scar tissue) in the arteries, a condition called atherosclerosis.

Indications/Criteria

Endovascular Repair of Abdominal Aortic Aneurysm (EVAR)

Endovascular repair for abdominal aortic aneurysm is covered with an FDA approved endoprosthesis for patients with a documented unruptured abdominal aortic aneurysm who meet the criteria listed below.

Asymptomatic Abdominal Aortic Aneurysm

Elective endovascular repair of an asymptomatic abdominal aortic aneurysm is covered when any of the following indications have been met:

- abdominal aortic aneurysm measuring 5cm or greater in diameter;
- abdominal aortic aneurysm measuring 4cm or greater in diameter with a documented expansion of 0.5 cm in a six (6) month interval;
- abdominal aortic aneurysm measuring 3cm or greater in diameter with an iliac aneurysm.

Symptomatic Abdominal Aortic Aneurysm

Elective endovascular repair of a symptomatic abdominal aortic aneurysm is covered when any of the following indications have been met:

- a symptomatic abdominal aortic aneurysm with tenderness on palpation and/or pain that may occur in the back, flank, groin or abdomen; or
- symptoms related to compression of nearby structures such as veins or ureters.

Endovascular Repair of Thoracic Aortic Aneurysms (TEVAR)

Endovascular repair for thoracic aortic aneurysm is covered for patients with a documented unruptured thoracic aortic aneurysm who meet the criteria listed below.

 Thoracic endovascular prostheses must be used in accordance with the FDA approved package labeling.

<u>Asymptomatic Thoracic Aortic Aneurysms</u>

Elective endovascular repair of an asymptomatic thoracic aortic aneurysm is covered when any of the following indications have been met:

- an ascending aorta measuring 5.5cm or greater in diameter;
- an ascending aorta measuring >4.5cm in diameter and aortic regurgitation of 3+ or 4+;
- a descending aorta measuring 6.0cm or greater in diameter;
- aneurysms associated with weakening of the aortic wall due to connective tissue disorders such as Marfan and Ehler-Danlos syndromes measuring > 5cm in diameter; or

Symptomatic Thoracic Aortic Aneurysms

Elective endovascular repair of a symptomatic thoracic aortic aneurysm is covered when any of the following indications have been met:

- pain that may occur in the chest, lower back, jaw, or abdomen;
- expansion into the esophagus confirmed by CT/MRI;
- laryngeal nerve paralysis;

- CNS event;
- dysphagia from esophageal compromise by CT/MRI;
- compromise of airway; or
- compromise of pulmonary vessels.

Note: Clinical experience indicates that contrast-enhanced spiral computed tomographic angiography with 3D reconstruction is the required image modality to accurately assess patient anatomy prior to treatment.

Thoracoabdominal Aortic Aneurysms

 A thoracoabdominal aortic aneurysm involves both the thoracic aorta and the abdominal aorta.

Saccular Aneurysm

Elective endovascular repair of a saccular aneurysm is covered when any of the following indications have been met:

Reviewed on a case-by-case basis by the medical director

Percutaneous Transluminal Angioplasty of the Carotid Artery with Stenting

Percutaneous transluminal angioplasty of the carotid artery with stenting is covered with the placement of a Food and Drug Administration (FDA) approved carotid stent with an FDA-approved or cleared embolic protection device, for patients who meet the following conditions:

- Patients with symptomatic carotid artery stenosis ≥50%; and
- Patients with asymptomatic carotid artery stenosis ≥70%.

The above conditions are covered when all the following criteria are met:

- Neurological assessment by a neurologist or NIH stroke scale (NIHSS) certified health professional before and after carotid artery stenting (CAS) must be performed.
- First-line evaluation of carotid artery stenosis must use duplex ultrasound.
- Computed Tomography angiography or magnetic resonance angiography, if not contraindicated, must be used to confirm the degree of stenosis and provide additional information about the aortic arch, and extra- and intracranial circulation.
- Intra-arterial digital subtraction (catheter) angiography may be used only when there is significant discrepancy between non-invasive imaging results, or in lieu of computed tomography angiography or magnetic resonance angiography if these are contraindicated.

<u>Percutaneous Transluminal Angioplasty and Percutaneous Transluminal Atherectomy, other than coronary and carotid.</u>

Percutaneous transluminal angioplasty or percutaneous atherectomy are covered in the management of patients with symptomatic arterial stenosis, such as hypertension or renal failure in the case of renal artery stenosis, claudication, ischemic rest pain or ulceration in the case of lower extremity stenosis. The specific lesions covered are as follows:

- atherosclerotic obstructive lesions
 - lower extremity:
 - iliac;
 - femoral; and
 - popliteal;
 - o upper extremity (the upper extremities do not include head or neck vessels):
 - innominate;
 - subclavian;
 - axillary; and
 - brachial;
 - o renal arteries: obstructive lesions in customers for whom there is an inadequate response to a thorough medical management of symptoms and for whom surgery is the likely alternative. PTA for this group of customers is an alternative to surgery, not simply an addition to medical management; or
 - o arteriovenous dialysis fistulas and grafts when performed through either a venous or arterial approach.

Exclusions

Endovascular Repair of Abdominal Aortic Aneurysm

- The endoprosthesis is not FDA approved for the treatment of abdominal aortic aneurysms.
- Wireless abdominal aortic aneurysm pressure measuring systems are considered investigational and are not covered.
- Fenestrated endovascular grafting for the repair of a juxtarenal abdominal aortic aneurysm is considered investigational and is not covered.
- Fabric wrapping of abdominal aneurysms is not considered reasonable and necessary and is not covered.

Endovascular Repair of Thoracic Aortic Aneurysms

 Thoracic endoprosthesis is not recommended in patients who cannot tolerate agents necessary for intra-operative and post-operative follow-up imaging.

• Endovascular stent grafts for the treatment of aortic arch aneurysms are considered investigational and are not covered.

The safety and effectiveness of the endoprosthesis has not been evaluated in the following patient populations:

- acute and chronic dissections
- aortic fistulas:
- aortotitis or inflammatory aneurysms;
- intramural hematoma;
- mycotic aneurysms;
- penetrating ulcers;
- ruptured aneurysms;
- traumatic aortic transections;
- pseudoaneurysms resulting from previous graft placement;
- patients with active systemic infections;
- patients less than 21 years old; or
- pregnant or nursing females.

The Gore TAG Thoracic endoprosthesis and the Medtronic TalentTM Thoracic Stent Graft System have not been approved for use in patients with genetic connective tissue disease (e.g., Marfans and Ehlers-Danlos syndrome).

<u>Percutaneous Transluminal Angioplasty and Percutaneous Transluminal Atherectomy</u> <u>other than Coronary</u>

- Percutaneous transluminal angioplasty and atherectomy to treat obstructive lesions
 of the cerebral and vertebral arteries is considered investigational and is not covered.
- Laser angioplasty for non-coronary vessels is considered investigational and is not covered.
- Laser atherectomy is considered investigational and is not covered.

Medicare

Based on review, there is no Medicare National Coverage Determination (NCD) or Local Coverage Determination for Endovascular Repair of Aortic Aneurysms.

There is a Medicare National Coverage Determination (NCD) for Percutaneous Transluminal Angioplasty (PTA) (20.7). Effective Date 01/01/2013. Available: https://www.cms.gov/

There is a Centers for Medicare & Medicaid Services (CMS) National Coverage Analysis (NCA) Decision Memo for Percutaneous Transluminal Angioplasty (PTA) of the Carotid

Artery Concurrent with Stenting (CAG-00085R8) October 11, 2023. Available: MCD Search (cms.gov)

There is a Medicare National Coverage Determination (NCD) for Fabric Wrapping of Abdominal Aneurysms (20.23). Effective Date: not posted. Available: https://www.cms.gov/

References (Updated 2023)

- 1. Wilt, T.J., Lederle, F.A., MacDonald, R., Jonk, Y.C., Rector, T.S., Kan, R.L. Comparison of endovascular and open surgical repairs for abdominal aortic aneurysm. Evidence Report/Technology Assessment No. 144. (Prepared by the University of Minnesota Evidence-based Practice Center under Contract No. 290-02-0009.) AHRQ Publication No. 06-E017. Rockville, MD. Agency for Healthcare Research and Quality. Aug 2006.
- 2. EVAR trial participants. Endovascular aneurysm repair versus open repair in patients with abdominal aortic aneurysm (EVAR trial 1): Randomized controlled trial. *Lancet*. 2005 Jun 25-Jul 1; 365(9478):2179-86.
- 3. WL Gore & Associates. Instructions for use: Gore TAG thoracic endoprosthesis. 2016. Available: www.goremedical.com
- Centers for Medicare & Medicaid Services (CMS). Medicare Coverage Database. NCD for Percutaneous Transluminal Angioplasty (PTA) (20.7). Implementation Date Mar 11, 2013. Available: <u>Home - Centers for Medicare & Medicaid Services | CMS</u>
- Centers for Medicare & Medicaid Services (CMS). National Coverage Analysis (NCA)
 Decision Memo Percutaneous Transluminal Angioplasty (PTA) of the Carotid Artery
 Concurrent with Stenting (CAG-00085R8) October 11, 2023. Available: MCD Search
 (cms.gov)
- 6. Ates, M., Prates, P., LeMaire, S., Coselli, J.S. Use of endovascular stent grafts in thoracoabdominal aortic aneurysms. *Eur J Gen Med* 2006; 3(4):178-181.
- 7. Brewster, D., et al. Guidelines for the treatment of abdominal aortic aneurysms. Report of the Joint Council of the American Association for Vascular Surgery and Society for Vascular Surgery. Journal of Vascular Surgery. 2003; 37(5): 1106-1117.
- 8. Hiratzka, L., et al. 2010 ACCF/AHA/AATS/ACR/ASA/SCA/SCAI/SIR/STS/SVM guidelines for the diagnosis and management of patients with thoracic aortic disease. Journal of the American College of Cardiology. 2010. 55(14): e27-129.
- Chambers, D. et al. Use of non-randomized evidence alongside randomized trials in a systematic review of endovascular aneurysm repair: strengths and limitations. Eur J Vascualar Surery (2010) 39, 26-34. Available: http://www.ejves.com/article/S1078-5884(09)00490-0/pdf
- 10. De Bruin JL, et al. Long term outcome of open or endovascular repair of abdominal aortic aneurysm. New England Journal of Medicine. 2010. May 20;362(20):1881-9. Available: http://www.nejm.org/doi/full/10.1056/NEJMoa0909499#t=articleTop

- 11. Greenhalgh RM and Powell JT. Endovascular repair of abdominal aortic aneurysm. New England Journal of Medicine 2008. Jan 31;358(5):494-501.
- 12. Chaikof, E. L., et al. The care of patients with an abdominal aortic aneurysm: The Society of Vascualr Surgery practice guidelines. Journal of Vascular Surgery. 50(4): Supplement S2-S49. Available: http://www.jvascsurg.org/article/S0741-5214(09)01368-8/fulltext
- 13. Brown LC, Powell JT, Thompson SG, et al. The UK EndoVascular Aneurysm Repair (EVAR) trials: Randomised trials of EVAR versus standard therapy. Health Technol Assess. 2012;16(9):1-218.

Customer Product	Medical Management Requirements*
New York Products	-
HMO	Retrospective Review
PPO in Plan	Retrospective Review
PPO OOP	Potential for Retrospective Review
POS in Plan	Retrospective Review
POS OOP	Potential for Retrospective Review
Essential Plan	Retrospective Review
MVP Medicaid Managed Care	Retrospective Review
MVP Child Health Plus	Retrospective Review
MVP Harmonious Health Care Plan	Retrospective Review
MVP Medicare Complete Wellness	Retrospective Review
MVP Medicare Preferred Gold HMO POS	Retrospective Review
MVP Medicare Secure HMO POS	Retrospective Review
MVP Medicare Secure Plus HMO POS	Retrospective Review
MVP Medicare WellSelect PPO	Retrospective Review
MVP Medicare WellSelect Plus PPO	Retrospective Review
MVP Patriot Plan PPO	Potential for Retrospective Review
MVP DualAccess D-SNP HMO	Retrospective Review
MVP DualAccess Complete D-SNP HMO	Retrospective Review
MVP DualAccess Plus D-SNP HMO	Retrospective Review
UVM Health Advantage Select PPO	Retrospective Review
USA Care	Retrospective Review
Healthy NY	Retrospective Review
MVP Premier	Retrospective Review
MVP Premier Plus	Retrospective Review
MVP Premier Plus HDHP	Retrospective Review
MVP Secure	Retrospective Review
MVP EPO	Retrospective Review
MVP EPO HDHP	Retrospective Review
MVP PPO	Retrospective Review
MVP PPO HDHP	Retrospective Review
Student Health Plans	Retrospective Review
ASO	See SPD
Vermont Products	000 0.1 5
PPO in Plan	Retrospective Review
PPO OOP	Potential for Retrospective Review
MVP Medicare Preferred Gold HMO POS	Retrospective Review
MVP Medicare Secure Plus HMO POS	Retrospective Review
MVP VT HMO	Retrospective Review
MVP VT HDHP HMO	Retrospective Review
MVP VT Plus HMO	Retrospective Review
MVP VT Plus HDHP HMO	Retrospective Review
MVP Secure	Retrospective Review
ASO	See SPD

[♦] Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Revision History:

10/01/2021 – Added that elective endovascular repair of a saccular aneurysm is covered and require prior authorization review with a medical director.

04/01/2023 - Prior authorization removed.

11/10/2023 – Added coverage to percutaneous transluminal angioplasty of the carotid artery stenting based on Medicare decision memo CAG-00085R8 for all lines of business. Added 37216 to retrospective review.



Epidermal Nerve Fiber Density Testing

Type of Policy: Medical

Prior Approval Date: 02/07/2022

Approval Date: 02/05/2024

Effective Date: 04/01/2024

Related Polices: N/A

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

N/A

Codes Requiring Retrospective Review

CPT Codes: 88399 - Unlisted surgical pathology procedure

95999 - Unlisted neurological or neuromuscular diagnostic procedure

Experimental/Investigational

N/A

Common Diagnosis Codes

ICD-10-CM Diagnosis Codes: G90.0, G90.01, G90.09, G90.1, G90.2, G90.3, G90.4, G90.5, G90.50, G90.51, G90.511, G90.512, G90.513, G90.519, G90.52, G90.521, G90.522, G90.523, G90.529, G90.59, G90.8, G90.9

Common Diagnosis Codes associated with this policy have been provided for informational purposes only. The list of codes may not be all-inclusive and may be updated to reflect any applicable revisions to the ICD-10 code set and/or medical necessity guidelines applied in this policy.

Common Procedure Codes

CPT Code: 88356 - Morphometric analysis; nerve

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-

authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

Epidermal Nerve Fiber Density testing is performed in individuals who have sensory symptoms or signs that suggest peripheral neuropathies but with no evidence of large fiber neuropathy on electrodiagnostic studies. Below a normal reference range i.e., 4-9 fibers per mm, epidermal nerve fiber density is considered confirmation of small fiber peripheral neuropathy. However, epidermal nerve fiber density within the normal range, greater than 9 fibers per mm, suggests the need for testing for etiologies other than those known to produce peripheral neuropathy.

Indications/Criteria

Epidermal Nerve Fiber Density testing is considered medically necessary when all of the following criteria have been met:

- the patient presents with painful sensory neuropathy; and
- physical examination shows no evidence of findings consistent with large fiber neuropathy, such as reduced or absent muscle-stretch reflexes or reduced proprioception and vibration sensation; and
- no history of a disorder known to predispose to painful neuropathy (e.g., diabetic neuropathy, toxic neuropathy, HIV neuropathy, celiac neuropathy, inherited neuropathy); and
- electromyography and nerve-conduction studies are normal and show no evidence of large fiber neuropathy.

Exclusions

- 1. Requests not meeting medical necessity criteria listed in this policy.
- The use of epidermal nerve fiber density testing to detect preclinical small fiber neuropathy in asymptomatic patients, who have diabetes, impaired glucose intolerance, complex regional pain syndrome, or other disease known to cause peripheral neuropathy is considered experimental/investigational.

References (Reviewed 2023)

- 1. Caro XJ, Winter EF. Evidence of abnormal epidermal nerve fiber density in fibromyalgia: Clinical and immunologic implications. Arthritis Rheumatol. 2014;66(7):1945-1954.
- 2. Devigili G, Tugnoli V, Penza P, et al. The diagnostic criteria for small fibre neuropathy: from symptoms to neuropathology. Brain. 2008;131(Pt 7):1912-1925.

- England JD, Gronseth GS, Franklin G, et al. Practice Parameter: evaluation of distal symmetric polyneuropathy: role of autonomic testing, nerve biopsy, and skin biopsy (an evidence-based review). Report of the American Academy of Neurology, American Association of Neuromuscular and Electrodiagnostic Medicine, and American Academy of Physical Medicine and Rehabilitation. Neurology. 2009; 72(2):177-184.
- 4. Food and Drug Administration (FDA) [website]. Center for Devices and Radiological Health (CDRH). Clinical Laboratory Improvement Amendments (CLIA) Database [search: nerve fiber; ENFD; IENFD]. Available: www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/clia.cfm
- 5. Gorson KC, Herrmann DN, Thiagarajan R, et al. Non-length dependent small fibre neuropathy/ganglionopathy. J Neurol Neurosurg Psychiatry. 2008;79(2):163-169.
- 6. Haroutounian S, Todorovic MS, Leinders M, et al. Diagnostic criteria for idiopathic small fiber neuropathy: A systematic review. Muscle Nerve. 2021;63(2):170-177.
- 7. Kharkar S, Venkatesh YS, Grothusen JR, et al. Skin biopsy in complex regional pain syndrome: Case series and literature review. Pain Physician. 2012;15(3):255-266.
- 8. Lauria G, Cornblath DR, Johansson O, et al.; European Federation of Neurological Societies EFNS guidelines on the use of skin biopsy in the diagnosis of peripheral neuropathy. Eur J Neurol. 2005; 12(10): 747-758.
- 9. Lauria G, Lombardi R, Camozzi F, Devigili G. Skin biopsy for the diagnosis of peripheral neuropathy. Histopathology. 2009;54(3):273-285.
- 10. Lauria, G., e al. European Federation of Neurological Societies/Peripheral Nerve Society Guideline on the use of skin biopsy in the diagnosis of small fiber neuropathy. Report of a joint task force of the European Federation of Neurological Societies and the Peripheral Nerve Society. Eur J Neurol. 2010 Jul; 17(7): 703-12. Available: http://www.guideline.gov/content.aspx?id=24527#Section420
- 11. Saperstein DS. Small fiber neuropathy. Neurol Clin. 2020;38(3):607-618.
- 12. Sommer C. Skin biopsy as a diagnostic tool. Curr Opin Neurol. 2008;21(5):563-568.
- 13. Tzatha E, Chin RL. Small fiber abnormalities in skin biopsies of patients with benign fasciculations. J Clin Neuromuscul Dis. 2014;16(1):12-14.
- 14. Vlckova-Moravcova E, Bednarik J, Dusek L, et al. Diagnostic validity of epidermal nerve fiber densities in painful sensory neuropathies. Muscle Nerve. 2008;37(1):50-60.
- 15. Walk D, Wendelschafer-Crabb G, Davey C, Kennedy WR. Concordance between epidermal nerve fiber density and sensory examination in patients with symptoms of idiopathic small fiber neuropathy. J Neurol Sci. 2007;255(1-2):23-26.

16. Weaver J, Kim K-W, Carey B, et al. Sweat gland nerve fiber density by skin biopsy: Frequency of abnormalities and clinical characteristics. 65th Annual Meeting of the Academy of Neurology. March 16 to 23, 2013. (Abstract # S26.001).

Customer Product	Medical Management Requirements*
New York Products	-
HMO	Retrospective Review
PPO in Plan	Retrospective Review
PPO OOP	Retrospective Review
POS in Plan	Retrospective Review
POS OOP	Retrospective Review
Essential Plan	Retrospective Review
MVP Medicaid Managed Care	Retrospective Review
MVP Child Health Plus	Retrospective Review
MVP Harmonious Health Care Plan	Retrospective Review
MVP Medicare Complete Wellness	Retrospective Review
MVP Medicare Preferred Gold HMO POS	Retrospective Review
MVP Medicare Secure HMO POS	Retrospective Review
MVP Medicare Secure Plus HMO POS	Retrospective Review
MVP Medicare WellSelect PPO	Retrospective Review
MVP Medicare WellSelect Plus PPO	Retrospective Review
MVP Medicare MVP Patriot Plan PPO	Retrospective Review Retrospective Review
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MVP DualAccess D-SNP HMO	Retrospective Review
MVP DualAccess Complete D-SNP HMO	Retrospective Review
MVP DualAccess Plus D-SNP HMO	Retrospective Review
UVM Health Advantage Select PPO	Retrospective Review
USA Care PPO	Potential for Retrospective Review
Healthy NY	Retrospective Review
MVP Premier	Retrospective Review
MVP Premier Plus	Retrospective Review
MVP Premier Plus HDHP	Retrospective Review
MVP Secure	Retrospective Review
MVP EPO	Retrospective Review
MVP EPO HDHP	Retrospective Review
MVP PPO	Retrospective Review
MVP PPO HDHP	Retrospective Review
Student Health Plans	Retrospective Review
ASO	See SPD
Vermont Products	
POS in Plan	Retrospective Review
POS OOP	Retrospective Review
MVP Medicare Preferred Gold HMO POS	Retrospective Review
MVP Medicare Secure Plus HMO POS	Retrospective Review
MVP VT HMO	Retrospective Review
MVP VT HDHP HMO	Retrospective Review
MVP VT Plus HMO	Retrospective Review
MVP VT Plus HDHP HMO	Retrospective Review
MVP Secure	Retrospective Review
ASO	See SPD

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Revision History:

04/01/2022 - Annual review. Added criteria to check for contributing history and added exclusion for use to diagnosis complex regional pain syndrome. Eliminated the specialist requirement as this is not in line with Medicare.

04/01/2024 – Annual Review; no changes to the indications or criteria, references reviewed.



Erectile Dysfunction

Type of Policy: Medical

Prior Approval Date: 04/04/2022

Approval Date: 03/04/2024

Effective Date: 06/01/2024

Related Polices: Penile Implant for Erectile Dysfunction

Durable Medical Equipment

Quantity Limits for Prescription Drugs

Cialis for BPH

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

CPT Codes:

Prior Authorization for MVP Medicaid Managed Care Only:

37788 - Penile revascularization, artery, with or without vein graft

37790 - Penile venous occlusive procedure

54231- Dynamic cavernosometry, including intracavernosal injection of vasoactive drugs (eg, papaverine, phentolamine)

54235- Injection of corpora cavernosa with pharmacologic agent(s) (eg, papaverine, phentolamine)

54240 - Penile plethysmography

54250- Nocturnal penile tumescence and/or rigidity test

HCPCS Codes:

Prior Authorization for **ALL** MVP Lines of Business:

L7900- Male vacuum erection system

L7902 -Tension ring, for vacuum erection device, any type, replacement only, each

Erectile Dysfunction Page 1 of 9

Codes Subject to Retrospective Review

N/A

Experimental/Investigational

N/A

Common Diagnosis Codes

ICD-10- CM Diagnosis Codes: F52.21, F52.22, N52.01, N52.02, N52.03, N52.1, N52.2, N52.31, N52.32, N52.33, N52.34, N52.39, N52.8, N52.9

Common Procedure Codes

N/A

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy.

Overview

Erectile Dysfunction (ED) is the persistent or repeated inability, for at least three months, to achieve or maintain an erection sufficient for satisfactory sexual performance. Erectile dysfunction is generally categorized as organic, psychogenic, or mixed.

To determine causes of erectile dysfunction, a thorough medical history should be conducted evaluating medical risk factors such as diabetes, hypertension, hypercholesterolemia, cardiovascular disease, spinal cord injury, peripheral vascular disease, endocrine abnormalities, pelvic surgery, depression, arthritis, renal failure, and trauma. Evaluation of lifestyle risk factors would include smoking, alcohol, drug use, and obesity.

Prescription drug usage also would be evaluated including beta blockers, antidepressants, thiazide diuretics, and anticholinergics. The sexual history would include the severity and onset of erectile dysfunction, psychological and social issues, such as depression and stresses from relationships, jobs, and libido. An assessment of goals and objectives of the couple is an important aspect of therapy.

Management/treatment options should be based on the needs of the individual and his partner and should be appropriate for the age of the man and his health condition. In most cases, first-line treatment includes oral medications.

A mix of psychological or relationship factors and organic disease frequently co-exist. Minimal organic disease may result in performance anxiety leading to secondary psychogenic sexual dysfunction.

Erectile Dysfunction Page 2 of 9

Indications/Criteria

The evaluation and diagnosis of erectile dysfunction should include the following:

- persistent erectile dysfunction that has occurred for at least three months;
- complete sexual, psychosocial, and medical histories have been done to determine the customer's perception of the problem and expectations, desires, and needs. If possible, the partner should be included in this evaluation;
- the diagnosis of erectile dysfunction has been differentiated from other forms of sexual problems, such as lack of sexual desire, premature or delayed ejaculation, and delayed orgasm;
- screening for potentially reversible causes of erectile dysfunction, such as
 prescription and non-prescription drug use, substance abuse, depression, and
 relationship problems or marital tensions. Depending on the issues and their
 complexity, they can be addressed directly (i.e., smoking cessation and change in
 medications) or the customer may be referred for appropriate counseling (i.e.,
 psychotherapy or couples therapy); or
- a physical examination with follow-up on abnormal findings, such as suspected endocrine diseases or abnormal prostate.

Diagnostic Testing for Erectile Dysfunction

The evaluation of individuals with erectile dysfunction consists of a structured interview, a thorough physical examination, and basic laboratory studies. In selected patients, further physiologic or invasive studies may be indicated.

Pharmacological response test using vasoconstrictive medications such as papavarine HCL or prostaglandin E 1.

Routine use of nocturnal penile tumescence and/or rigidity tests (54250) is generally considered not medically necessary. Nocturnal penile tumescence is indicated only when the clinical evaluation is unable to distinguish psychogenic from organic impotence.

Duplex scan of the penile vessels is generally considered not medically necessary. Duplex scans are indicated for young men with erectile dysfunction due to pelvic or perineal trauma, men who have a lifetime history of erectile dysfunction, and men who have a psychological need to know whether the cause of their erectile dysfunction is psychogenic or vascular in origin.

Cavernosometry or cavernosography are indicated for patients who meet the criteria for arterial revascularization listed below.

Treatments for erectile dysfunction are as follows:

Erectile Dysfunction Page 3 of 9

- the oral erectogenic agents, such as sildenafil (Viagra®), tadalafil (Cialis®), vardenafil (Levitra®). Refer to ACC/AHA expert consensus document for recommendations for sildenafil and the cardiac patient;
- intracavernosal injections (Edex, Caverject);
- intraurethral suppositories such as alprostadil;
- testosterone injections are indicated for customers with documented subnormal testosterone levels;
- vacuum constriction devices: penile vacuum constriction devices use a hand pump and cylindrical component to create a vacuum around the penis, drawing blood into the penis, resulting in an erection;
- penile arterial revascularization is indicated when all the following are met¹:
 - a focal blockage of arterial inflow is demonstrated by duplex Doppler ultrasonography or arteriography; and
 - o diagnostic work-up reveals normal corporeal venous function; and
 - customer is not actively smoking; and
 - customer is not diabetic and has no evidence of systemic vascular occlusive disease; and
 - the erectile dysfunction is the direct result of an arterial injury caused by blunt trauma to the pelvis and/or perineum.
- penile prosthetic implants: non-inflatable (malleable) and inflatable. (Refer to MVP's Penile Implant for Erectile Dysfunction Policy).

Oral, intracavernosal injections, and intraurethral suppositories such as alprostadil are covered under the Pharmacy benefit (when used to treat organic and mixed ED) and may be subject to quantity limits. (Refer to the MVP Prescription Drug Quantity Limits Policy.)

For oral erectogenic agents, such as sildenafil (Viagra®), tadalafil (Cialis®), vardenafil (Levitra® or Staxyn®), refer to the MVP Prescription Drug Quantity Limits Policy.

Vacuum/constriction devices are considered durable medical equipment (DME) and are a covered benefit when the diagnosis of organic erectile dysfunction (ED) is substantiated in the medical record.

Treatment/counseling for psychosexual dysfunction is a covered mental health benefit according to the customer's contract.

Exclusions

Any indication not listed in the Indications/Criteria section of this policy.

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- Routine use of penile plethysmography (54240) is generally considered not medically necessary.
- Routine use of nocturnal penile tumescence and/or rigidity tests (54250) is generally considered not medically necessary. Nocturnal penile tumescence is indicated only when the clinical evaluation is unable to distinguish psychogenic from organic impotence.
- Venous ligation of the penis for venous leakage is considered an investigational procedure.
- Cavernosal nerve mapping is considered not medically necessary.
- Corpora cavernosal electromyography is considered not medically necessary.
- Evoked potential measurements are considered not medically necessary.
- Use of oral, intracavernosal, or intraurethral medications for the prevention of erectile dysfunction after a prostatectomy is considered investigational. (Refer to the Pharmacy Program's Administration Policy.)
- Coverage and coverage exclusion for DME is specific to the individual plan's coverage.

MVP Medicaid Managed Care Variation

- Drugs or injections used to treat sexual or erectile dysfunction are not covered unless drugs are used to treat other conditions and have been FDA approved for that purpose. Available: https://www.health.ny.gov/health_care/medicaid/program/update/2006/jun2006.htm
- Vacuum erection systems (L7900) are limited to diagnosis of impotence, with an order from a urologist or neurologist.

To implement Chapter 645 of the Laws of 2005, which seeks to ensure that the Medicaid program will not provide coverage for erectile dysfunction (ED) drugs, procedures, or supplies to convicted sex offenders, prior approval is required with MVP Health Care. Prior approval requests for recipient's ineligible for ED services per Chapter 645 of the Laws of 2005 will be denied.

Medicare Variation

Drugs

 Drugs used to treat erectile dysfunction are not covered under Medicare Part D (SSA 1927(d)(2).

Vacuum Erection Systems (L7900, L7902)

• Vacuum Erection Systems are statutorily excluded from Medicare coverage.

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There is a CMS National Coverage Determinations (NCD) for Cavernous Nerves by Electrical Stimulation with Penile Plethsmography (160.26). Effective Date: 08/24/2006. Available: www.cms..gov/

There is a CMS National Coverage Determinations (NCD) for Diagnosis and Treatment of Impotence (230.4). 01/01/1966. Available: www.cms..gov/

Based on review, there is no National Government Services Local Coverage Decision for Vacuum Erection Systems.

There is a CMS MLN Matters "Discontinued Coverage of Vacuum Erection Systems (VES) Prosthetic Devices in Accordance with the Achieving a Better Life Experience Act of 2014."

References (Updated 2024)

- 1. Brock, Gerald, Pharmacologic Advancements in the Treatment of Erectile Dysfunction. Medscape. (April 15th, 2004).
- 2. Dey, Jayant, Shepherd, Mark D., Evaluation and Treatment of Erectile Dysfunction in Men with Diabetes Mellitus, Mayo Clin. Proc., 2002; 77:276-282.
- 3. Cheitlin, Melvin D., Hutter, Adolph M., et al., Use of Sildenafil (Viagra) in Patients with Cardiovascular Disease. ACC/AHA Expert Consensus Document. Circulation J. Am. Coll. Cardiology. 1999; 33:273-82.
- 4. McVary, K.T. Clinical Practice. Erectile Dysfunction. New England Journal of medicine. 2007 Dec. 13;357(24): 2472-81.
- Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD) for Diagnosis and Treatment of Impotence (230.4). Available: www.cms.hhs.gov/
- 6. Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD) for Cavernous Nerves by Electrical Stimulation with Penile Plethsmography (160.26). Effective Date: 08/24/2006. Available: www.cms.hhs.gov/
- 7. Centers for Medicare & Medicaid Services (CMS). MLN Matters. Number: SE1511. Effective Date: July 1, 2015. Discontinued Coverage of Vacuum Erection Systems (VES) Prosthetic Devices in Accordance with the Achieving a Better Life Experience Act of 2014.
- 8. American Association of Clinical Endocrinologists (AACE) and American College of Endocrinology (ACE). 1998. AACE clinical practice guidelines for the evaluation and treatment of male sexual dysfunction. Male Sexual Dysfunction Task Force.
- 9. Qaseem, A, et al. Hormonal testing and pharmacologic treatment of erectile dysfunction: a clinical practice guideline from the American College of Physicians. Annals of Internal Medicine. 2009; 151.

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- 10. Guay, A.T., et al. American Association of Clinical Endocrinologists Medical Guidelines for Clinical Practice for the Evaluation and Treatment of Male Sexual Dysfunction: A couple's problem-2003 Update. Endocrine Practice. 2003 Jan/Feb 9 (1) 77-95.
- 11. Burnett AL, Nehra A, Breau RH et al: Erectile dysfunction: AUA guideline. J Urol 2018; 200: 633. Monatague DK, Jarow JP, Broderick GA, et al.; Erectile Dysfunction Guideline Update Panel. The management of erectile dysfunction: An update. Linthicum, MD: American Urological Association (AUA)
- 12. Insurance Department of the State of New York. Thirty-sixth amendment to regulation No. 62 (11 NYCRR 52) Minimum standards for the form, content and sale of health insurance, including standards for full and fair disclosure. October 2008.
- 13. American Academy of Neurology. Assessment: Neurological evaluation of male sexual dysfunction. Report of the Therapeutic and Technology Assessment Subcommittee of the American Academy of Neurology. Neurology. 1995;45 (12):2287-2292.
- 14. Pickard, RS., et al. The clinical application of dorsal penile nerve cerebral-evoked response recording in the investigation of impotence. British Journal of Urology. 1994; 74(2);231-235.
- 15. Broderick, GA. Evidenced based assessment of erectile dysfunction. International Journal of Impotence Research. 1998; 10 Suppl 2:S64-S73; discussion S77-S79.
- 16. Delodovici, ML, et al. Clinical value of the pudendal somatosensory evoked potential. Electroencephalography and Clinical Neurophysiology. 1995; 96(6):509-515.
- 17. Babaei, AR., et al. Penile revascularization for erectile dysfunction: a systematic review and meta-analysis of effectiveness and complications. Urology Journal. 2009 Winter; 6(1):1-7.
- 18. Hsu, GL, et al. Clinical experience of a refined penile venous stripping surgery procedure for patients with erectile dysfunction: is it a viable option? Journal of Andrology 201 May-June; 31 (3):271-80
- 19. Hellstrom WJ, Montague DK, Moncada I, et al. Implants, mechanical devices, and vascular surgery for erectile dysfunction. J Sex Med. 2010; 7(1 Pt 2):501-523.
- 20. Office of Medical Management Department of Health Medicaid Update January 2006 Vol. 21, No. 1 Available:

 https://www.health.ny.gov/health_care/medicaid/program/update/2006/jan2006.htm
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Customer Product	Medical Management Requirements*
New York Products	-
HMO	Potential for Retrospective Review
PPO in Plan	Potential for Retrospective Review
PPO OOP	Potential for Retrospective Review
POS in Plan	Potential for Retrospective Review
POS OOP	Potential for Retrospective Review
Essential Plan	Potential for Retrospective Review
MVP Medicaid Managed Care	Prior Auth
MVP Child Health Plus	Not Covered
MVP Harmonious Health Care Plan	Potential for Retrospective Review
MVP Medicare Complete Wellness	Potential for Retrospective Review
MVP Medicare Preferred Gold HMO POS	Potential for Retrospective Review
MVP Medicare Secure HMO POS	Potential for Retrospective Review
MVP Medicare Secure Plus HMO POS	Potential for Retrospective Review
MVP Medicare WellSelect PPO	Potential for Retrospective Review
MVP Medicare WellSelect Plus PPO	Potential for Retrospective Review
MVP Medicare Patriot Plan PPO	Potential for Retrospective Review
MVP DualAccess D-SNP HMO	Potential for Retrospective Review
MVP DualAccess Complete D-SNP HMO	Potential for Retrospective Review
MVP DualAccess Plus D-SNP HMO	Potential for Retrospective Review
UVM Health Advantage Select PPO	Potential for Retrospective Review
USA Care	Potential for Retrospective Review
Healthy NY	Potential for Retrospective Review
MVP Premier	Potential for Retrospective Review
MVP Premier Plus	Potential for Retrospective Review
MVP Premier Plus HDHP	Potential for Retrospective Review
MVP Secure	Potential for Retrospective Review
MVP EPO	Potential for Retrospective Review
MVP EPO HDHP	Potential for Retrospective Review
MVP PPO	Potential for Retrospective Review
MVP PPO HDHP	Potential for Retrospective Review
Student Health Plans	Potential for Retrospective Review
ASO	See SPD
Vermont Products	366 3FD
POS in Plan	Potential for Retrospective Review
POS OOP	Potential for Retrospective Review
MVP Medicare Preferred Gold HMO POS	Potential for Retrospective Review
MVP Medicare Preferred dold Timo POS MVP Medicare Secure Plus HMO POS	Potential for Retrospective Review
MVP VT HMO	Potential for Retrospective Review
MVP VT HDHP HMO	Potential for Retrospective Review
MVP VT Plus HMO	Potential for Retrospective Review
MVP VT Plus HDHP HMO	Potential for Retrospective Review
MVP Secure	Potential for Retrospective Review
ASO	See SPD
AJU	SEE SED

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit
See SPD See Specific Plan Design

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Revision History:

06/01/2022 – Annual Review with no changes to the indications or criteria.

06/01/2024 – Annual review, no changes to criteria, references reviewed.

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Evaluation of New Technology, Procedures, Behavioral Health Services and Programs

Type of Policy: N/A

Prior Approval Date: 06/06/2022

Approval Date: 05/06/2024

Effective Date: 08/01/2024

Related Polices: N/A

Objective

This policy describes the process for evaluation of new technology, procedures, behavioral health services, and programs that are not directly related to a specific coverage request for a customer.

The process for evaluating pharmaceuticals can be found in the Pharmacy Programs Administrative Policy.

Policy

The process of assessing new technologies and services allows MVP to make decisions to optimize quality and cost effectiveness and to manage utilization and resources. The goal of this process is to use facts and evidence to make informed decisions about coverage and clinical use. Evaluation requests can originate outside of MVP from providers, institutions, the Community Technology Assessment Advisory Board (CTAAB) or from within MVP. Services evaluated can include, but are not limited to, community programs, medical devices, procedures, behavioral health services, therapies, and diagnostic products. FDA approval or clearance is necessary, but not sufficient, to consider a technology to be proven.

The assessment process is a multidisciplinary approach that involves the requestor, Medical Policy Task Force (MPTF), Medical Management Committee Workgroup, Product, and Network Management. MVP uses principles of evidence-based medicine in

its evaluation of clinical literature, in development of its reviews and in preparing published medical coverage policies.

PROCEDURE

- 1. The request is communicated to a Medical Director or leadership of the Medical Policy Task Force. A preliminary review of the request will be done to determine if:
 - the organization has a coverage position regarding the requested service and no new information is presented for consideration; and
 - an alternative review process is more appropriate, such as medical policy modification or benefit change.

If the new technology evaluation process is not appropriate, the requestor will be notified in writing of this decision.

- 2. If the new technology evaluation process is appropriate, an MVP Review Application Form is available to assist the requestor (see attached form at end of policy). The form may be completed and returned to MVP along with the documentation and scientific evidence to support the request.
 - The submitted scientific evidence must permit conclusions concerning the effectiveness of the technology or service and the impact on health outcomes.
 - The evidence should consist of well-designed and well-conducted investigations, published in peer-reviewed journals. The quality of the body of the studies and the consistency of the results are considered in evaluating the evidence.
 - The evidence should demonstrate that the beneficial effects of the technology or service outweigh any harmful effects. In addition, the beneficial effects should improve the health outcomes as much as, or more than, the established alternatives.
 - In general, new technology and services will not be approved based on submitted case studies without controls.
 - Expert opinions and evaluations by national medical associations, consensus panels, or other technology evaluation bodies will be evaluated according to the scientific quality of the supporting evidence and rationale.
- 3. An extensive review of the medical literature is completed by members of the Medical Policy Task Force. Information is obtained from various sources. Examples include:
 - contracted research company (e.g., Hayes);
 - Governmental regulatory agencies such as Centers for Medicare and Medicaid Services (CMS) and NYS Department of Health;

Evaluation of New Technology, Procedures, Behavioral Health Services and Programs

- Cochrane Review and UpToDate;
- Internet web sites (i.e., Physician On-line, MEDLINE, AIDSLINE, CANCERLINK, NCCN);
- NIH, CDC, and FDA; or
- National Provider Organizations such as the American Medical Association, American College of Physicians, and the American College of Obstetricians and Gynecologists.
- 4. Specialist and professional input, including Behavioral Health and Substance Use practitioners, when applicable, is sought from individuals with expertise in the technology. Providers are consulted over the phone and through written communication.
- 5. When appropriate, input from internal departments is sought including Legal, Product, and Network.
- 6. The Medical Policy Task Force reviews all the information gathered and makes a recommendation to the Medical Management Committee. The Medical Policy Task Force will make its recommendation based on the evidence in the medical literature, the position of regulatory bodies, the impact on health outcomes, the value of the new technology compared to conventional therapy, and the need for the technology for reasons other than convenience or cosmetic care.
- 7. The Medical Management Committee reviews the Medical Policy Task Force's recommendation and determines the organization's coverage position.
- 8. An implementation plan is developed. The need for medical or administrative policy modifications, contractual changes, and system modifications is considered.
- 9. MVP's coverage position is implemented and communicated in writing to the requestor.



Review Application for Coverage of New Programs, Procedures, Drugs, or Technology

General Information

- 1. Facility/Practice Name and Address
- 2. MVP Provider Number
- 3. Provider/Operator Name and Address (if different from above)
- 4. Site(s)/Location(s) of Proposed Activity (if different from above)
- 5. Contact Person/Representative (include phone number, FAX, e-mail)
- 6. Name of Person (include Title) Completing this Application
- 7. Description of the Proposed Requisition

What are you requesting? Please list specific HCPCS, CPT, and or ICD-10 codes. Is your request approved by the FDA? If so, is it approved for the indication that is being requested?

Is this an enhancement or replacement of current service(s)?

What is the expected utilization of these services in the community?

8. Description of Proposed Costs

What is the total cost?

What are the itemized costs?

What are the actual/proposed cost savings (if any)?

9. Description of Measured Outcomes

Please provide an analysis of benefits and risks including measurements of critical outcomes.

- 10. Provide a listing of clinical indications for which the proposed request is considered acceptable, as documented in peer reviewed literature. Provided a listing of clinical contraindications for which the proposed request is considered unacceptable. Please provide documentation from the medical literature, if available. (If not provided, MVP will assume merits cannot be documented).
- 11. How does the proposed request compare to existing services currently available? Does it enhance or replace current services?

- 12. What is your estimate of the community need for this service? Please provide detailed methodology for the basis of your estimate. How is this need being addressed presently?
- 13. Provide documentation of any professional society and/or other regulatory agencies (i.e., Centers for Medicare and Medicaid Services, N.Y. State Dept. of Health) that have reviewed this technology.
- 14. Please indicate any specialized training requirements for primary users and/or providers of this proposed request. Include a list of individuals in your organization who have already received this training requirement.

Return the completed form to your MVP Professional Provider Representative.



Experimental or Investigational Procedures, Behavioral Health Services, Drugs and Treatments, Off-Label use of FDA Approved Drugs, and Clinical Trials

Type of Policy: Medical

Prior Approval Date: 09/11/2023

Approval Date: 10/03/2023

Effective Date: 12/01/2023

Related Polices: N/A

Overview

This policy is used as criteria for the review of specific coverage requests for customers.

Policy Criteria

New Technology

Because of rapid changes within health care, an MVP Health Care customer may require the use of new technology before the organization has defined a coverage position. When a coverage position has not been determined, requests for coverage of new technology will be reviewed on a case-by-case basis utilizing the guidelines that follow:

- the technology must have demonstrable efficacy in the diagnosis or treatment of a particular medical problem;
- early studies of such technology must prove equal to or superior to present standards of medical care and ongoing studies will allow conclusions on its cost effectiveness. These studies should not have sponsorship or financial incentives from the manufacturer or pharmaceutical company. These studies must show appropriate patient selection outside of the initial principal investigational setting;
- the new technology must have measurable impact on patient outcomes outside the research and investigational arena;

the new technology must have a governmental agency approval (state or federal);
 and

Experimental or Investigational

A medical or surgical procedure, behavioral health service (e.g. psychiatric, substance use), drug therapies, devices, and other health care technologies, supplies, treatments, or diagnostic procedures is considered experimental or investigational when it is not recognized to be therapeutically effective. Experimental services mean a service that has been applied primarily in the laboratory setting. Investigational services mean a service that has been applied to human subjects because it has theoretic rationality or has shown promise in preliminary human study. In either case, no final conclusions have been reached concerning the efficacy/effectiveness of the service, nor has a specific role in clinical evaluation, management or treatment for the service been defined. Further study, such as controlled clinical trials comparing two treatment alternatives, are usually required to resolve these issues. The results of such studies are published and available for critical review in peer-reviewed medical literature.

Medical professionals chosen by MVP Health Care evaluate each service or item to determine if it is experimental or investigational. The criteria that are considered when making this determination include, but are not limited to, the following:

- it cannot be lawfully marketed without the approval of the Food and Drug Administration (FDA) and such approval has not been granted at the time of its use or proposed use;
- it is the subject of a current investigational new drug or new device application currently on file with the FDA;
- the service is subject to Investigational Review Board (IRB) review or approval for its proposed use;
- the service is the subject of a clinical trial that meets the definition of a Phase I, II, III, or IV, as set forth by FDA regulations, regardless of whether the trial is actually subject to FDA oversight;
- the service is considered not to have demonstrated value based on clinical evidence reported by prevailing peer-reviewed medical literature and by generally recognized academic experts;
- the predominant opinion among experts as expressed in published peer-review literature is that further research is necessary in order to define safety, toxicity, or effectiveness compared with conventional alternatives;
- when used in conjunction with a drug treatment, device, or procedure which is experimental/investigational;
- when a Hayes Health Technology Assessment, Medicare policy, Medicaid policy or

Medicare coverage decision supports that the service is not proven;

- Current Procedural Terminology (CPT) Category III codes that are developed to track
 the utilization of emerging technologies, services, and procedures. Category III codes
 can be identified by the T alpha character that follows the four initial numerical digits
 (i.e., four digits followed by the letter T). These codes are also referred to as T Codes
 (American Medical Association [AMA], 2019).
 - Category III T codes are considered experimental, investigational, or unproven because they are used to track the utilization of emerging technologies, services and procedures that lack evidence from peer-reviewed literature and do not establish a service or procedure as safe, effective, or applicable to the clinical practice of medicine.
 - There may be some Category III T codes that are considered medically appropriate based on peer-reviewed scientific literature. Certain Category III T codes may be recommended for coverage if coverage criteria are met as addressed in relevant MVP coverage policies.
 - There may be some Category III T codes that are considered medically appropriate for Medicare plans if coverage criteria are met as addressed in Medicare National Coverage Determinations (NCD), Local Coverage Determinations (LCD), or Articles.
- with respect to drugs (if the Customer's plan includes prescription drug coverage):
 - the drug is not approved for use by the U.S. Food and Drug Administration (FDA) to be lawfully marketed for the proposed use (off-label prescribing) and is not identified in one of the appropriate compendia listed in this policy; or
 - the drug is classified as IND (investigational new drug) by the FDA, except as otherwise required by law.

If benefits for a service/drug are denied on the basis that the service/drug is experimental or investigational, no benefits will be available for services/drugs provided in connection with the experimental or investigational services/drugs. The fact that a service/drug may be the only available treatment for a particular condition does not mean that the service/drug will be approved for benefits or that the service/drug is not experimental or investigational.

The Medical Director or designee may consider benefit coverage outside of a clinical trial when the request meets **ALL** of the following criteria:

- the service has governmental agency approval (State or Federal); and
- the customer has a life-threatening or disabling condition; and
- the customer's board certified or board eligible physician who is qualified to treat the customer's life threatening or disabling condition recommends the experimental

or investigational service/drug; and

- medical and scientific evidence supports the benefits of the requested service/drug.
 At least two documents from the available medical and scientific evidence support
 that the service/drug is likely to be more beneficial than any standard health service,
 procedure or drug. The physician must provide the evidence that was relied upon in
 certifying his or her recommendation; and
- there must be a measurable impact on patient outcomes outside of the research or investigational arena; and
- the service/drug would otherwise be covered except that the service/drug was determined to be experimental or investigational; and

FDA designated Category B medical devices being studied under Investigational Device Exemptions (IDE):

The U.S. Federal Food Drug & Cosmetic Act (FD&C Section 201 (h)) defines a device as follows:

A device is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

- recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them;
- intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in humans or other animals; or
- intended to affect the structure or any function of the body of humans or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of humans or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.

Category B devices are newer generations of proven technologies. Initial questions of safety and effectiveness have been resolved. Category B devices that are in an FDA approved clinical trial under Investigational Device Exemptions (IDEs) must meet all of the following criteria:

- must be used within the context of the FDA approved clinical trial; and
- must be used according to the clinical trial's approved patient protocols; and
- must be medically necessary for the particular patient; and
- must be medically appropriate in amount, duration and frequency of use or application of the device; and

- must be furnished in a setting appropriate to the patient's medical needs and condition; and
- must meet national or local Medicare policy guidelines for similar FDA approved devices.

Refer to the appropriate MVP Pharmacy/Administrative Policy for off-label use of FDA approved drugs and clinical trials.

Exclusions

Services or technologies will be denied as investigational/experimental when any of the following are indicated:

- Category A devices for which the absolute risk of the device type has not been established and initial questions of safety and effectiveness have not been resolved; or
- service or technology is in the developmental or testing stage; or
- does not have final regulatory or governmental approval; or
- long-term scientific evidence is not available or is inconclusive relative to outcomes;
 or
- scientific evidence does not support that net improvement is equal to or greater than established alternatives; or the predominant opinion among experts as expressed in published peer-reviewed literature is that further research is necessary in order to define safety, toxicity, and effectiveness, or effectiveness compared to conventional alternatives.

If benefits for a service are denied on the basis that the service is experimental, no benefits will be available for services provided in connection with the experimental services.

Any procedure related to repositioning or removing a device that is considered experimental or investigational by MVP is not considered to be medically necessary and is excluded from coverage.

Note: Category B devices are not FDA approved medications.

Clinical Trials

The Medical Director or designee may consider benefit coverage within a clinical trial when the request meets **ALL** of the following criteria:

- the customer is eligible to participate in the clinical trial (phase I, phase II, phase III, or phase IV); and
- the customer's physician recommends that the customer participate in the clinical trial when the customer has cancer, a life-threatening or disabling condition or the

customer provides medical and scientific information establishing that the individual's participation of such trial would be appropriate based on the individual has cancer, a life-threatening or disabling condition; and

- the clinical trial has been approved by one of the following:
 - Agency for Health Care Research and Quality (AHRQ);
 - National Institute of Health (NIH);
 - Centers for Disease Control and Prevention (CDC);
 - NIH Cooperative Group or NIH Center;
 - Food and Drug Administration;
 - Department of Veterans Affairs;
 - Centers for Medicare and Medicaid Services (CMS);
 - a qualified, non-government research entity identified by the National Institute of Health (NIH);
 - the Department of Veterans Affairs, the Department of Defense, or the Department of Energy; or
 - the Institutional Review Board of a facility that has multiple project assurance approved by the NIH; and
- there is no clearly superior, non-investigational alternative; and
- clinical or pre-clinical data shows reasonable expectation that the treatment will be at least as effective as the non-investigational alternatives; and

If a service or item is covered as part of a clinical trial, MVP will only cover the cost of services required to provide treatment to the customer according to the design of the trial. MVP will not cover the costs of investigational drugs or devices, non-health care services, the managing of research, or costs of non-experimental services which are not covered under the customer's contract.

Clinical Trials Coverage for Medicare Advantage

Original Medicare covers the routine costs of qualifying clinical trials for all Medicare enrollees, including those enrolled in Medicare Advantage (MA) plans, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participating in qualifying clinical trials. All other original Medicare rules apply.

Routine costs of a clinical trial include all items and services that are otherwise generally available to Medicare beneficiaries (i.e., there exists a benefit category, it is not statutorily excluded, and there is not a national non-coverage decision) that are provided in either the experimental or the control arms of a clinical trial except:

- The investigational item or service, itself unless otherwise covered outside of the clinical trial;
- Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient (e.g., monthly CT scans for a condition usually requiring only a single scan); and
- Items and services customarily provided by the research sponsors free-of-charge for any enrollee in the trial.

Routine costs in clinical trials include:

- Items or services that are typically provided absent a clinical trial (e.g., conventional care);
- Items or services required solely for the provision of the investigational item or service (e.g., administration of a noncovered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and
- Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service in particular, for the diagnosis or treatment of complications.

Providers should bill Medicare intermediaries and carriers for clinical trials care provided to customers of MVP Medicare Advantage plans. MVP is not responsible for these costs. CMS will make payments for Medicare Advantage enrollees on a fee-for-service basis for covered clinical trial costs under the September 2000 National Coverage Decision.

Payment for covered clinical trial services furnished to beneficiaries enrolled in Medicare managed care plans is determined according to the applicable fee-for-service rules, except that MA enrollees are not responsible for meeting either the Part A or Part B deductible (i.e., the deductible is waived). MVP is responsible for MA enrollees' coinsurance amounts for clinical trial services that exceed MVP's in-network cost sharing for the same category of service. Clinical trial cost sharing must be included in the out-of-pocket maximum calculation.

To be eligible for reimbursement, an Medicare Advantage (MA) customer (or providers acting on the customer's behalf) must notify their plan that the enrollee received a qualified clinical trial service and provide documentation of the cost-sharing incurred, such as a provider bill. MAOs also are permitted to seek the MA enrollee's original Medicare cost-sharing information directly from clinical trial providers.

It is mandatory to report a clinical trial number on claims for items and services provided in clinical trials that are qualified for coverage as specified in the "Medicare National Coverage Determination (NCD) Manual," Section 310.1.

(Medicare Managed Care Manual Chapter 4, section 10.7.1)

Payment for Investigational Device Exemption (IDE) Studies

MVP Medicare Advantage (MA) plans are responsible for payment of claims related to a customer's participation in both Category A and B IDE studies that are covered by the Medicare Administrative Contractor (MAC) with jurisdiction over MVP's service area. The MVP Medicare Advantage (MA) plan is responsible for payment of routine care items and services in the CMS-approved Category A and Category B IDE studies. The MVP Medicare Care Advantage (MA) plan is also responsible for CMS-approved Category B devices. CMS and MVP will not approve Category A devices because they are statutorily excluded from coverage. (Medicare Managed Care Manual Chapter 4, section 10.7.2)

<u>Payment for Clinical Studies Approved Under Coverage with Evidence Development</u> (CED)

MVP Medicare Advantage (MA) plans are responsible for payment of items and services in CMS-approved CED studies unless CMS determines that the significant cost threshold is exceeded for that item or service (Medicare Managed Care Manual Chapter 4, section 10.7.3) Approved CED studies are posted on the CMS Coverage with Evidence Development webpage (see https://www.cms.gov/medicare/coverage/coverage-with-evidence-development).

Off-Label Coverage of FDA Approved Drugs

An off-label use of a drug is defined as use for a non-FDA approved indication, that is, one that is not listed on the drug's official label/prescribing information. Off-label use is further defined as giving the drug in a way that deviates significantly from the labeled prescribing information for a particular indication. This includes, but is not limited to, dosage, route of administration duration and frequency of administration, and the population to whom the drug would be administered. The individual components of compounded drug products are subject to these definitions as well. Services related to non-covered services/drugs are also not covered (e.g., administration services).

For drugs other than anti-cancer chemotherapeutic regimen, off-label use is not covered if the usage is not supported by one of the following:

- one of the following compendia identifies the use as appropriate:
 - American Hospital Formulary Service-Drug Information (AHFS-DI) indication is supportive or
 - NCCN Drugs and Biologics Compendium indication is a Category 1 or 2A or
 - o Micromedex DrugDex® indication is Class I, Class IIa, or Class IIb or
 - o Clinical Pharmacology indication is supportive or

- o Lexi-Drugs indication is rated as "Evidence Level A" or
- Local Coverage Determination/article; (Medical or Part B coverage for For Medicare beneficiaries only); or
- clinical research that appears in at least two Phase III clinical trials and definitely demonstrates safety and effectiveness. The trials must come from different centers and be published in national or international peer-reviewed journals;
- if no Phase III trial evidence is available, at least two Phase II clinical trials with reasonably large patient samples showing consistent results of safety and efficacy may be considered in certain instances such as use in rare diseases in which a Phase III study might be difficult to complete in a reasonable period of time after the completion of the Phase II studies, or when overwhelmingly good evidence of safety and effectiveness is noted in the Phase II study. The trials must come from different centers and be published in national or international peer-reviewed journals; or
- the off-label use of the drug is an accepted standard of medical practice.
 Acceptance by individual health care practitioners or a limited group of practitioners does not normally indicate general acceptance by the medical community. The broad range of available evidence must be considered, and the drug quality must be evaluated before a conclusion is made. The Harriet Lane Handbook may be utilized as a drug dosing guide for pediatric patients only.

The physician-administered drugs that meet the coverage requirements above are included in National Government Services articles.

For anti-cancer chemotherapeutic regimen (pharmacy and medical drugs), off-label use is not covered if the usage is not supported by one of the following:

- one of the following compendia identifies the use as appropriate:
 - American Hospital Formulary Service Drug Information (AHFS DI); or
 - NCCN Drugs and Biologics Compendium (Category 1 or 2A is supportive for coverage); or
 - Truven Health Analytics Micromedex DrugDex® (Class I, Class IIa, or Class IIb is supportive for coverage); or
 - o Elsevier/Gold Standard Clinical Pharmacology;
 - Lexi-Drugs indication is rated as "Evidence Level A" or
 - Local Coverage Determination/article; (Medical or Part B coverage for Medicare beneficiaries only) or
- select peer reviewed publications support use. This applies only when an off-label use does not appear in any of the compendia or is listed as insufficient data or investigational. Peer reviewed literature must be from the regular editions (not

supplements) of the journals listed below. In determining whether the literature supports the off-label use, the reviewer will consider the study design, the outcomes of the study, and whether the chemotherapy and clinical characteristics of the customer are adequately represented in the literature.

MVP will use peer-reviewed medical literature appearing in the following publications for review of off-label use for anti-cancer chemotherapeutic regimen drugs:

- American Journal of Medicine;
- Annals of Internal Medicine:
- Annals of Oncology;
- Annals of Surgical Oncology;
- Biology of Blood and Marrow Transplantation;
- Bone Marrow Transplantation;
- Clinical Cancer Research;
- Gynecologic Oncology;
- The Journal of the American Medical Association;
- Journal of Clinical Oncology;
- Journal of the National Comprehensive Cancer Network (NCCN);
- Journal of Urology;
- Blood;
- Journal of the National Cancer Institute;
- International Journal of Radiation, Oncology, Biology, and Physics;
- The New England Journal of Medicine;
- British Journal of Cancer;
- British Journal of Hematology;
- British Medical Journal;
- Cancer;
- Drugs;
- European Journal of Cancer;
- Radiation Oncology;
- Lancet;
- Lancet Oncology; and

Leukemia.

Documentation Requirements

Medical necessity must be documented in the medical record. In addition, the following should be provided from the practitioner requesting coverage:

- detailed written documentation explaining why this service/drug is the only appropriate alternative treatment for the customer's condition; and
- the scientific evidence supporting MVP coverage. [Abstracts (including meeting abstracts) are excluded from consideration.]

For Clinical Trials

- The study protocol including the phase of the trial, the approving agency, and the eligibility criteria.
- Evidence that there is no clearly superior, non-investigational treatment alternative.
- Clinical or pre-clinical data showing reasonable expectation that the treatment will be at least as effective as the non-investigational alternative.

Variations

Medicare Part D

If the off-label use is not supported in the recognized Medicare compendia for a drug, the request does not meet guidelines for coverage. Please refer to Chapter 6(10.6) of the Medicare Prescription Drug Manual for Part D drugs.

MVP Child Health Plus

New technology that is considered investigational or experimental will not be considered for the MVP Option Child contract unless an external appeal agent approves coverage in connection with a clinical trial.

Vermont

In Vermont, when a clinical trial is a cancer clinical trial, insurers are obligated to provide coverage for the costs of routine patient care services for patients who participate in all four types of approved cancer clinical trials (Phases I, II, III, and IV) that are conducted under the auspices of cancer care providers (CVR 21 040 01).

Health Insurance Coverage for Cancer Clinical Trials

Additionally, any internal appeals of denials for use of a prescription drug for the treatment of cancer as not medically necessary, or as experimental or investigational use, shall be treated as an emergency or urgent appeal (8 VSA § 4089f).

References (Updated 2023)

- 1. New York State Public Health Law, Article 49. Available: https://www.health.ny.gov/health_care/managed_care/docs/phlart49.pdf
- 2. Centers for Medicare & Medicaid Services (CMS). Medicare Coverage Database. National Coverage Determination (NCD) for Routine Costs of Clinical Trials (310.1). July 9, 2007. Available: MCD Search (cms.gov).
- 3. National Government Services, LCD for Drugs and Biologicals, Coverage of, for Drugs for Label and Off-Label Uses. Local Coverage Determination (LCD) L33394. Revision Effective Date: November 01, 2022. Available: MCD Search (cms.gov))
- 4. Centers for Medicare and Medicaid Services. MLN Matters®. MLN Matters® Number MM8401 Revised. Mandatory Reporting of an 8-Digit Clinical Trial Number on Claims. Effective Date: January 1, 2014. Available: MM8401.pdf (hhs.gov)
- 5. Office of the Legislative Counsel. Compilation of Patient Protection and Affordable Care Act. May 2010. Available: http://www.hhs.gov/sites/default/files/ppacacon.pdf
- 6. Centers for Medicare and Medicaid Services. Medicare Benefit Policy Manual. Chapter 15. Covered Medical and Other Health Services. Rev.212, 11-06-15. 50 Drugs and Biologicals. Available: https://www.cms.gov/Regulations-and-Guidance/Manuals/downloads/bp102c15.pdf.
- 7. Centers for Medicare and Medicaid Services (CMS). Wisconsin Physicians Service Insurance Corporation Local Coverage Determination (LCD) L35490 Category III Codes Original Effective Date: 10/01/2015 Revision Effective Date: 01/01/2022 Available: MCD Search (cms.gov).
- 8. Current Procedural Terminology (CPT®), © 2020 Professional Edition, American Medical Association: Chicago, IL.
- 9. Centers for Medicare and Medicaid Services (CMS). Medicare Managed Care Manual. Chapter 4 – Benefits and Beneficiary Protections. Section 10.7 – Clinical Trials. Available: MCM Chapter 4 (cms.gov)
- 10. Centers for Medicare and Medicaid Services (CMS). National Government Services, Inc. Clinical Trials Medical Policy Article A52840. Original Effective Date: 10/01/2015 Available: MCD Search (cms.gov)

Revision History

06/01/2021 - Annual review added exclusion for repositioning or removing implanted devices. Updated criteria for the off-label usage of drugs.

10/01/2022 – updated Category III section.

09/22/2023 – updated section on clinical trials, payment for clinical trials, Investigational Device Exemption (IDE) Studies and Coverage with Evidence Development (CED).



External Breast Prosthesis

Type of Policy: Medical

Prior Approval Date: 01/27/2023

Approval Date: 03/28/2025

Effective Date: 06/01/2025

Related Polices: N/A

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

HCPCS Codes:

L8033 - Nipple prosthesis, custom fabricated, reusable, any material, any type, each

L8035 - Custom breast prosthesis, post mastectomy, molded to patient model

L8039 - Breast prosthesis, not otherwise specified

Codes Requiring Retrospective Review

L8031 - Breast prosthesis, silicone or equal, with integral adhesive

Experimental/Investigational

N/A

Common Diagnosis Codes

ICD-10 Diagnosis Codes: C50.019, C50.119, C50.219, C50.319, C50.419, C50.519, C50.619, C50.819, C50.919, Z85.3, Z90.10

Common Procedure Codes

L8000, L8001, L8002, L8010, L8020, L8030, L8032

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has

External Breast Prosthesis Page 1 of 5

been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

Breast reconstruction is an option for those customers who have had a mastectomy or lumpectomy, usually as a result of breast cancer. An external breast prosthesis is an option for customers who have decided not to undergo breast reconstruction or are waiting to undergo breast reconstruction.

Indications/Criteria

Documentation Requirements

- Medical necessity must be documented in the customer's record and be made available to the Medical Director upon request.
- Documentation must be submitted describing the necessity for replacement items
 when there is a change in the patient's medical condition sufficient to render the
 original prosthesis no longer useable or when the item has been irreparably
 damaged.

An external breast prosthesis is determined to be medically necessary under the following indications/criteria:

- a breast prosthesis is medically necessary for a customer who has had a mastectomy;
- an external breast prosthesis garment, with a mastectomy form, is considered
 medically necessary for use in the post-operative period prior to a permanent breast
 prosthesis or as an alternative to a mastectomy bra and breast prosthesis;
- consideration for replacement of a silicone breast prosthesis will be made every two
 (2) years;
- consideration for replacement of a fabric, foam, or fiber filled breast prostheses will be made every six (6) months;
- consideration for replacement of a prefabricated nipple prostheses will be made every (3) three months;
- four (4) mastectomy bras per year will be considered;
- a camisole type undergarment with polyester fill for post mastectomy use prior to a
 permanent breast prosthesis or as an alternative to a mastectomy bra and breast
 prosthesis will be considered for replacement every six (6) months;
- an external breast prosthesis of the same type can be replaced at any time if it is lost or is irreparably damaged (this does not include ordinary wear and tear); and
- replacement is allowed at any time when there is a change in the patient's medical condition necessitating a different type of item.

Exclusions

External Breast Prosthesis Page 2 of 5

- More than one external breast prosthesis per side (spare or "back-up" items) will be denied as not medically necessary.
- The additional features of a custom fabricated breast prosthesis (L8035) are not medically necessary because they have not been demonstrated to have a clinical advantage compared to the prefabricated silicone breast prosthesis.
- Breast prostheses with integral adhesive (L8031) have not been demonstrated to have a clinical advantage over those without the integral adhesive and are considered not medically necessary.

Medicaid Variation

Providers are no longer able to bill MVP Managed Medicaid or HARP members for Pharmacy and pharmacy related durable medical equipment and supplies because NYS Medicaid covers these items. This includes certain durable medical equipment (DME), enteral and parenteral nutrition, family planning supplies, medical/surgical supplies, miscellaneous supplies and hearing aid batteries as designated by the New York State Department of Health.

The full list of codes that must be billed to Medicaid Fee-For-Service is located at https://www.emedny.org/ProviderManuals/Pharmacy/index.aspx - See the **OTC and Supply Fee Schedule.**

Providers should bill these directly to New York State Medicaid Fee-For-Service using the Medicaid member client identification number (CIN) after 04/01/2023. Claims submitted directly to MVP for items that are carved out to Fee-For-Service will deny as not a covered benefit.

References (Updated 2025)

- 1. Centers for Medicare & Medicaid Services Noridian Healthcare. Local Coverage Determination (LCD) for External Breast Prosthesis (L33317). Revision Effective Date: 01/01/2020. Available: MCR Search (cms.gov)
- 2. Centers for Medicare & Medicaid Services Noridian Healthcare. Local Coverage Article (LCA) for External Breast Prosthesis (A52478). Revision Effective Date: 01/01/2020. Available: MCR Search (cms.gov)

Customer Product	Medical Management Requirements*
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External Breast Prosthesis Page 3 of 5

New York Products	
	D: A d
HMO	Prior Auth
PPO in Plan	Prior Auth
PPO OOP	Prior Auth
POS in Plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Prior Auth
MVP Child Health Plus	Prior Auth
MVP Harmonious Health Care Plan	Prior Auth
MVP Medicare Complete Wellness	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP Medicare WellSelect PPO	Prior Auth
MVP Medicare WellSelect Plus PPO	Prior Auth
MVP Medicare Patriot Plan PPO	Prior Auth
MVP DualAccess D-SNP HMO	Prior Auth
MVP DualAccess Complete D-SNP HMO	Prior Auth
MVP DualAccess Plus D-SNP HMO	Prior Auth
UVM Health Advantage Select PPO	Prior Auth
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	
POS in Plan	Prior Auth
POS OOP	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP VT HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD
	555 5. 5

[♦] Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

*Medical Management Requirements

Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Revision History:

02/01/2022 - Removed prior authorization from L8031

06/01/2022 – Annual Review; Removed exclusion for L8033, references and websites sections updated.

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MVP Health Care Medical Policy 04/01/2023 –Updated to reflect NYS Medicaid Carve-in 06/01/2025 – Annual Review; no changes to criteria

External Breast Prosthesis Page 5 of 5



Extracorporeal Shock Wave Therapy for Musculoskeletal Indications

Type of Policy: Medical

Prior Approval Date: 03/04/2024

Approval Date: 03/28/2025

Effective Date: 06/01/2025

Related Polices: N/A

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

N/A

Codes Requiring Retrospective Review

CPT Codes:

28890 - Extracorporeal shock wave, high energy, performed by a physician or other qualified health care professional, requiring anesthesia other than local, including ultrasound guidance, involving the plantar fascia

0101T- Extracorporeal shock wave involving musculoskeletal system, not otherwise specified

0102T -Extracorporeal shock wave performed by a physician, requiring anesthesia other than local, and involving the lateral humeral epicondyle

Experimental/Investigational

CPT Codes: 28890, 0101T, 0102T

Common Diagnosis Codes

N/A

Common Procedure Codes

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

Extracorporeal Shock Wave Therapy is a non-invasive t treatment that uses acoustic waves to deliver targeted energy to tissues in the body. It is proposed to promote healing, reduce pain, and improve mobility, primarily for conditions like tendonitis, plantar fasciitis, and other musculoskeletal disorders. The therapy is proposed to stimulate cell repair, increase blood flow, and break down calcifications in affected areas.

Indications/Criteria

Extracorporeal Shock Wave Therapy has not been validated in peer-reviewed literature as an effective treatment for improving health outcomes in individuals with musculoskeletal conditions. As a result, it is regarded as experimental, investigational, and unproven for the treatment of musculoskeletal disorders and soft tissue injuries.

Medicare

Based on review there is no CMS National Coverage Decision or National Government Service Local Coverage Decision for Extracorporeal Shock Wave Therapy.

Exclusions

Requests not meeting criteria under Indications/Criteria stated in this policy.

References (Updated 2025)

- 1. Bisset L, Paungmali A, Vicenzino B, Beller E. A systematic review and meta-analysis of clinical trials on physical interventions for lateral epicondylalgia. Br J Sports Med. 2005;39 (7):411-422.
- Centers for Medicare and Medicaid Services. Palmetto GBA Local Coverage
 Determination (LCD) L38775 Extracorporeal Shock Wave Therapy (ESWT) Original
 Effective Date: 02/14/2021 Revision Effective Date: 09/12/2024. Available: Medicare
 Coverage Database (MCD)
- 3. Cinar E, Saxena S, Akkurt HE, Uygur F. Extracorporeal shockwave therapy in the management of plantar fasciitis: A randomized controlled trial. Foot (Edinb). 2020 Sep;44:101679. doi: 10.1016/j.foot.2020.101679. Epub 2020 Jul 13. PMID: 32674009.

- 4. EngebretsenK, Grotle M. et al. SupervicesSupervised exercises compared with radial extraxorporeal shock-wave therapy for subacromial shoulder pain: 1-year results of a single-blind randomized controlled study. Phys Ther. 2011 Jan;91(1):37-47.
- 5. Furia JP and Rompe JD. Extracorporeal shock wave therapy in the treatment of chronic plantar fasciitis and Achilles tendinopathy. Current Opinion in Orthopaedics. 2007;18:102-111.
- 6. Goff, J.D. and Crawford, R. Diagnosis and Treatment of Plantar Fasciitis. American Family Physician. September 15, 2011. Volume 84, Number 6.
- 7. Haake M, Konig IR, Decker T, et al. Extracorporeal shock wave therapy in the treatment of lateral epicondylitis: a randomized multicenter trial. J Bone Joint Surg Am. 2002a;84-A(11):1982-1991.
- 8. HAYES Health Technology Assessment: Focused Extracorporeal Shock Wave Therapy For Chronic Plantar Fasciitis. HAYES, Inc.; © 2021 Hayes, a symplr company. October 6, 2021 Annual Review February 3, 2021. Archived November 6, 2021.
- 9. HAYES Health Technology Assessment: Radial Extracorporeal Shock Wave Therapy For Chronic Plantar Fasciitis. HAYES, Inc.; © 2021 Hayes, a symplr company. November 10, 2016 Annual Review March 23, 2021. Archived December 10, 2021.
- 10. Lee SY, Cheng B, Grimmer-Somers K. The midterm effectiveness of extracorporeal shockwave therapy in the management of chronic calcific shoulder tendinitis. J Shoulder Elbow Surg. 2011 Jul;20(5):845-54. Epub 2011 Jan 13.
- 11. National Institute for Health and Clinical Excellence. Extracorporeal Shockwave Therapy for Refractory Tennis Elbow. 2009 Aug. Available: http://www.nice.org.uk/quidance/index.jsp
- 12. National Institute for Health and Clinical Excellence. Extracorporeal Shockwave Therapy for Refractory Achilles Tendinopathy. 2009 Aug. Available: http://www.nice.org.uk/guidance/index.jsp.
- 13. NHS. North East Treatment Advisory Group. Extracorporeal shockwave therapy for refractory plantar fasciitis: Evidence updates and cost analysis. June 2012.
- 14. Schofer MD, et al. High-versus low-energy extracorporeal shock wave therapy of rotator cuff tendinopathy: a prospective, randomized, controlled study. Acta Orthop Belg 2009 Aug;75(4):452-8.
- 15. Van Leeuwen MT, et al. Extracorporeal shockwave therapy for patellar tendinopathy: a review of the literature. Br J Sports Med 2009 Mar;43(3):163-8.

Customer Product	Medical Management Requirements*
New York Products	
HMO	Retrospective Review
PPO in Plan	Retrospective Review
PPO OOP	Retrospective Review
POS in Plan	Retrospective Review
POS OOP	Retrospective Review
Essential Plan	Retrospective Review
MVP Medicaid Managed Care	Retrospective Review
MVP Child Health Plus	Retrospective Review
MVP Harmonious Health Care Plan	Retrospective Review
MVP Medicare Complete Wellness	Retrospective Review
MVP Medicare Preferred Gold HMO POS	Retrospective Review
MVP Medicare Secure HMO POS	Retrospective Review
MVP Medicare Secure Plus HMO POS	Retrospective Review
MVP Medicare WellSelect PPO	Retrospective Review
MVP Medicare WellSelect Plus PPO	Retrospective Review
MVP Medicare Patriot Plan PPO	Retrospective Review
MVP DualAccess D-SNP HMO	Retrospective Review
MVP DualAccess Complete D-SNP HMO	Retrospective Review
MVP DualAccess Plus D-SNP HMO	Retrospective Review
UVM Health Advantage Select PPO	Retrospective Review
USA Care	Retrospective Review
Healthy NY	Retrospective Review
MVP Premier	Retrospective Review
MVP Premier Plus	Retrospective Review
MVP Premier Plus HDHP	Retrospective Review
MVP Secure	Retrospective Review
MVP EPO	Retrospective Review
MVP EPO HDHP	Retrospective Review
MVP PPO	Retrospective Review
MVP PPO HDHP	Retrospective Review
Student Health Plans	Retrospective Review
ASO	See SPD
Vermont Products	
POS in Plan	Retrospective Review
POS OOP	Retrospective Review
MVP Medicare Preferred Gold HMO POS	Retrospective Review
MVP Medicare Secure Plus HMO POS	Retrospective Review
MVP VT HMO	Retrospective Review
MVP VT HDHP HMO	Retrospective Review
MVP VT Plus HMO	Retrospective Review
MVP VT Plus HDHP HMO	Retrospective Review
MVP Secure	Retrospective Review
ASO	See SPD

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review.

Retro Review Required
Not Covered Service is not a covered benefit
See SPD See Specific Plan Design

Revision History

06/01/2022 – Annual Review with an update to indicate that procedure codes 28890, 0101T, 0102T suspend for retrospective review as experimental procedures as noted in the indications/criteria. No change was made to the indications/criteria.

06/01/2024 – Annual review. No changes to criteria made.

06/01/2025 - Updated policy to indicate that Extracorporeal Shock Wave Therapy is experimental investigational instead of not medically necessary based on review. Overview rewritten. Removed outdated references.



Fertility Preservation Services Medical Policy

Type of Policy: Medical

Prior Approval Date: 09/07/2023

Approval Date: 12/04/2023

Effective Date: 02/01/2024

Related Polices: Advanced Infertility Services and In Vitro

Fertilization (IVF) Medical Policy

Basic Infertility Services Medical Policy. Infertility (Drug Therapy) Pharmacy Policy

Gender Affirming Treatment Policy

Codes Requiring Prior Authorization

CPT Code:	Description:	
58970	Follicle puncture for oocyte retrieval, any method	
89254	Oocyte identification from follicular fluid	
89259	Cryopreservation; sperm	
89337	Cryopreservation, mature oocyte(s)	
89343	Storage (per year); sperm/semen	
89346	Storage (per year); oocyte(s)	
89353	Thawing of cryopreserved; sperm/semen, each aliquot	
89356	Thawing of cryopreserved; oocytes, each aliquot	
S4030	Sperm procurement and cryopreservation services; initial visit	
S4031	Sperm procurement and cryopreservation services; subsequent visit	

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

Codes Subject to Retrospective Review for Experimental/Investigational Review:

CPT Code:	Description:
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89335	Cryopreservation, reproductive tissue, testicular	
89344	Storage (per year); reproductive tissue, testicular/ovarian	
89354	Thawing of cryopreserved; reproductive tissue, testicular/ovarian	
89398	Unlisted reproductive medicine laboratory procedure	

Common Diagnosis Codes

ICD-10 Diagnosis Codes: E23.0, N46.01, N46.021, N46.022, N46.023, N46.024, N46.025, N46.029, N46.11, N46.121, N46.122, N46.123, N46.124, N46.125, N46.129, N46.8, N46.9, N81.3, N97.0, N97.1, N97.2, N97.8, N97.9, Z31.83, Z31.84

Common Procedure Codes

CPT Code:	Description:
S4031	Sperm procurement and cryopreservation services; subsequent visit

Non-Covered Codes

CPT Codes: N/A

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy.

Authorization Requirements

MVP Health Care's authorization requirements comply with all relevant statutes and regulations, including but not limited to Part L of the Health and Mental Hygiene portion of the budget (A.2007-C/S.1507-C); New York State Insurance Laws §3216, §3221, §4303.

MVP Health Care's authorization requirements comply with all billing and coverage guidance issued by the NY State Department of Health.

This policy addresses fertility preservation services for iatrogenic infertility.

For plans that have in vitro fertilization coverage; see the MVP Health Care Advanced Infertility Services and In Vitro Fertilization (IVF) Medical Policy.

For plans that do not have in vitro fertilization coverage or fertility preservation coverage; see the MVP Health Care Basic Infertility Services (No IVF or FPS benefits) Medical Policy.

For pharmacologic treatment of infertility please refer to MVP Infertility (Drug Therapy) Pharmacy Policy.

Some ASO products may have fertility preservation services (FPS) coverage. Please consult the members individual plan description (SPD) regarding ASO group coverage

for IVF and fertility preservation services coverage. If an ASO group has coverage for IVF and FPS, then the coverage criteria described in this policy applies.

Overview

latrogenic infertility is an impairment of fertility by surgery, radiation, chemotherapy, or other medical treatment affecting reproductive organs or processes.

This policy addresses fertility preservation services for iatrogenic infertility.

Fertility Preservation Services

Fertility Preservation Services are covered when the member requires medical treatment that may directly or indirectly cause iatrogenic infertility. Iatrogenic infertility means impairment of fertility by surgery, radiation, chemotherapy, or other medical treatment affecting reproductive organs or processes. Coverage is for the collecting, freezing, preserving, and storage of mature oocytes (ova) or sperm for members who have no prior history of sterilization, in the presence or absence of ongoing infertility care. Fertility Preservation Services are also available to individuals receiving affirming care for the treatment of gender dysphoria. See the Gender Affirming Treatment Policy.

The following services are eligible for coverage for fertility preservation as a result of iatrogenic infertility:

- Collecting and retrieval of mature oocytes or sperm
- Cryopreservation of sperm or mature oocytes
- Monitoring, storage, and thawing of cryopreserved oocytes or sperm

Exclusions and Benefit Limitations:

- Cryopreservation as a routine procedure for backup in the absence of a confirmed physical or psychological diagnosis requiring cryopreservation is excluded from coverage.
- The following procedures for iatrogenic infertility done prior to commencing treatment that is likely to affect fertility are considered investigational and are not covered:
 - Cryopreservation of immature oocytes (89398);
 - Ovarian tissue cryopreservation and auto-transplantation procedures (0058T);
 - Testicular tissue or spermatogonial cryopreservation (89335);
 - Reimplantation or grafting of human testicular tissue;
 - Reproductive tissue (testicular/ovarian) cryopreservation, thawing or storage (89344, 89354);

- Ovarian suppression with gonadotropin releasing hormone (GnRHa) or antagonists;
- Testicular suppression with GnRHa or antagonists;
- o Cryopreservation to circumvent reproductive aging in healthy persons.

MVP Medicaid Managed Care and Medicare Exclusion

Fertility Preservation Services (FPS) are not a covered benefit for MVP Medicaid Managed Care Plans and Medicare Advantage Plans.

Any fertility preservation services rendered in connection with any non-covered infertility procedure, including frozen embryo transfer (FET), IVF, GIFT, ZIFT program, cycle or treatment are not covered.

References (Updated 2022)

- 1. State of New York Insurance Law § 7657, Amendment 11723, effective 2003 Jan. Part L of the Health and Mental Hygiene portion of the budget (A.2007-C/S.1507-C); New York State Insurance Laws §3216, §3221, §4303.
- American Society for Reproductive Medicine (ASRM). Definitions of infertility and recurrent pregnancy loss: a committee opinion. Fertil Steril. 2008; 90(Suppl 3):S60. Revised Fertil Steril® January 2013; 99:63. Available: https://www.asrm.org/globalassets/asrm/asrm-content/news-and-publications/practice-guidelines/for-non-members/definitions of infertility and recurrent pregnancy loss.pdf.
- 3. The Practice Committee of the American Society for Reproductive Medicine. Effectiveness and treatment for unexplained infertility. Fertil Steril 2006; 86:S111-4. Available: https://www.fertstert.org/article/S0015-0282(06)03249-3/fulltext.
- Speroff L, Fritz MA. Female infertility. In: Clinical Gynecologic Endocrinology and Infertility. Seventh ed. Philadelphia: Lippincott Williams & Wilkins; 2005. p. 1013-1067.
- American Society for Reproductive Medicine (ASRM). Practice Committee of the American Society for Reproductive Medicine. Diagnostic Evaluation of the Infertile Female. Fertil Steril. June 2000, revised November 2006, 2012d, revised 2015; 103:e44-50. ©2015 American Society for Reproductive Medicine. Available: https://www.asrm.org/globalassets/asrm/asrm-content/news-and-publications/practice-guidelines/for-non-members/diagnostic evaluation of the infertile female.pdf.
- 6. American Society for Reproductive Medicine (ASRM). Female age-related fertility decline. Committee Opinion No. 589. Fertil Steril®. 2014; 101:633-4. Available: https://www.asrm.org/globalassets/asrm/asrm-content/news-and-

- <u>publications/practice-guidelines/for-non-members/female-age-related-fertility-decline.pdf.</u>
- 7. American Society for Reproductive Medicine (ASRM). Use of clomiphene citrate in infertile women: a committee opinion. Fertil Steril. August 2013e 100(2) 341-348. Available: https://www.fertstert.org/article/S0015-0282(13)00643-2/fulltext.
- 8. American Society for Reproductive Medicine (ASRM). Endometriosis and infertility: a committee opinion. Fertil Steril. 2012; 98:591-598. Available: https://www.asrm.org/globalassets/asrm/asrm-content/news-and-publications/practice-guidelines/for-non-members/endometriosis and infertility.pdf.
- 9. American Society for Reproductive Medicine (ASRM). Diagnostic Evaluation of the Infertile Male: a committee opinion. Fertil Steril 2012e:98:294-301. Revised Fertil Steril® 2015;103:e18-e25. Available: <u>Diagnostic evaluation of the infertile male: a committee opinion Fertility and Sterility (fertstert.org).</u>
- American Society for Reproductive Medicine (ASRM). A Practice Committee Technical Bulletin. Sperm retrieval for obstructive azoospermia. Fertil Steril. 2008e Nov; 90(5 Suppl):S213-8. Available: https://www.fertstert.org/article/S0015-0282(08)03512-7/fulltext.
- 11. American Society for Reproductive Medicine (ASRM). A Practice Committee Report. The Role of Assisted Hatching in in vitro fertilization: a guideline. Fertil Steril 2014; 102-348-51. © 2014 American Society for Reproductive Medicine.
- 12. American Urological Association, Inc. (AUA) The Optimal Evaluation of the Infertile Male. AUA Best Practice Statement. Published April 2001. Revised 2010 (a). Reviewed and Validity Confirmed 2011. Available: https://www.auanet.org/guidelines/male-infertility-optimal-evaluation-best-practice-statement.
- 13. Guzick D.S., Carson S.A., Coutifaris C., Overstreet J.W., Factor-Litvak P., Steinkampf M.P., et al. Efficacy of super ovulation and intrauterine insemination in the treatment of infertility. National Cooperative Reproductive Medicine Network [see comments]. N Engl J Med 1999; 340:177-83.
- 14. Hershlag, A., et al. Acrobeads test as a predictor of fertilization In Vitro. American Journal of Reproductive Immunology. 1997; 37(4): 291-299.
- 15. Kervancioglu ME, Saridogan E, Atasu T, Camlibel T, Demircan A, Sarikamis B, Djahanbakhch O.Human Fallopian tube epithelial cell co-culture increases fertilization rates in male factor infertility but not in tubal or unexplained infertility. Hum Reprod. 1997 Jun;12(6):1253-8.
- 16. National Institute for Clinical Excellence. Fertility: assessment and treatment. Nice Guidance [CG156. February 2013. Available: http://www.nice.org.uk/guidance/cg156.

- 17. Rubio C, Simon C, Mercader A, Garcia-Velasco J, Remohi J, Pellicer A. Clinical experience employing co-culture of human embryos with autologous human endometrial epithelial cells. Hum Reprod. 2000 Dec;15 Suppl 6:31-8.
- 18. Wiemer KE, Cohen J, Tucker MJ, Godke RA. The application of co-culture in assisted reproduction: 10 years of experience with human embryos. Hum Reprod. 1998 Dec;13 Suppl 4:226-38.

New York Products	Prior Auth Prior Auth
IMO	
PPO in Plan	
PPO OOP	Prior Auth
POS in Plan	Prior Auth
POS OOP	Prior Auth
ssential Plan	Prior Auth
AVP Medicaid Managed Care	Not Covered
//VP Child Health Plus	Not Covered
//VP Medicare Complete Wellness	Not Covered
// MVP Medicare Preferred Gold HMO POS	Not Covered
// MVP Medicare Secure HMO POS	Not Covered
//VP Medicare WellSelect PPO	Not Covered
// MVP Medicare WellSelect Plus PPO	Not Covered
MVP Patriot Plan PPO	Not Covered
AVP DualAccess D-SNP HMO	Not Covered
MVP DualAccess Complete D-SNP HMO	Not Covered
MVP DualAccess Plus D-SNP HMO	Not Covered
JVM Health Advantage Select PPO	Not Covered
JSACare PPO	Not Covered
/IVP Secure	Prior Auth
MVP EPO	Prior Auth
AVP EPO HDHP	Prior Auth
AVP PPO	Prior Auth
NVP PPO HDHP	Prior Auth
tudent Health Plans	Prior Auth
ASO	See SPD/BCL
/ermont Products	
OS In Plan	Not Covered
POS OOP	Not Covered
AVP Medicare Preferred Gold HMO POS	Not Covered
// MVP Medicare Secure Plus PPO	Not Covered
// MVP Medicare WellSelect PPO	Not Covered
AVP VT HMO	Not Covered
NVP VT HDHP HMO	Not Covered
// AVP VT Plus HMO	Not Covered
MVP Secure	Not Covered
SO	See SPD/BCL

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro ReviewRetrospective Review RequiredNot CoveredService is not a covered benefit.See SPDSee Specific Plan Design

Revision History:

06/11/2021 – Updated policy format to only include CPT codes related to fertility preservation services addressed in the policy. Updated to reflect name changes of the Basic Infertility and Advanced Infertility and IVF Medical Policies.

12/01/2022 - Annual review with no changes.

09/22/2023 - Added language that coverage is available for treatment of gender dysphoria. Updated language that coverage is excluded from MVP MMC and Medicare plans.



Gas Permeable Scleral Contact Lens (e.g., BostonSight® Ocular Surface Prosthesis)

Type of Policy: Medical

Prior Approval Date: 06/02/2022

Approval Date: 05/06/2024

Effective Date: 08/01/2024

Related Polices: Lenses for Medical

Conditions of the Eye

Surgical Procedures for

Glaucoma

Prosthetic Devices;

(External) Eye and Facial

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

HCPCS Codes: N/A

Codes Requiring Retrospective Review

CPT Code:

66999 - Unlisted procedure, anterior segment of eye

Experimental/Investigational

N/A

Common Diagnosis Codes

ICD-10 Codes: D89.810, D89.811, D89.812, H04.121, H04.122, H04.123, H16.401, H16.402, H16.403, H16.411, H16.412, H16.413, H16.431, H16.432, H16.433, H16.433, H16.441, H16.442, H16.443, H17.01, H17.02, H17.03, H17.11, H17.821 H18.12, H18.413, H18.421, H17.01, H17.02, H17.03, H17.11, H17.12, H17.13, H17.811, H17.812, H17.813, H17.821,

H17.822, H17.823, H17.89, H17.9, H18.11, H18.12, H18.40, H18.411, H18.413 H18.412, H18.421, H18.422, H18.423, H18.43, H18.451, H18.452, H18.453, H18.461, H18.462, H18.463, H18.49, H18.601, H18.602, H18.603, H18.611, H18.612, H18.613, H18.621, H18.622, H18.623, H18.711 H18.70, H18.712, H18.713, H18.721, H18.722, H18.723, H18.731, H18.732, H18.733, H18.731

Common Procedure Codes

CPT Codes: 92071, 92072, 92313, 92317

HCPCS Codes: V2530, V2531, S0515

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

Ocular surface prostheses are made of a highly oxygen permeable polymer. Scleral contact lenses create an elevated chamber over the cornea that can be filled with artificial tears. The base or haptic is fit over the sclera. Scleral contact lens has been proposed to provide optical correction, mechanical protection, relief of symptoms, and facilitation of healing for a variety of corneal conditions. Specifically, the scleral contact lens may neutralize corneal surface irregularities and, by covering the corneal surface in a reservoir of oxygenated artificial tears, function as a liquid bandage for corneal surface disease. This may be called prosthetic replacement of the ocular surface ecosystem (PROSE).

There are multiple manufacturers and designs of scleral contact lens.

The Boston Ocular Surface Prosthesis (Boston Foundation for Sight) is a scleral contact lens that is custom fit using computer-aided design and manufacturing (i.e., computerized lathe). The Boston Ocular Surface Prosthesis is the prosthetic device used in prosthetic replacement of the ocular surface ecosystem (PROSE).

Another design is the Jupiter mini-scleral gas permeable contact lens (Medlens Innovations and Essilor Contact Lens). The Jupiter scleral lens is fit using a diagnostic lens series.

Indications/Criteria

A gas permeable scleral lens, also known as ocular surface prostheses, is considered medically appropriate for patients who have not responded to topical medications or standard spectacle or contact lens fitting for any of the following conditions:

- Corneal ectatic disorders (e.g., keratoconus, keratoglobus, pellucid marginal degeneration, Terrien's marginal degeneration, Fuchs' superficial marginal keratitis, post-surgical ectasia);
- Corneal scarring and/or vascularization;
- Irregular corneal astigmatism (e.g., after keratoplasty or other corneal surgery); or
- Ocular surface disease (e.g., severe dry eye, persistent epithelial defects, neurotrophic keratopathy, exposure keratopathy, graft vs. host disease, sequelae of Stevens Johnson syndrome, mucus membrane pemphigoid, post-ocular surface tumor excision, post-glaucoma filtering surgery) with pain and/or decreased visual acuity.

Ocular surface prostheses (e.g. PROSE device) must be ordered by an ophthalmologist.

Exclusions

Any indication not listed in the Indications/Criteria section.

References (Updated 2024)

- 1. Boston Foundation for Sight. Physician's guide to Prosthetic replacement of the ocular surface ecosystem (PROSE). [Boston Foundation for Sight Web site]. Available: https://www.bostonsight.org/
- 2. Heur, M., et al. Prosthetic replacement of the ocular surface ecosystem scleral lens therapy for patients with ocular symptoms of chronic stevens-johnson syndrome. Am J Ophthalmol. 2014 Jul;158(1):49-54.
- 3. Lim P., et al. Treatment of persistent corneal epithelial defect with overnight wear of a prosthetic device for the ocular surface. American Journal of Ophthalmology. 156 (6) (pp 1095-1101), 2013.
- 4. Jacobs DS, et al. Boston scleral lens prosthetic device for treatment of severe dry eye in chronic graft-versus-host disease. Cornea 2007 Dec;26(10):1195-1199.
- 5. Jacobs DS. Update on scleral lenses. Curr Opin Ophthalmol 2008 Jul;19(4):298-301.
- 6. Jupiter DG, et al. Management of irregular astigmatism with rigid gas permeable contact lenses. CLAO J 2000 Jan;26(1):14-7.
- 7. Lee J.C., Functional and visual improvement with prosthetic replacement of the ocular surface ecosystem scleral lenses for irregular corneas. Cornea. 32 (12) (pp 1540-1543), 2013.
- 8. Rosenthal P, et al. Fluid-ventilated, gas permeable scleral contact lens is an effective option for managing severe surface disease and many corneal disorders that would otherwise require penetrating keratoplasty. Eye Contact Lens 2005 May;31(3):130-4.

- 9. Schornack MM, et al. Jupiter scleral lenses in the management of chronic graft versus host disease. Eye Contact Lens 2008 Nov;34(6):302-5.
- 10. Stason WB, et al. Clinical benefits of the Boston Ocular Surface Prosthesis. Am J Ophthalmol 2010 Jan;149(1):54-61.
- 11. Ling J.D., et al. PROSE therapy used to minimize corneal trauma in patients with corneal epithelial defects. American Journal of Ophthalmology. 155 (4) (pp 615-619.e2), 2013.
- 12. Tougeron-Brousseau B, et al. Vision-related function after scleral lens fitting in ocular complications of Stevens-Johnson syndrome and toxic epidermal necrolysis. Am J Ophthalmol 2009 Dec;148(6):852-9.
- 13. Visser ES, et al. Modern scleral lenses part I: clinical features. Eye Contact Lens 2007 Jan;33(1):13-20.
- 14. Visser ES, et al. Modern scleral lenses part II: patient satisfaction. Eye Contact Lens 2007 Jan;33(1):21-25.
- 15. Takahide K., et al. Use of fluid-ventilated, gas-permeable scleral lens for management of severe keratoconjunctivitis sicca secondary to chronic graft-versushost disease. Biol Blood Marrow Transplant. 2007 Sep;13(9):1016-21.
- 16. Hayes Health Technology Assessment. BostonSight Prosthetic Replacement of the Ocular Surface Ecosystem (PROSE) Treatment for Dry Eye Disease. HAYES, Inc.; © 2021 Hayes, a symplr company. Annual Review: May 29, 2023.

Customer Product	Medical Management Requirements*
New York Products	-
НМО	Potential for Retrospective Review
PPO in Plan	Potential for Retrospective Review
PPO OOP	Potential for Retrospective Review
POS in Plan	Potential for Retrospective Review
POS OOP	Potential for Retrospective Review
Essential Plan	Potential for Retrospective Review
MVP Medicaid Managed Care	Potential for Retrospective Review
MVP Child Health Plus	Potential for Retrospective Review
MVP Harmonious Health Care Plan	Potential for Retrospective Review
MVP Medicare Complete Wellness	Potential for Retrospective Review
MVP Medicare Preferred Gold HMO POS	Potential for Retrospective Review
MVP Medicare Secure HMO POS	Potential for Retrospective Review
MVP Medicare Secure Plus HMO POS	Potential for Retrospective Review
MVP Medicare WellSelect PPO	Potential for Retrospective Review
MVP Medicare WellSelect Plus PPO	Potential for Retrospective Review
MVP Patriot Plan PPO	Potential for Retrospective Review
MVP DualAccess D-SNP HMO	Potential for Retrospective Review
MVP DualAccess Complete D-SNP HMO	Potential for Retrospective Review
MVP DualAccess Plus D-SNP HMO	Potential for Retrospective Review
UVM Health Advantage Select PPO	Potential for Retrospective Review
USA Care	Potential for Retrospective Review
Healthy NY	Potential for Retrospective Review
MVP Premier	Potential for Retrospective Review
MVP Premier Plus	Potential for Retrospective Review
MVP Premier Plus HDHP	Potential for Retrospective Review
MVP Secure	Potential for Retrospective Review
MVP EPO	Potential for Retrospective Review
MVP EPO HDHP	Potential for Retrospective Review
MVP PPO	Potential for Retrospective Review
MVP PPO HDHP	Potential for Retrospective Review
Student Health Plans	Potential for Retrospective Review
ASO	See SPD
Vermont Products	
POS in Plan	Potential for Retrospective Review
POS OOP	Potential for Retrospective Review
MVP Medicare Preferred Gold HMO POS	Potential for Retrospective Review
MVP Medicare Secure Plus HMO POS	Potential for Retrospective Review
MVP VT HMO	Potential for Retrospective Review
MVP VT HDHP HMO	Potential for Retrospective Review
MVP VT Plus HMO	Potential for Retrospective Review
MVP VT Plus HDHP HMO	Potential for Retrospective Review
MVP Secure	Potential for Retrospective Review
ASO	See SPD

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Revision History:

08/01/2022 – Annual Review; removed prior authorization from S0515.

08/01/2024 – Annual Review; no changes to indications or criteria, references updated.



Gender Affirming Treatment

Type of Policy: Surgical

Prior Approval Date: 09/07/2023

Approval Date: 12/04/2023

Effective Date: 02/01/2024

Related Polices:

Transgender Hormone Policy

Fertility Preservation Services Medical

Policy

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

CPT Codes: 55970, 55980, 57291, 57292, 57335, 55899

Codes Requiring Retrospective Review

N/A

Experimental/Investigational

N/A

Common Diagnosis Codes

ICD-10- CM Diagnosis Codes: F64.0, F64.1, F64.2, F64.8, F64.9, F66, Z87.890

Common Diagnosis Codes associated with this policy have been provided for informational purposes only. The list of codes may not be all-inclusive and may be updated to reflect any applicable revisions to the ICD-10 code set and/or medical necessity guidelines applied in this policy.

Common Procedure Codes

CPT Codes: 53430, 54520, 54690, 55150, 55180, 56625, 56800, 56805, 57106, 57107, 57110, 57111

Authorization Requirements

MVP Health Care's authorization requirements comply with all relevant statutes and regulations, including but not limited to 42 CFR Part 438, New York State Public Health Law Article 49, 18 NYCRR 505.2(*l*), the Medicaid Managed Care/Family Health Plus/HIV Special Needs Plan/Health and Recovery Plan Model Contract, 11 NYCRR § 52.75 and New York Insurance Law Article 49;

MVP Health Care's authorization requirements comply with all billing and coverage guidance issued by the NY State Department of Health.

MVP Health Care's coverage complies with all relevant statues and regulations in the State of Vermont Sec. 3.8 V.S.A. §4088m Coverage For Gender-Affirming Health Care Services.

MVP Health Care ensures that all service authorization determinations for hormone therapy and surgery for the treatment of gender dysphoria are determined as fast as the customer's condition requires;

MVP Health Care does not include time limits or requirements for submission of clinical documentation in support of a Service Authorization Request that have the effect of delaying or barring access to medically necessary services;

MVP Health Care does provide for at least one attempt to conduct a peer-to-peer consultation with the ordering provider prior to issuing an adverse determination;

MVP Health Care ensures that at least one clinical peer involved in adverse determinations and plan appeals has clinical expertise in the treatment of gender dysphoria; and

In the case of an adverse determination or upheld denial on appeal, MVP Health Care ensures the notice of decision includes:

If the decision is administrative, the specific benefit coverage criteria that has not been met or other specific reason for denial; or

If the decision is based on medical necessity/utilization review, the clinical rationale specifying;

- a. How the documentation provided does not support the customer's diagnosis of gender dysphoria, or
- b. How the documentation provided does not support the medical necessity of the proposed treatment for the customer's gender dysphoria, or
- c. There was not enough information to make a decision, and, for initial adverse determinations, what specific information would be necessary for review on appeal.

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

Gender dysphoria is a complex mental health condition in which a person feels a strong life-long identification with a gender other than their birth assigned gender accompanied by a severe sense of discomfort with the person's own gender or a sense of inappropriateness in the gender role of their biological sex.

Gender confirmation surgery is a complex process involving multiple medical, psychiatric or psychological counseling, hormonal therapy and surgical modalities to help the candidate for gender confirmation achieve successful behavioral and medical outcomes.

Gender identity is not limited to binary gender identity (exclusively masculine or feminine) but may include non-binary gender identity (a combination of masculine or feminine or neither).

Indications/Criteria

Coverage of medically necessary services is allowed for binary and non-binary gender identities. MVP Health Care follows all the provisions of NYS DOH's "Criteria Standards for the Authorization and Utilization Management of Hormone Therapy and Surgery for the Treatment of Gender Dysphoria." Gender Affirming Services are considered medically necessary when <u>ALL</u> of the following are met:

- The customer has capacity to grant fully informed consent for treatment and associated risks; and
- 2. The customer has persistent, well-documented gender dysphoria per DSM-5-TR criteria, which means in adolescents and adults, gender dysphoria diagnosis involves a difference between one's experienced/expressed gender and assigned gender, and significant distress or problems functioning. It lasts at least six months and is shown by at least two of the following:
 - a. A marked incongruence between one's experienced/expressed gender and primary and/or secondary sex characteristics; *or*
 - b. A strong desire to be rid of one's primary and/or secondary sex characteristics; *or*
 - c. A strong desire for the primary and/or secondary sex characteristics of the other gender; *or*

- d. A strong desire to be of the other gender (or some alternative gender different from one's assigned gender); *or*
- e. A strong desire to be treated as the other gender (or some alternative gender different from one's assigned gender); *or*
- f. A strong conviction that one has the typical feelings and reactions of the other gender (or some alternative gender different from one's assigned gender); and
- 3. The customer has received mental health screening and assessment with documentation from a qualified mental health professional as part of a multi-disciplinary team for gender affirming procedures and with experience in diagnosing and treating gender dysphoria; and
- 4. If significant medical or mental health concerns are present, they must be reasonably well controlled or under treatment; *and*
- 5. For adolescents, the customer must have documentation of the following additional assessments to meet criteria:
 - a. A comprehensive biopsychosocial assessment should be completed with mental and/or medical professionals as part of a multidisciplinary team; and
 - b. The customer has adequate home support and involvement of parent(s)/guardian(s) in the assessment process, unless their involvement is determined to be harmful to the adolescent or not feasible; *and*
 - c. The customer has realistic expectations regarding the possibilities and limitations of surgery and a full understanding of the long-term consequences of surgical procedures; and
 - d. The customer has been evaluated for safety and the customer has been assessed for any co-existing mental health concerns and is not requesting surgery as an initial response to gender dysphoria puberty.

Hormone Therapy

Hormone therapy, whether or not in preparation for gender confirmation surgery, is covered as follows:

- 1. Treatment with gonadotropin-releasing hormone agents (pubertal suppressants), based upon a determination by a qualified medical professional that an individual is eligible and ready for such treatment, that the individual:
 - a. Meets the criteria for a diagnosis of gender dysphoria;
 - b. Has experienced puberty to at least Tanner stage 2, and pubertal changes have resulted in an increase in gender dysphoria;
 - c. Does not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment;

- d. Has adequate psychological and social support during treatment; and
- e. Demonstrates knowledge and understanding of the expected outcomes of treatment with pubertal suppressants and cross-sex hormones, as well as the medical and social risks and benefits of sex reassignment;
- 2. Treatment with cross-sex hormones for patients who are sixteen (16) years of age and older*, based upon a determination of medical necessity made by a qualified medical professional; patients who are under eighteen (18) years of age must meet the applicable criteria for coverage of pubertal suppressants.

*Coverage for cross-sex hormones for patients under sixteen years of age shall be made if medical necessity is demonstrated. Hormone therapy is necessary if it is appropriate to the customer's gender goals, recommended by the customer's treating provider, clinically appropriate for the type of surgery requested, not medically contraindicated, and the customer is otherwise able to take hormones.

- The Customer must have prescription drug coverage and is responsible for all applicable copayments and coinsurance as required by their contract, rider or specific benefit design.
- Hormone therapy is subject to the applicable prescription drug formulary, prior authorization, step therapy and/or quantity limits.
- Health care professionals must inform and counsel all individuals seeking hormone treatment about the options available for fertility preservation prior to initiating puberty suppression or hormone therapy. See Fertility Preservation Services Medical Policy.

Surgical Gender Confirmation

- Customer must have a diagnosis of Gender Dysphoria and meets the medically necessary criteria listed above.
- Customer has received hormone therapy appropriate to the individual's gender goals, which shall be for a minimum of 12 months in the case of an individual seeking genital surgery, unless hormone therapy is medically contraindicated, or the individual is otherwise unable to take hormones. (Hormone therapy is not a prerequisite for mastectomy).
- Customer has lived for 12 months in a gender role congruent with the individual's gender identity, and has received mental health counseling, as deemed medically necessary, during that time.
- Customer must have the capacity to make a fully informed decision and to consent to treatment.

- Customer has no other significant medical or mental health conditions that would contraindicate gender confirmation surgery, or if so, those conditions are reasonably well-controlled prior to surgery.
- Customer must be informed and counselled on the options available for fertility preservation prior to any and all surgeries. See Fertility Preservation Services Medical Policy.

Adolescents

*Although the minimum age for Medicaid and Commercial coverage of gender confirmation surgery is generally 18 years of age, the revised regulations allow for coverage for individuals less than 18 years of. Gender confirmation surgery for customers less than the age of 18 will be considered on a case-by-case basis for medical necessity.

Parental or legal guardian consent is required prior to gender confirmation surgery of a minor.

For Medicaid Managed Care (MMC) plans, the New York State Department of Health (DOH) has determined that the Sterilization Consent Form (LDSS-3134) is only required when the procedure being performed is solely for the purpose of rendering the individual incapable of reproducing. This form is not required where sterilization is an ancillary result of a procedure, such as gender reassignment surgery.

However, for MMC plan customers, if a hysterectomy is being performed, regardless of the purpose, an LDSS-3113, "Acknowledgement of Receipt of Hysterectomy Information," is required. The form is available at:

Provider Forms Library (mvphealthcare.com)

<u>Prior to surgery for the treatment of gender dysphoria, the following documentation is required:</u>

Letters are required from two New York State licensed health professionals who have independently assessed the individual and are referring the Customer for surgery.

- One of the letters must be from licensed New York State psychiatrist, or psychologist, or psychiatric nurse practitioner, or licensed clinical social worker with whom the individual has an established and ongoing relationship. The recommendation for surgery in the letter must be based on an independent assessment/evaluation of the Customer; and
- One of the letters may be from a New York State licensed psychiatrist, psychologist, psychiatric nurse practitioner, physician, or licensed clinical social worker working within the scope of their practice and who has only had an

evaluative role with the individual. The recommendation for surgery in the letter must be based on an independent assessment/evaluation of the Customer.

The letters written by the qualified New York State licensed health professionals, who are referring the customer for the surgery or procedure:

- a. Are accepted as an attestation of the customer's condition and circumstances without additional supporting documentation or justification; and
- b. Are not to be looked at individually, but rather must be looked at together in their totality. MVP Health Care accepts the referral letters as being satisfactory, if the totality of the referral letters together indicate that the customer:
 - i. Has a persistent and well-documented case of gender dysphoria, and;
 - ii. Has received hormone therapy appropriate to the customer's gender goals, which shall be for a minimum of 12 months in the case of an customer seeking genital surgery, unless such therapy is medically contradicted or the customer is otherwise unable to take hormones, and;
 - iii. Has lived for 12 months in a gender role congruent with the customer's gender identity and has received mental health counseling as deemed medically necessary by the customer's treating NYS licensed health professional. The duration and frequency of mental health counseling is dependent on the customer's unique clinical profile and biopsychosocial circumstances. There is no requirement that mental health counseling be provided continuously for 12 months prior to surgery and;
 - iv. Has no other significant medical or mental health conditions that would be a contraindication to the surgery, or if so, those conditions are reasonably well-controlled prior to the surgery; and
 - v. Has the capacity to make a fully informed decision and to consent to the treatment.
 - vi. Customer was informed and counselled on the options available for fertility preservation prior to any and all surgeries.

The requirement for the providers being licensed in NYS is not required for customers with plans outside New York State.

Gender Confirmation Surgeries

MVP Health Care does have administrative prior authorization requirements on select procedures; however, MVP does not conduct utilization review for medical necessity and accepts the customer's treating provider's determination of medical necessity using the documentation listed above.

For procedures that require specific anatomical/body part size, shape, feature, presentation or assessment as part of those procedures' service coverage criteria, MVP Health Care accepts the customer's treating provider's determination of the customer's anatomical/body part size, shape, feature, presentations and/or assessment;

MVP Health Care does not require the evaluation of photographic documentation in the administrative prior authorization processes of procedures that require specific anatomical/body part size, shape, feature, presentation or assessment as part of those procedures' service coverage criteria.

When all of the above criteria are met, the following surgeries are covered:

- Orchiectomy: removal of testicles;
- Penectomy: removal of penis;
- Vaginoplasty: creation of vagina;
- · Clitoroplasty: creation of clitoris;
- Labiaplasty: creation of labia;
- Electrolysis when required for phalloplasty or vaginoplasty
- Breast augmentation when both of the following are met:
 - The customer meets all the criteria for gender confirmation surgery listed in the Indications/Criteria section above, and
 - The customer has completed a minimum of 24 months of hormone therapy during which time no breast growth has occurred, or hormone therapy is medically contraindicated, or the patient is otherwise unable to take hormones
- Mastectomy and/or reduction mammoplasty* (Hormone therapy is not a prerequisite).
- Hysterectomy**: removal of uterus;
- Salpingo-oophorectomy***: removal of fallopian tubes and ovaries;
- Salpingectomy: removal of fallopian tubes;
- Oophorectomy: removal of ovaries;
- Vaginectomy: removal of vagina;
- Metoidioplasty: creation of micro-penis, using the clitoris;
- Phalloplasty: creation of penis, with or without urethra;
- Urethroplasty: creation of urethra within the penis;
- Scrotoplasty: creation of scrotum;

- Placement of a testicular prostheses: implantation of artificial testes;
- Penile prosthesis;

Coverage will not be made for any procedures that are performed solely for the purpose of improving an individual's appearance (i.e., cosmetic procedures). The following procedures will be presumed to be performed solely for the purpose of improving appearance and will not be covered, unless the medical necessity criteria above for gender affirming services and surgery has been met:

- Abdominoplasty, blephoraplasty, neck tightening, or removal of redundant skin;
- Breast, brow, face, or forehead lifts;
- Calf, cheek, chin, nose, or pectoral implants;
- Collagen injections;
- Drugs to promote hair growth or loss;
- Electrolysis, unless clinically indicated for vaginoplasty or phalloplasty;
- Facial bone reconstruction, reduction, or sculpturing, including jaw shortening and rhinoplasty;
- Gluteal augmentation;
- Hair transplantation;
- Lip reduction;
- Liposuction/Lipofilling;
- Thyroid chondroplasty;
- Voice therapy, voice lessons, speech therapy or
- Voice modification surgery (31599, 31899)

*Mastectomy (CPT code 19303) requires administrative prior authorization only for gender confirmation surgery.

**Hysterectomy (CPT codes 58150, 58260, 58262, 58275, 58280, 58290, 58291, 58292, 58541, 58542, 58543, 58544, 58550, 58552, 58553, 58554, 58570, 58571, 58572, 58573) requires administrative prior authorization only if requested for gender confirmation surgery.

*** Salpingo-oophorectomy (CPT codes 58661, 58720) requires administrative prior authorization only if requested for gender confirmation surgery.

Requested services, surgeries, and procedures for the treatment of gender dysphoria shall not be automatically denied on the basis that they are cosmetic in nature but must be reviewed to determine medical necessity for the treatment of the customer's gender dysphoria.

MVP Health Care covers surgical revisions (modifications and/or corrections to a prior surgery) for the treatment of gender dysphoria. MVP handles requests for surgical revisions for the treatment of gender dysphoria in the same manner as initial surgical requests for the treatment of gender dysphoria. There is no medical necessity review if the request is for a revision surgery, unless it is for a procedure that is not listed above.

Exclusions

• Conversion therapy (counseling and psychotherapy to attempt to change an individual's sexuality and/or gender identity) is not considered medically necessary. The medical literature does not support that this treatment is necessary nor is there evidence that sexual orientation or gender identity can be altered through therapy.

There is no coverage for the following services:

- Reversal of genital and/or breast surgery;
- Reversal of surgery to revise secondary sex characteristics;
- Reversal of any procedure resulting in sterilization; and

Any other surgeries, services, and procedures in connection with gender confirmation not listed above, or to be performed in situations not described above, including those done to change the patient's physical appearance to more closely conform secondary sex characteristics to those of the patient's identified gender, will be covered if it is demonstrated that such surgery, service, or procedure is medically necessary to treat a particular patient's gender dysphoria, and prior approval is received. Coverage is not available for surgeries, services, or procedures that are purely cosmetic, i.e., that enhance a patient's appearance but are not medically necessary to treat the patient's underlying gender dysphoria.

References (Updated 2023)

- 1. American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders (DSM), Fifth Edition, Text Revision (DSM-V-TR). 2013. Arlington, VA.
- 2. American Academy of Child and Adolescent Psychiatry, Practice Parameter on Gay, Lesbian, or bisexual Sexual Orientation, Gender Nonconformity, and Gender Discordance in Children and Adolescents, 51 J. Am. Acad. Child & Adolescent Psychiatry 957 (2012).
- 3. American Psychological Association. Just the facts about sexual orientation and youth. A primer for principles, educators, and school personnel. Available: http://www.apa.org/pi/lqbt/resources/just-the-facts.aspx.
- 4. Butler RM, Horenstein A, Gitlin M, Testa RJ, et al. Social anxiety among transgender and gender nonconforming individuals: The role of gender-affirming medical interventions. J Abnorm Psychol. 2019; 128(1):25-31.
- 5. CMS Manual System. Pub 100-03 Medicare National Coverage Determinations. Transmittal 169. Invalidation of National Coverage Determination 140.3 Transsexual

Surgery. June 27, 2014. Available: http://www.cms.gov/Regulations-and-duidance/Guidance/Transmittals/Downloads/R169NCD.pdf.

- 6. Committee on Adolescent Health Care. Committee Opinion No. 685: Care for Transgender Adolescents. Obstet Gynecol. 2017 Jan;129(1):e11-e16.
- 7. de Vries AL, McGuire JK, Steensma TD, et al. Young adult psychological outcome after puberty suppression and gender reassignment. Pediatrics. 2014; 134(4):696-704.
- 8. Djordjevic ML, Bizic MR, Duisin D, et al. Reversal surgery in regretful male-to-female transsexuals after sex reassignment surgery. J Sex Med. 2016; 13(6):1000-1007.
- 9. Guss C, Shumer D, Katz-Wise SL. Transgender and gender nonconforming adolescent care: psychosocial and medical considerations. Curr Opin Pediatr. 2015; 27(4):421-426.
- 10. Hembree, WC, Cohen-Kettenis, P, Delemare-van-de Waal, HA, et al. Endocrine Treatment of Transsexual Persons: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab 94: 3132-3154, 2009.
- 11. Maharaj NR, Dhai A, Wiersma R, Moodley J. Intersex conditions in children and adolescents: surgical, ethical, and legal considerations. J Pediatr Adolesc Gynecol. 2005 Dec;18(6):399-402.
- 12. Moore, E, Wisniewski, A, Dobs, A. Endocrine Treatment of Transsexual People: A Review of Treatment Regimens, Outcomes, and Adverse Effects. Clinical Review 161. Department of Medicine and Pediatrics, The Johns Hopkins School of Medicine. The Journal of Clinical Endocrinology & Metabolism 88(8) 3467-3473.
- 13. Melmed, S, Casanueva, FF, Hoffman, AR, et al. Diagnosis and Treatment of Hyperprolactinemia: An Endocrine Society Clinical Practice Guideline. The Journal of Clinical Endocrinology & Metabolism 96: 273-288, 2011. Available: https://academic.oup.com/endocrinesociety.
- 14. New York State Register. Rule Making Activities. December 17, 2014. Available: http://docs.dos.ny.gov/info/register/2014/dec17/pdf/rulemaking.pdf.
- 15. New York State Register. Rule Making Activities. March 11, 2015. Available: http://docs.dos.ny.gov/info/register/2015/march11/pdf/rulemaking.pdf.
- 16. New York State Department of Health Medicaid Program. Medicaid Update. June 2015. Volume 31, Number 6. Available: http://www.health.ny.gov/health_care/medicaid/program/update/2015/jun15_mu.pdf.
- 17. New York State Department of Health New York State Medicaid Update. May 2016. Volume 32. Number 5. Available:

http://www.health.ny.gov/health_care/medicaid/program/update/2016/2016-05.htm#allergy.

- 18. New York State Department of Health New York State Medicaid Update Article on Conversion Therapy. 2/6/16. Available:
- https://www.governor.ny.gov/sites/governor.ny.gov/files/atoms/files/ConversionTherapy_Medicaid_Update.pdf.
- 19. New York State Department of Health Medicaid Program. Medicaid Update. January 2017. Volume 33, Number 1. Available:
- https://www.health.ny.gov/health_care/medicaid/program/update/2017/2017-01.htm.
- 20. New York State Department of Health Medicaid Program. Medicaid Update. April 2017. Volume 33, Number 4. Available:
- https://www.health.ny.gov/health_care/medicaid/program/update/2017/apr17_mu.pdf.
- 21. New York Codes, Rules and Regulations, Volume C § 505.2 (I) (2016).
- 22. New York State Department of Health Medicaid Program. Medicaid Update. December 2019 Medicaid Update:
- https://www.health.ny.gov/health_care/medicaid/program/update/2019/dec19_mu.pdf.
- 23. New York State Department of Financial Services. IVF and Fertility Preservation Law Q&A Guidance for Health Insurers. <u>Available: Health Insurers FAQs: IVF and Fertility Preservation Law Q&A Guidance | Department of Financial Services (ny.gov)</u>
- 24. MEDICAID MANAGED CARE/ FAMILY HEALTH PLUS/ HIV SPECIAL NEEDS PLAN MODEL CONTRACT March 1, 2014
- https://www.health.ny.gov/health care/managed care/docs/medicaid managed care fhp hiv-snp model contract.pdf.
- 25. Policy and Position Statements on Conversion Therapy. Human Rights Campaign. 2016. Available: http://www.hrc.org/resources/policy-and-position-statements-on-conversion-therapy.
- 26. State of Vermont Department of Financial Regulation. Division of Insurance Bulletin No. 174. Guidance Regarding Prohibited Discrimination on the Basis of Gender Identity Including Medically Necessary Gender dysphoria Surgery and Related health Care. April 22, 2013. Available: https://dfr.vermont.gov/reg-bul-ord/guidance-regarding-prohibited-discrimination-basis-gender-identity-including-medically.
- 27. World Professional Association for Transgender Health (WPATH). Standards of care for the health of transsexual, transgender, and gender nonconforming people. 7th version. 2012. Available: https://www.wpath.org/publications/soc.
- 28. World Professional Association for Transgender Health (WPATH). Position on rapid onset gender dysphoria. 9/4/2018. Available: https://www.wpath.org/publications/soc.
- 29. World Professional Association for Transgender Health (WPATH). The Harry Benjamin International Gender Dysphoria Association. Standards of Care for Gender

Identity Disorders. 6th version. 2001 Feb. Available: https://www.wpath.org/publications/soc.

30. State of Vermont Department of Financial Regulation. Sec. 3. 8 V.S.A. § 4088m Coverage For Gender-Affirming Health Care Services.

Customer Product	Medical Management Requirements*
New York Products	
HMO	Prior Auth
PPO in Plan	Prior Auth
PPO OOP	Prior Auth
POS in Plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Prior Auth
MVP Child Health Plus	Prior Auth
MVP Harmonious Health Care Plan	Prior Auth
MVP Medicare Complete Wellness	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP Medicare WellSelect PPO	Prior Auth
MVP Medicare WellSelect Plus PPO	Prior Auth
MVP Medicare Patriot Plan PPO	Prior Auth
MVP DualAccess D-SNP HMO	Prior Auth
MVP DualAccess Complete D-SNP HMO	Prior Auth
MVP DualAccess Plus D-SNP HMO	Prior Auth
UVM Health Advantage Select PPO	Prior Auth
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	366 31 5
POS in Plan	Prior Auth
POS OOP	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP VT HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD
ASO	366 3FD

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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Medical Management Requirements

Prior Auth
Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review.

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Revision History:

08/01/2022 – Combined separate medical policies for Commercial and Medicaid into one policy.

09/22/2023 - Gender Dysphoria diagnosis criteria moved from overview to indications/criteria section, added criteria for adolescents, added coverage criteria for potentially cosmetic procedures. Added references to VT mandated coverage. Policy approved by NYS/OMH 8/4/2023.



Genetic and Molecular Diagnostic Testing

Type of Policy: Medical

Prior Approval Date: 11/04/2024

Provisional Approval 03/27/2025

Date:

Provisional Effective

Date:

04/01/2025

BRCA Testing Genetic Testing for Susceptibility to Breast and **Related Polices:**

Ovarian Cancer

Colorectal Cancer Susceptibility Genetic Testing OncotypeDX® and Cancer Gene Expression Tests

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

CPT Codes: 81201, 81202, 81203, 81228, 81288, 81292, 81293, 81294, 81295, 81296, 81297, 81298, 81299, 81300, 81301, 81317, 81318, 81319, 81321, 81322, 81323, 81413, 81414, 81418, 81552

Codes Subject to Retrospective Review

CPT Codes: 81225, 81226, 81355, 81410, 81411, 81412, 81434, 81437, 81438, 81415, 81416, 81417, 81427, 81479, 81430, 81431, 81435, 81440, 81442, 81443, 81445, 81450, 81460, 81465, 81599, 84999

HCPCS Codes: S3722, S3852, S3854, S3865, S3866, S3870, S3890

PLA Codes: 0064U, 0065U, 0066U, 0067U, 0068U, 0069U, 0070U, 0071U, 0072U, 0073U, 0074U, 0075U, 0076U, 0077U, 0079U, 0080U, 0082U, 0171U, 0172U, 0174U, 0177U,

0178U, 0203U, 0204U, 0205U, 0208U, 0209U, 0210U, 0211U, 0212U, 0213U, 0214U, 0215U, 0216U, 0217U, 0218U, 0239U, 0242U, 0244U, 0004M

Experimental/Investigational

CPT Codes: 81410, 81411, 81412, 81415, 81416, 81417, 81427, 81430, 81431, 81434, 81435, 81436, 81437, 81438, 81440, 81441, 81442, 81443, 81449, 81450, 81451, 81456, 81460, 81465, 81599, 84999

HCPCS Codes: S3722, S3852, S3854, S3865, S3866, S3870, S3890

PLA Codes: 0064U, 0065U, 0066U, 0067U, 0068U, 0069U, 0070U, 0071U, 0072U, 0073U, 0074U, 0075U, 0076U, 0077U, 0079U, 0080U, 0082U, 0171U, 0172U, 0174U, 0177U, 0178U, 0203U, 0204U, 0205U, 0208U, 0209U, 0210U, 0211U, 0212U, 0213U, 0214U, 0215U, 0216U, 0217U, 0218U, 0239U, 0242U, 0004M

Common Diagnosis Codes

N/A

Common Procedure Codes

CPT Codes: 81161, 81200, 81209, 81218, 81219, 81220, 81221, 81222, 81223, 81224, 81227, 81229, 81235, 81240, 81241, 81242, 81243, 81244, 81251, 81252, 81253, 81254, 81255, 81256, 81257, 81260, 81270, 81272, 81273, 81279, 81290, 81291, 81302, 81304, 81314, 81324, 81325, 81326, 81329, 81330, 81331, 81332, 81403, 81404, 81405, 81406, 81408, 81455, 96040

HCPCS Codes: S3800, S3840, S3844

PLA Codes: 0022U, 0037U, 0048U

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy.

Overview

Genetic counseling is the process in which a practitioner attempts to determine the risk of the occurrence or re-occurrence of a genetic disease.

Genetic testing is "the analysis of human DNA, RNA, chromosomes, proteins, and certain metabolites in order to detect heritable disease-related genotypes, mutations, phenotypes, or karyotypes for clinical purposes." This definition reflects the broad range of techniques that can be used in the testing process. Genetic tests also have diverse purposes, including the diagnosis of genetic disease in newborns, children, and adults; the identification of future health risks; the prediction of drug responses; and the assessment of risks to future children.

Genetic tests are also used to detect genetic mutations that may be involved in the development of certain types of tumors. The information obtained from this test can be used by healthcare providers to make more informed decisions about the diagnosis, prognosis, and treatment of the patient's condition. For example, the presence of a specific genetic mutation may indicate a higher likelihood of a certain type of tumor, or a more aggressive form of the disease. Additionally, the results of this test can help inform the selection of targeted therapies that are specifically designed to treat the underlying genetic mutations.

Genetic testing should only be done after the customer has a thorough history reviewed and testing is felt to be necessary by both customer and physician because of potential changes in management.

It is important that the purpose of the test is clear and that both the physician and customer understand how testing is intended to change management.

Proprietary Laboratory Analysis (PLA) codes correspond to laboratories or manufacturers that want to more specifically identify their test that they provide for genetic testing. The PLA codes include many types of tests that are addressed under molecular pathology or next generation sequencing. The Proprietary Laboratory Analysis (PLA) codes describe proprietary clinical laboratory analysis and can either be provided by a single (sole source) laboratory or licensed or marketed to multiple providing laboratories. This analysis may include a range of medical laboratory tests including but not limited to, multianalyte assays with algorithmic analysis (MAAA) and genomic sequencing procedures (GSP).

Indications/Criteria

Documentation Requirements

Medical necessity must be documented in the medical record and available upon request. Documentation must include third generation pedigree analysis for any genetic test and intends to provide pre** and post-test counseling. Documentation of a pre-disposing condition for genetic counseling and testing should be submitted upon request.

**NYS Article 26 (ISC § 2615) and Article 79-1 (CVR §) 79-1 requires informed consent.

Genetic Counseling

A total of three visits (including pre-test counseling, informed consent counseling and post-test genetic counseling) may be necessary for genetic testing. Laboratory visit may be done at the time of informed consent; but can be done independently as long as informed consent has been completed at an earlier visit. Counseling should only be done by an adequately trained provider who is knowledgeable about the indications for testing and the different tests that are available.

Genetic Testing

Genetic testing may be indicated for:

- assistance in reproductive planning;
- diagnosis of a customer's condition;
- evaluation of a customer's future health risks;
- predicting response to treatment.
- prior to initiation of drug therapy; refer to the pharmacy coverage policy for pharmacogenomic testing requirements.

In all circumstances, MVP only covers testing if:

- there is a clear plan how the testing results could change the customer management and that the customer agrees with the plan;
- customer has not previously received genetic testing for the disorder. In general, genetic testing for a particular disorder should be performed once per lifetime.
- history, physical exam, and conventional testing are insufficient to develop a treatment plan;
- testing is only covered for covered care and services. Services in conjunction with noncovered services are not covered;
- the testing has been proven to be accurate outside the investigational setting;
- signs, symptoms, family history, and /or clinical guidelines (American Congress of Obstetricians and Gynecologists [ACOG]) recognized by MVP support testing;
- genetic testing is ordered by an adequately trained physician or health care professional with certification and/or expertise in genetics.

Prenatal Screening

Prenatal testing is available to people at-risk for having children with a chromosomal abnormality or an inherited genetic condition. Pre-natal testing via amniocentesis or CVS (chorionic villus sampling) is covered. Carrier screening for couples planning pregnancy or going through infertility treatments are available to customers at-risk for having children with a chromosomal abnormality or an inherited genetic condition.

No prior authorization required for Prenatal screening tests listed below:

- Spina Bifida;
- Cystic Fibrosis;
- Canavan's Disease:
- Tay-Sachs;

- Familial dysautonomia;
- Fanconi anemia group C;
- Niemann-Pick type A and type B;
- Mucolipidosis IV;
- Muscular dystrophies (DMD, BMD, EDMD, DM1, DM2, SM)
- Bloom Syndrome;
- Gaucher's Disease;
- Spinal Muscular Atrophy (SMA) SMN1 and SMN2 gene mutation analysis
- Fragile-X gene analysis); and
- Familial history, maternal age, ethnicity, or suggestive markers from fetal ultrasounds, amniocentesis, chorionic villus sampling (CVS) and genetic testing guidelines as indicated by ACOG.

Newborn Screening is covered as defined by state law.

For prenatal testing for Medicaid, see the Medicaid variation below.

Genetic Tests

The following genetic tests are covered when indications and criteria are met:

Alpha 1 Antitrypsin: Alpha-1 antitrypsin (AAT)

Alpha 1 Antitrypsin: Alpha-1 antitrypsin (AAT) testing is covered when all of the following criteria are met:

• customer has a serum alpha-1 antitrypsin level in the range of severe deficiency;

AND either 1 OR 2

1. customer may be at high risk of having alpha-1 antitrypsin deficiency due to a first-degree relative (parent, child or sibling) with AAT deficiency;

OR

- 2. customer is suspected of having alpha-1 antitrypsin (AAT) deficiency due to the following clinical factors:
 - o early-onset emphysema (age of 45 years or less);
 - emphysema in the absence of a recognized risk factor (smoking, occupational dust exposure, etc.);
 - o emphysema with prominent basilar hyperlucency;
 - o otherwise unexplained liver disease;
 - o necrotizing panniculitis;

- anti-proteinase 3-positive vasculitis (C-ANCA [anti-neutrophil cytoplasmic antibody]-positive vasculitis);
- o bronchiectasis without evident etiology.

Breast Cancer

(refer to MVP BRCA Testing medical policy, MVP Oncotype DX Test medical policy)

Celiac Disease

Celiac disease testing is covered when all the following criteria are met:

- customers with gastrointestinal symptoms including chronic or recurrent diarrhea, malabsorption, weight loss, and abdominal distention or bloating, and
- customers without other explanations for signs and symptoms such as iron deficiency anemia, folate or vitamin B12 deficiency, persistent elevation in serum amniotransferases, short stature, delayed puberty, recurrent fetal loss, low birth weight infants, and reduced fertility aphthous stomatitis, dental enamel hypoplasia, idiopathic peripheral neuropathy, non-hereditary cerebellar ataxia, or recurrent migraine headaches; and
- inconsistent results of both serology testing and duodenal biopsy of iron levels.

Cowden Syndrome Testing

Cowden Syndrome testing is covered when the following criteria are met:

- individual from a family with a known PTEN mutation;
- individual meeting clinical diagnostic criteria for Cowden Syndrome/PTEN Hamartoma Tumor Syndrome (CS/PHTS)
- individual with a personal history of:
 - o Bannayan-Riley-Ruvalcaba Syndrome; or
 - o Adult Lhermitte-Duclos disease (cerebellar tumors); or
 - o autism spectrum disorder and macrocephaly; or
 - o two or more biopsy proven trichilemmomas; or
 - o two or more major criteria (one must be macrocephaly); or
 - o three major criteria, without macrocephaly; or
 - o one major and ≥ three minor criteria; or
 - ≥ four minor criteria:
- at-risk individual with a relative with a clinical diagnosis of Cowden Syndrome or Bannayan-Riley-Ruvalcaba Syndrome.

The at-risk individual must have the following:

- o any one major criterion; or
- o two minor criteria.

Major Criteria	Minor Criteria
Breast cancer	thyroid structural lesions (e.g., adenoma, nodule(s), goiter)
 Mucocutaneous lesions One biopsy proven trichilemmoma Multiple palmoplantar keratoses Multifocal or extensive oral mucosal papillomatosis Multiple cutaneous facial papules (often verrucous) 	Intellectual disability (intellectual developmental disorder) (i.e., IQ ≤75)
Macrocephaly (megalocephaly) (i.e., ≥97 th percentile, 58 cm in adult women, 60 cm in adult men)	Autism spectrum disorder
Endometrial cancer	Single GI hamartoma or ganglioneuroma
Follicular thyroid cancer	Vascular anomalies (including multiple intracranial developmental venous anomalies)
Multiple GI hamartomas or ganglioneuromas	Lipomas
Macular pigmentation of glans penis	Papillary or follicular variant of papillary thyroid cancer
	Renal cell carcinoma
	Testicular lipomatosis
	Colon cancer
	Esophageal glycogenic acanthosis (≥ 3)

Factor V Leiden

Factor V Leiden testing is covered for the any of the following:

• individuals with recurrent pregnancy loss or unexplained severe pre-eclampsia, placental abruption, intrauterine growth retardation, or still birth, when this knowledge will influence future pregnancy management; or

- Any venous thrombosis before age 50; or
- Venous thrombosis in unusual sites (portal hepatic, mesenteric, cerebral); or
- Recurrent venous thrombosis; or
- Venous thrombosis in an individual with a strong family history (a first or second degree relative) of thrombotic disease; or
- Venous thrombosis in a pregnant individual OR an individual on oral contraceptives; or
- Myocardial infarction in female smokers before age 50.

Hemochromatosis

Hemochromatosis testing is covered when unable to diagnose after electrophoresis.

HER-2 Testing

HER-2 Testing for invasive breast cancer is covered as follows:

- HER-2 testing by immunohistochemistry assay is covered;
- HER-2 testing by fluorescence in situ hybridization (FISH) assay is covered.

Long QT Syndrome

Genetic testing for Long QT syndrome (sequence analysis of the appropriate gene, including duplication/deletion analysis, as needed) is covered when ordered by a cardiologist for the following indications:

- confirmatory testing with full sequence analysis when there is confirmed prolonged QT interval on electrocardiogram, or Holter monitor, and an acquired cause has been ruled out;
- predictive testing with full sequence analysis for individuals at risk for LQTS who do not meet the clinical criteria for LQTS and meet one of the following:
 - there is a first degree relative with a history of prolonged QT interval on electrocardiogram or Holter monitor (i.e. QT interval of >.470 msec [males] or>.480 msec [females], sudden death, or near sudden death; or
 - o there is a first degree relative with a known LQTS mutation;
- genetic testing for LQTS with deletion and duplication analysis is covered when the criteria listed above for LQTS testing have been met, sequence analysis is negative and the clinical suspicion of LQTS remains high.

Chromosomal Microarray Analysis

Chromosomal Microarray Analysis is considered medically necessary for evaluation of a fetus for either of the following indications:

- the individual with a structurally normal fetus is undergoing invasive prenatal testing (i.e., amniocentesis, chorionic villus sampling or fetal tissue sampling); or
- intrauterine fetal demise or stillbirth with congenital anomalies during third trimester; or
- the individual is considered at high risk for fetal aneuploidy with one or more of the following:
 - o birthing person age of 35 years or older at the time of delivery; or
 - the fetus has ultrasonographic findings that indicate an increased risk of aneuploidy; or
- o either parent has a history of a prior pregnancy with trisomy; or positive first or second-trimester standard biomarker screening test.

Chromosomal Microarray Analysis is considered medically necessary in a child 13 years or younger for any of the following indications:

- autism spectrum disorder; or
- non-syndromic developmental delay or intellectual disability; or
- multiple congenital anomalies not specific to a well-delineated genetic syndrome.

Chromosomal Microarray Analysis is considered not medically necessary for first trimester and second trimester pregnancy losses or recurrent pregnancy loss as the medical literature does not support it improves health outcomes and therefore is considered investigational.

Multiple Endocrine Neoplasia (medullary cancer of the thyroid) familial history of medullary thyroid cancer required.

Ovarian cancer (see MVP Genetic Testing for Susceptibility to Breast and Ovarian Cancer (BRCA Testing).

Polycystic Kidney Disease

Genetic testing for autosomal dominant polycystic kidney disease (ADPKD) is covered when there is limited availability of ultrasound or ultrasound is not adequate for diagnosis of ADPKD.

Methylation Studies (Several genetic diseases are caused by defects within the methylation machinery, like the Rett Syndrome, Fragile X Syndrome and ICF (Immunodeficiency-Centromeric Instability-Facial Anomalies Syndrome).

Thiopurine Methyltransferase (TPMT)

Thiopurine methyltransferase (TPMT) genotype testing is covered when either one of the following is met:

- TPMT genotype testing for customers with inflammatory bowel disease (IBD) prior to being treated with azathioprine or 6-MP; or
- if standard dosing of azathrioprine/6-MP fails to produce a therapeutic response.

Pharmacogenomics Testing:

Genetic testing to predict response to a specific medication, as indicated by the FDA in the package label or recognized by national medical organizations, will be considered on a case-by-case basis, unless indicated below. Some medication may require genetic testing to determine effectiveness of the therapeutic regimen.

myChoice CDx (PLU Code: 0172U)

Somatic/tumor BRCA testing (e.g., myChoice CDx) to identify targeted cancer treatment is considered investigational based primarily upon an NCCN category for low level of evidence, as well as the above criteria and assessment of the peer-reviewed literature.

Foundation One CDx (F1CDx)

FoundationOne CDx testing to determine tumor mutational burden (TMB) in customers with solid tumors for identifying individuals who may respond to specific medication is considered investigational based upon the above criteria and assessment of the peer-reviewed literature.

CYP2C9 Genotyping (81227)

CYP2C9 genotyping is covered when the following criteria are met:

- Individual has been diagnosed with multiple sclerosis; and
- Prior to initiation of Mayzent (siponimod) (Please refer to pharmacy coverage criteria)

Genetic testing using multi-gene pharmacogenetics panels for the diagnosis and management of mental health disorders is considered investigational in all situations, including but not limited to informing the selection or dose of medications used to treat mental health disorders. These tests include but are not limited to the following: Genecept Assay, GeneSight and NeuroIDgenetix.

The following genetic tests are also covered. No prior authorization is required for the tests listed below:

Cystic Fibrosis

Duchenne's Muscular Dystrophy

Huntington's Disease

Karyotype (Trisomy 21-Downs Syndrome, Trisomy18-Edwards Syndrome)

Methylation Studies (Several genetic diseases are caused by defects within the methylation machinery, like the Rett Syndrome, Fragile X Syndrome and ICF (Immunodeficiency-Centromeric Instability-Facial Anomalies Syndrome)

Prader-Willi Syndrome

All genetic tests must have US Food and Drug Administration (FDA) approval.

Close blood relatives include first, second, and third-degree relatives.

1st degree relatives include; parents, siblings and children.

2nd degree relatives include; grandparents, grandchildren, aunts, uncles, half-siblings, nieces and nephews.

3rd degree relatives include great grandmother, great grandfather, great granddaughter, great grandson, great aunt, great uncle, grand-niece, grand-nephew, first female cousin or first male cousin.

Targeted Genomic Sequence Analysis Panels consisting of 50 or fewer genes (CPT Code 81445) are covered when the customer has one of the following solid organ neoplasms:

- Non-small cell lung cancer (NSCLC), metastatic (advanced) or recurring after initial treatment (C34.00 – C34.92); or
- Pancreatic adenocarcinoma, locally advanced or metastatic (C25.0 C25.9)
- Assessment of solid tumors other than NSCLC or pancreatic adenocarcinoma are considered experimental and investigational.

Targeted hematologic genomic sequencing panel (5-50 genes) (CPT Code: 81450, 81451) are covered for the following hematologic malignancies:

- acute myeloid leukemia (AML); or
- · chronic myelogenous leukemia (CML); or
- myelodysplastic syndromes (MDS); or
- myeloproliferative neoplasms (MPN); or
- Chronic MyeloMonocytic Leukemia (CMML); or
- Juvenile MyeloMonocytic Leukemia (JMML).

Testing of all other hematologic malignancies is considered not medically necessary.

Exclusions

- Not meeting criteria under Indications/Criteria in this policy.
- ThyroSeq® v.2 Next Generation Sequencing is considered investigational and therefore not covered as there is insufficient evidence to determine the test improves clinical outcomes.

- Drug metabolizing enzyme genotyping systems (e.g., Amplichip™) are considered experimental/investigational and, therefore, are not covered.
- Gene expression profiling to identify tissue of origin in individuals with occult primary cancer has not demonstrated better clinical outcomes and, therefore, is considered experimental and investigational.
- Genetic cancer susceptibility testing panels or diagnostic genetic testing using panels of genes (CPT 81434, 81437, 81438, 81442):
 - There may be one portion/component of the genetic panel that is medically necessary, however the medical literature does not support that the entire genetic panel improves health outcomes and therefore the entire panel is considered investigational.
- Genetic cancer susceptibility testing panels (e.g., myRisk[™], BreastNext[™], OvaNext[™], PancNext[™], CancerNext[™], GYNplus[™], ColoNext[™], RenalNext[™]) using next-generation sequencing for hereditary cancer are considered investigational as the entire panels have not been proven to improve health outcomes.
 - There may be one portion/component of the genetic panel that is medically necessary, however there may be portion/components of the genetic panel that a patient is not at risk and therefore the entire genetic panel does not meet medical policy criteria.
- Whole Genome Sequencing (WGS), Whole Exome Sequencing (WES) and Whole
 Mitochondrial Genome Sequencing are considered experimental and investigational
 because there is a lack of evidence from peer-reviewed literature demonstrating
 improved patient outcomes and poor support in professional medical clinical
 quidelines and position statements.
- Diagnostic genetic testing using panels of genes (with or without next generation sequencing), do not meet the criteria listed in the Indications/Criteria section above and therefore the entire genetic panel does not meet medical policy criteria.

Next generation sequencing (NGS) based cancer profiling tests include, but may not be limited to:

- o FoundationOne CDx™(F1CDx) (Foundation Medicine, Inc.)
- IntelligGen Myeloid Assay
- Illumina TruSeq Myeloid Panel
- LeukoVantage MPN
- Liquid biopsy (e.g. Guardant360 panel (0242U), FoundationACT,
 FoundationOne Liquid (0239U), CancerIntercept, Colvera, GeneStrat, Neolab
 Prostate, Natera Signatera, Resolution ctDx Lung™)

- MSK-IMPACT (Memorial Sloan Kettering Cancer Center's (MSK) IMPACT (Integrated Mutation Profiling of Actionable Cancer Targets) (0048U)
- Myeloid CLL Mutation Panel by NGS
- Myeloid Molecular Profile by Gentopix
- o Oncomine Dx Target Test (Thermo Fisher Scientific, Inc.) (0022U)
- Oncotype MAP Pan-Cancer tissue test (formerly known as Paradigm Cancer Diagnostic (PCDx) (0244U)
- Oncology (prostate), mRNA, gene expression profiling by real-time RT-PCR of 17 genes (12 content and 5 housekeeping), utilizing formalin-fixed paraffinembedded tissue, algorithm reported as a risk score (0048U)
- OnkoSight NGS MDS
- Targeted genomic sequence analysis panel, acute myelogenous leukemia,
 DNA analysis, 194 genes, interrogation for sequence variants, copy number variants or rearrangements (0050U)
- Targeted genomic sequence analysis panel, acute myeloid leukemia, myelodysplastic syndrome, and myeloproliferative neoplasms, DNA analysis, 23 genes, interrogation for sequence variants, rearrangements and minimal residual disease, reported as presence/absence (MyMRD Gene Panel Analysis 0171U)
- Thunderboltz MSK HemeMultiplex pharmacogenomics tests/genotyping /mutation analysis (e.g. GeneSight® Psychotropic, Genecept™ Assay), but not limited to the aforementioned) are considered investigational and not medically necessary as they have not been proven to improve health outcomes.
- Predictive genetic testing or on individuals with average risk.
- Chromosomal Microarray Analysis is considered not medically necessary for first trimester and second trimester pregnancy losses or recurrent pregnancy loss as the medical literature does not support it improves health outcomes and therefore is considered investigational.
- Proprietary Laboratory Analysis (PLA) codes mean that the code applies to only one unique lab test made by a specific manufacturer or performed by a specific laboratory. Proprietary Laboratory Analysis (PLA) codes can be identified by the U alpha character that follows the four initial numerical digits (i.e., four digits followed by the letter U). When the PLA code is released, it generally is not released with information clearly demonstrating that clinical validity or clinical utility have been proven or that a definitive positive impact on clinical outcomes have been established. PLA codes are considered experimental and investigational until the

laboratory test the code represents is formally documented. The exceptions to this rule are clearly indicated in policy.

- Envisia Genomic Classifier (Veracyte) Molecular Test proposes to help diagnose a lung disease called idiopathic pulmonary fibrosis (IPF) however, is experimental, investigational, or unproven. There is limited published evidence of clinical validity and clinical utility that demonstrated a change in patient management or patient outcomes with this genetic testing.
- DNA-based prognostic testing proprietary tests, such as ScoliScore (CPT Code: 0004M), have not been proven in peer reviewed literature to predict the risk of progression in most of those with a primary diagnosis of adolescent idiopathic scoliosis (AIS) and is considered to be investigational.

Based upon our criteria and assessment of the peer-reviewed literature, non-targeted/multi-gene panel testing for preconception or prenatal carrier screening (CPT Code: 81443) (e.g., Horizon Advanced Carrier Screening, Natera; Myriad Foresight Screening, Myriad, SEMA4 Elements and Invitae carrier screening) are considered experimental and investigational.

Variations

Vermont Variation

Genetic testing for autism spectrum disorders is covered for children beginning at 18 months of age and continuing until the child reaches age six or enters the first grade, whichever occurs first.

Medicare Variation

Pharmacogenomics testing:

Psychotropic pharmacogenetic testing panel(s) are covered for Medicare customers only when the following criteria are met:

- ordering is restricted to clinicians who have the licensure, qualifications, and necessary
 experience / training to both diagnose the condition being treated and also to
 prescribe medications (the provider must be able to do both) for the condition;
- the test is for a Medicare customer who is diagnosed with major depressive disorder (MDD) or other specified neuropsychiatric disorders in accordance with the DSM criteria (most recent version);
- the ordering clinician is considering a specific alteration in neuropsychiatric medication for the customer.

The following multi-gene testing panels are covered for a major depressive disorder (MDD) or neuropsychiatric disorder:

Test Name:	Intended Use:
Genesight	Major Depressive Disorder (MDD) or other Neuropsychiatric
Genomind Professional PGx Express	Neuropsychiatric
NeurolDgenetix	Major Depressive Disorder (MDD) or other Neuropsychiatric
Neuropharmagen	Neuropsychiatric
PGXPSYCH	Neuropsychiatric
Psychotropic Pharmacogenomics Gene Panel	Neuropsychiatric

For full Medicare coverage details please refer to the following LCD website for Medicare Customers: National Government Services. Local Coverage Determination (LCD) MoIDX: Pharmacogenomics Testing (L38394) and Billing and Coding Article: Pharmacogenomics Testing (A58324) Revision Effective Date:01/01/2025. Available: Medicare Coverage Database Search

Genomic Sequence Analysis Panels in the Treatment of Solid Organ Neoplasms

For full Medicare coverage details please refer to the following LCD website for Medicare Customers: National Government Services. Local Coverage Determination (LCD) Genomic Sequence Analysis Panels in the Treatment of Solid Organ Neoplasms (L37810) Original Effective Date: 04/01/2019. Available: https://www.ngsmedicare.com/

Next Generation Sequencing (NGS) as a diagnostic laboratory test is reasonable and necessary and is covered for patients with cancer when performed in a CLIA-certified laboratory, when ordered by a treating physician and when all the following requirements are met:

1. Somatic (Acquired) Cancer

a. Patient has:

- i. Either recurrent, relapsed, refractory, metastatic, or advanced stages III or IV cancer; and
- ii. Not been previously tested using the same NGS test for the same primary diagnosis of cancer or repeat testing using the same NGS test only when a new primary cancer diagnosis is made by the treating physician; and

- iii. Decided to seek further cancer treatment (e.g., therapeutic chemotherapy); and
- b. The diagnostic laboratory test using NGS must have:
 - i. The test has satisfactorily completed a Technology Assessment (TA) by MoIDX for the stated indications of the test; and
 - ii. FDA approval or clearance as a companion in vitro diagnostic; and
 - iii. An FDA approved or cleared indication for use in that patient's cancer; and
 - iv. Results provided to the treating physician for management of the patient using a report template to specify treatment options.

2. Germline (Inherited) Cancer

Effective for services performed on or after January 27, 2020, CMS has determined that NGS as a diagnostic laboratory test is reasonable and necessary and covered nationally for patients with germline (inherited) cancer, when performed in a CLIA-certified laboratory, when ordered by a treating physician and when all of the following requirements are met:

- a. Patient has:
 - i. ovarian or breast cancer; and,
 - ii. a clinical indication for germline (inherited) testing for hereditary breast or ovarian cancer; and,
 - iii. a risk factor for germline (inherited) breast or ovarian cancer; and
 - iv. not been previously tested with the same germline test using NGS for the same germline genetic content.
 - b. The diagnostic laboratory test using NGS must have all of the following:
 - i. FDA-approval or clearance; and,
 - ii. results provided to the treating physician for management of the patient using a report template to specify treatment options.

For full Medicare coverage details about next-generation sequencing please refer to the following NCD for Medicare Customers: National Coverage Determination (NCD) Next-Generation Sequencing (NGS) (90.2) and Revision Effective Date: 01/27/2020. Available: https://www.cms.gov/medicare-coverage-database

Targeted hematologic genomic sequencing panel (5-50 genes) (CPT Code: 81450, 81451) are covered for acute lymphocytic leukemia (AML), acute myeloid leukemia, chronic myelogenous leukemia, myelodysplastic syndromes (MDS) and myeloproliferative neoplasms (MPN).

For full Medicare coverage details about genomic sequence analysis panels please refer to the following LCD for Medicare Customers: Local Coverage Determination (LCD) Genomic Sequence Analysis Panels in the Treatment of Hematolymphoid Diseases (L37606) Revision Effective Date: 10/03/2019. Available: MCD Search (cms.gov)

Envisia Genomic Classifier (Veracyte) is covered for Medicare plans only when the following conditions are met:

- The customer is healthy enough to undergo a bronchoscopy with transbronchial biopsies, and
- High-resolution CT scan of the chest (defined by high kernel ~1mm axial reconstructions, including both inspiratory and expiratory imaging) showing one of the following:
 - A "Probable UIP" pattern (See comment below) as defined by the 2018 Fleischner Society White paper (https://www.ncbi.nlm.nih.gov/pubmed/29154106), or
 - An "Indeterminate for UIP" pattern as defined by the 2018 Fleischner Society White paper (https://www.ncbi.nlm.nih.gov/pubmed/29154106)
- Exclusion of autoimmune disease by clinical evaluation and serologic testing, including, when indicated, an evaluation by a rheumatologist
- Absence of a definitive occupational, environmental, medication-related, or other cause of the patient's lung disease

For full Medicare coverage details please refer to the following Noridian Health Solutions, LLC Local Coverage Determination (LCD): Envisia, Veracyte, Idiopathic Pulmonary Fibrosis Diagnostic Test (L37887) Revision Effective Date: 05/27/2019. Available: https://www.cms.gov/medicare-coverage-database

Guardant360 liquid biopsy is covered for Medicare plans when all the following conditions are met:

Criteria for Coverage

Guardant360[®] is covered only when **all** of the following conditions are met:

- Patient has been diagnosed with a recurrent, relapsed, refractory, metastatic, or advanced solid tumor that did not originate from the central nervous system.
 Patients who would meet all of the indications on the Food and Drug Administration (FDA) label for <u>larotrectinib</u> if they are found to have a neurotrophic receptor tyrosine kinase (NTRK) mutation may be considered to have advanced cancer, and
- Patient has not previously been tested with the Guardant360[®] test for the same genetic content. For a patient who has been tested previously using

Guardant360® for cancer, that patient may not be tested again unless there is clinical evidence that the cancer has evolved wherein testing would be performed for different genetic content. Specifically, in patients with previously tested cancer, who have evidence of new malignant growth despite response to a prior targeted therapy, that growth may be considered to be sufficiently genetically different to require additional genetic testing, **and**

- Patient is untreated for the cancer being tested, or the patient is not responding to treatment (e.g., progression or new lesions on treatment), **and**
- The patient has decided to seek further cancer treatment with the following conditions:
 - The patient is a candidate for further treatment with a drug that is either FDA-approved for that patient's cancer, or has a National Comprehensive Cancer Network (NCCN) 1 or NCCN 2A recommendation for that patient's cancer, and
 - The FDA-approved indication or NCCN recommendation is based upon information about the presence or absence of a genetic biomarker tested for in the Guardant360[®] assay, and
- Tissue-based, comprehensive genomic profiling (CGP) is infeasible (e.g., quantity not sufficient for tissue-based CGP or invasive biopsy is medically contraindicated) or specifically in NSLC Tissue-based CGP has shown no actionable mutations.

If no alteration is detected by Guardant360[®] or if circulating tumor deoxyribonucleic acid (ctDNA) is insufficient/not detected, tissue-based genotyping should be considered.

For full Medicare coverage details refer to the following in the Palmetto GBA Local Coverage Determination (LCD): MoIDX: Plasma-Based Genomic Profiling in SOLID TUMORS (L38043) Effective 02/03/2020. Available: https://www.cms.gov/medicare-coverage-database

Technology Assessments (TA) requirement for all genetic tests for Medicare:

Medicare's MoIDX program will review all new test/assay clinical information to determine if a test meets Medicare's reasonable and necessary requirement. Labs must submit a comprehensive dossier on each new test/assay prior to claim submission. MoIDX will only cover and reimburse tests that demonstrate analytical and clinical validity, and clinical utility at a level that meets the Medicare reasonable and necessary requirement. There may be other Medicare LCD or NCD that address medical necessity that must also be met along with Medicare's MoIDX program approval for coverage and reimbursement.

MoIDX will reimburse:

 approved tests covered for dates of service consistent with the effective date of the coverage determination.

These tests have been evaluated by Medicare and are reasonable and necessary to be covered if they meet medical necessity criteria.

The tests may require prior authorization or retrospective review in order to determine medical necessity.

For covered molecular diagnostic tests refer to the Local Coverage Article: Billing and coding: MolDX: Molecular Diagnostic Tests (MDT)(A56853) effective date: 01/01/2021 available here: https://www.cms.gov/medicare-coverage-database/new-search/search.aspx

Minimal Residual Disease (MRD) Testing for Cancer:

(CPT and PLA Codes: 81445, 0340U, 0422U, 0356U)

MRD testing for cancer is rapidly becoming a sensitive and specific method for monitoring the relative amounts of tumor-derived genetic material circulating in the blood of cancer patients. Medicare plans have coverage for minimally invasive molecular deoxyribonucleic acid (DNA) and ribonucleic acid (RNA) tests that detect minimal residual disease (MRD) in patients with a personal history of cancer. Covered tests include Next Generation Sequencing (NGS-based) MRD tests for the purpose of diagnosing disease progression, recurrence, or relapse.

Examples of current uses for this testing include use for colorectal cancer and other solid tumors using such tests as Signatera[™](PLA Code: 0340U),Guardant Reveal[™], Guardant Response[™](PLA Code: 0422U), NavDx®(PLA Code: 0356U) and Invitae Personalized Cancer Monitoring.

For full Medicare coverage details refer to the following in the Local Coverage Determination (LCD): MoIDX: Minimal Residual Disease Testing for Cancer (L38814 and A58454) with Noridian Healthcare Solutions, LLC Effective 01/01/2024. Available: MCD Search (cms.gov).

Medicaid Variation

Medicaid will cover prenatal testing for spinal muscular atrophy in all Medicaid customers who are planning to become pregnant and who are currently pregnant. NYS Medicaid SMA carrier screening (CPT Code: 81329) will be covered once per customer per lifetime.

References (Updated 2025)

1. American Thoracic Society; European Respiratory Society American Thoracic Society/European Respiratory Society statement: standards for the diagnosis and

- management of individuals with alpha-1 antitrypsin deficiency. Am J Respir Crit Care Med 2003; 168(7):818-900.
- 2. Miller, David. Use of array genomic hybridization (ACGH) in obstetrics. UpToDate®. June 3, 2013.
- 3. Reiff, M., et al. Genomic variation: what does it mean? Issue Brief. Leonard Davis Institute of Health Economics. 2013 Feb-Mar; 18(4): 1-4.
- 4. Carter, MT. and Scherer. Autism spectrum disorder in the genetics clinic: a review. Clin Genet. 2013 May; 83(5): 339-407.
- 5. Beaudet, AL. The utility of chromosomal microarray analysis in developmental and behavioral pediatrics. Child Dev. 2013. Jan-Feb; 84(1): 121-32.
- 6. Subramonia-Iyer, S, Sanderson, S, Sagoo, G, et al. Array-based comparative genomic hybridization for investigating chromosomal abnormalities in patients with learning disability: systematic review meta-analysis of diagnostic and false-positive yields. Genet Med. 2007 Feb;9(2):74-9.
- 7. Moeschler, JB, Shevell, M. Clinical genetic evaluation of the child with mental retardation or developmental delays. Pediatrics. 2006 Jun;117(6):2304-16.
- 8. Schaefer, GB, Mendelsohn, NJ. Clinical genetics evaluation in identifying the etiology of autism spectrum disorders. Genet Med. 2008 Apr;10(4):301-5.
- BlueCross BlueShield Association (BCBSA). Technology Evaluation Center (TEC).
 Special Report: aCGH for the Genetic Evaluation of Patients with Developmental Delay/Mental Retardation or Autism Spectrum Disorder TEC Assessment Program. Vol 25. No. 10. Chicago, IL. BCBSA. 2009 Apr.
- 10. Michelson, D. J., Shevell, M. I, Sherr, E. H. Moeschler, J. B., Gropman, A. L., Ashwal, S. (2011). Evidence report: Genetic and metabolic testing on children with global developmental delay: Report of the Quality Standards Subcommittee of the American Academy of Neurology and the Practice Committee of the Child Neurology Society. Neurology, 77, 1629-35.
- 11. Moeschler, J. B., & Shevell, M., (2006). Clinical genetic evaluation of the child with mental retardation or developmental delays. Pediatrics, 117, 2304-2316.
- 12. Lotan M, Ben-Zeev B. Rett syndrome. A review with emphasis on clinical characteristics and intervention. The Scientific World Journal 2006; 6:1517-41.
- 13. Reiff, M., et al. Genomic variation: what does it mean? Issue Brief. Leonard Davis Institute of Health Economics. 2013 Feb-Mar; 18(4): 1-4.
- 14. Smith J and Camp G. Nonsyndromic hearing loss and deafness, DFNB1. Gene Review. Initial Posting: 1998, Last update: 2012 Jan 5.

- 15. American College of Medical Genetics. Genetics Evaluation Guidelines for Etiologic Diagnosis of Congenital Hearing Loss. Genet Med. 2002; 4(3):162-71. (Reaffirmed 2005). Available: https://www.nature.com/articles/gim20142.
- 16. Smith J, Van Camp G. Nonsyndromic Hearing Loss and Deafness, DFNB1. Gene Review. Funded by the NIH. Developed at the University of Washington, Seattle. Initial posting: 1998 September 28. Last Update: July 14, 2011. Available: http://www.ncbi.nlm.nih.gov/bookshelf/br.fcgi?book=gene&part=dfnb1.
- 17. Genetics Evaluation Guidelines for the Etiologic Diagnosis of Congenital Hearing Loss. Genetic Evaluation of Congenital Hearing Loss Expert Panel. American College of Medical Genetics statement. Genetics in Medicine. 2002; 4(3): 162-171.
- 18. Smith, RJ, et al. Deafness and hereditary hearing loss overview. Seattle, WA: GeneTests; 2012
- 19. Hilgert, N., et al. Forty-six genes causing non-syndromic hearing impairment: which ones should be analyzed in DNA diagnostics? Mutat Res, 2009. 681(2-3) 198-196.
- 20. The National Comprehensive Cancer Network, Invasive Breast Cancer, Clinical Practice Guidelines in Oncology, Version 2.2016. Available: www.nccn.org.
- 21. The National Comprehensive Cancer Network, Genetic/Familial High-Risk Assessment Breast, Ovarian, and Pancreatic Guidelines, Clinical Practice Guidelines in Oncology, Version 1.2022. Available: www.nccn.org.
- 22. ACC/AHA/ESC 2006 Guidelines for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death: A Report of the American College of Cardiology/American Heart Association Task Force and the European Society of Cardiology Committee for Practice Guidelines (Writing Committee to Develop Guidelines for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death). J Am Col Cardiol 2006: j.jacc.2006.07.010.
- 23. Tester, D.J and Ackerman, M.J. Genetic testing for potentially lethal, highly treatable inherited cardiomyopathies/channelopathies in clinical practice. Circulation. 2011; 123:1021-1037.
- 24. Modell, SM., et al. Genetic testing for long QT syndrome and the category of cardiac ion channelopathies. Plos Currents. 2012 May 3; 4: e419995f69e6c7.
- 25. Imboden, M., Swan, H., Denjoy, I., Van Langen, I.M., Latinen-Forsblom, P.J., Napolitano, C., et al. Female predominance and transmission distortion in the long-QT syndrome. N Engl J Med. 2006 Dec 28; 355(26):2744-51.
- 26. Roden, D.M. Long-QT Syndrome. N Engl J Med 2008 January 10, 358(2) 169-176.
- 27. Crotti L, Celano G, Dagradi F, Schwartz PJ. Congenital long QT syndrome. Orphanet J Rare Dis. 2008 Jul 7;3:18.

- 28. Ackerman MJ, Priori SG, Willems S, Berul C, Brugada R, Calkins H, et al. HRS/EHRA Expert Consensus Statement on the State of Genetic Testing for the Channelopathies and Cardiomyopathies: This document was developed as a partnership between the Heart Rhythm Society (HRS) and the European Heart Rhythm Association (EHRA). Endorsed by the American Heart Association (AHA) June of 2011. Reaffirmed August 2018. Available: https://www.hrsonline.org/Policy-Payment/Clinical-Guidelines-Documents/2011-HRS-EHRA-Expert-Consensus-Statement-on-the-State-of-Genetic-Testing-for-the-Channelopathies-and-Cardiomyopathies.
- 29. Behr, E., Wood, D.A., Wright, M., Syrris, P., Sheppard, M.N., Casey, A., et al. Sudden Arrhythmic Death Syndrome Steering Group. Cardiological assessment of first-degree relatives in sudden arrhythmic death syndrome. Lancet. 2003 Nov 1; 362 (9394):1457-9.
- 30. Dubinsky, M.C., et al. A cost-effectiveness analysis of alternative disease management strategies in patients with Crohn's disease treated with azathiopurine or 6-mercaptopurine. American Journal of Gastroenterology. 2005; 100(10):2239-2247.
- 31. Dubinsky MC, Lamothe S, Yang YH, Targan SR, Sinnett D, Theoret Y, et al. Pharmacogenomics and metabolite measurement of 6-mercaptopurine therapy in inflammatory bowel disease. Gastroenterology. 2000 Apr;118:705-13.
- 32. Gisbert JP, Nino P, Rodrigo L, Cara C, Guijarro LG. Thiopurine Methyltransferase (TPMT) Activity and Adverse Effects of Azathioprine in Inflammatory Bowel Disease: Long-Term Follow-Up Study of 394 Patients. Am J Gastroenterol. 2006 Oct 6.
- 33. Lichtenstein GR, Abreu MT, Cohen R, Tremaine W; American Gastroenterological Association. American Gastroenterological Association Institute medical position statement on corticosteroids, immunomodulators, and infliximab in inflammatory bowel disease. Gastroenterology 2006 Mar;130(3):935-9.
- 34. Regueiro M, Mardini H. Determination of thiopurine methyltransferase genotype or phenotype optimizes initial dosing of azathioprine for the treatment of Crohn's disease. J Clin Gastroenterol. 2002;35(3):240-4.
- 35. Kaskas, B.A., et al. Safe treatment of thiopurine S-methyltransferase deficient Crohn's disease patients with azathiopurine. Gut. 2003; 52:140-142.
- 36. U.S. National Library of Medicine, National Institute of Health Department of Health and Human Services: Genetic Testing, August 1, 2005.
- 37. ACOG Committee on Genetics, Committee Opinion Number 298, August 2004, Prenatal and Pre-conceptional Carrier Screening for Genetic Diseases in Individuals of Eastern European Jewish Decent.

- 38. Goetz, MP, et al. Tamoxifen pharmacogenomics: the role of CYP2D6 as a predictor of drug response. Clinical Pharmacology and Therapeutics. 2008; 83(1):160-166.
- 39. Goetz, MP, et al. The impact of cytochrome P450 2D metabolism in women receiving adjuvant tamoxifen. Breast Cancer Research Treatment. 2007; 101(1):113-121.
- 40. Nowell, SA, et al. Association of genetic variation in tamoxifen-metabolizing enzyme with overall survival and recurrence of disease in breast cancer patients. Breast Cancer Research Treatment. 2005; 91(3):249-258.
- 41. Mega, JL et al. Cytochrome P-450 polymorphisms and response to clopidegrel. New England Journal of Medicine. 2009; 360:354-362.
- 42. Collet, JP et al. Cytochrome P450 2C19 polymorphisms in young patients treated with clopidegrel after myocardial infarction: a cohort study. Lancet. 2009; 373(9660):276-278.
- 43. Simon, T et al. The French registry of acute s-elevation and non-st-elevation myocardial infarction (FAST-MI) investigators. Genetic determinants of response to clopidegrel and cardiovascular events. New England Journal of Medicine. 2008; 360(4):363-375.
- 44. Higgins, MJ et al. Pharmacogenetics of tamoxifen: who should undergo CYP2D6 genetic testing? Journal National Comprehensive Cancer Network. 2009; 7(2):203-213.
- 45. The Vermont Statutes Online. Title 8: Banking and Insurance, Chapter 107: HEALTH INSURANCE 8 V.S.A. § 4088i. Coverage for diagnosis and treatment of autism spectrum disorders.
- 46. Weischer, M., et al. CHEK2*1100delC genotyping for clinical assessment of breast cancer risk: meta-analyses of 26,000 patient cases and 27,000 controls. Journal of Clinical Oncology. 2008 Feb 1; 26 (4):542-8.
- 47. Offit, K. et al. Time to check CHEK2 in families with breast cancer? Journal of Clinical Oncology. 2008. Feb 1; 26 (4):519-20.
- 48. Suchowersky, Oksana. Huntington disease: Clinical features and diagnosis. UpToDate®. Sept. 19, 2013.
- 49. Torres, Vincent and Bennet, William. Diagnosis of a screening for autosomal dominant polycystic kidney disease. UpToDate®. Jan. 11, 2013.
- 50. Soltanzadeh P, Friez MJ, Dunn D et al. Clinical and genetic characterization of manifesting carriers of DMD mutations. Neuromuscul Disord 2010; 20(8):499-504. Available: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2944769/.

- 51. Bowles DE, McPhee SW, Li C et al. Phase 1 gene therapy for Duchenne muscular dystrophy using a translational optimized AAV vector. Mol Ther 2012; 20(2):443-55. Available: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3277234/.
- 52. Zimetbaum, Peter and Josephson. Genetics of congenital and acquired long QT syndrome. UpToDate®. April 18, 2013.
- 53. Bacon BR, Adams PC, Kowdley KV, Powell LW, and Tavill AS. Diagnosis and Management of Hemochromatosis: 2011 Practice Guideline by the American Association for the Study of Liver Diseases. Hepatology;54(1);2011:328-43.
- 54. Bryant J, Cooper K, Picot J, Clegg A, Roderick P, Rosenberg W, and Patch C. A systematic review of the clinical validity and clinical utility of DNA testing for hereditary hemochromatosis type 1 in at-risk populations. Journal Medical Genetics;2008;45:513-518.
- 55. Clark P, Britton LJ, Powell LW. The Diagnosis and Management of Hereditary Hemochromatosis. Clinical Biochemistry Review; (31); February 2010:1-8.
- 56. U.S. National Library of Medicine. Factor V Leiden thrombophilia Genetics Home Reference. Available: https://ghr.nlm.nih.gov/condition/factor-v-leiden-thrombophilia.
- 57. Grody, W.W., Griffin, J.H., Taylor, A.K. et al. American College of Medical Genetics Consensus statement of factor V Leiden mutation testing. Available: http://www.acmg.net/PDFLibrary/Factor-V-Ledien-Mutation-Testing.pdf.
- 58. The National Comprehensive Cancer Network. Head and Neck Cancers Clinical Practice Guidelines in Oncology, Version 2.2018. Available: www.nccn.org.
- 59. National Institute for Health and Clinical Excellence (NICE). Diagnosis and management of metastatic malignant disease of unknown primary origin (clinical guideline no. 104). London (UK): 2010. Available online at: http://guidance.nice.org.uk/CG104.
- 60. New York public health law 79-l: http://codes.lp.findlaw.com/nycode/CVR/7/79-l.
- 61. Hall-Flavin DK, et al. Using a pharmacogenomic algorithm to guide the treatment of depression. Transl Psychiatry. 2012:2.
- 62. .Hall-Flavin DK, et al. Utility of integrated pharmacogenomic testing to support the treatment of major depressive disorder in a psychiatric outpatient setting. Pharmacogenet Genomics. 2013 Oct; 3(10):535-48
- 63. Winner JG, et al. A prospective, randomized, double-blind study assessing the clinical impact of integrated pharmacogenomic testing for major depressive disorder. Discov Med. 2013 Nov; 16(89):219-27.

- 64. Pilarski, R., et al. Cowden syndrome and the PTEN Hamartoma Tumor Syndrome: systematic review and revised diagnostic criteria. J Natl Cancer Inst 2013; 105:1607-1616. Available: http://jnci.oxfordjournals.org/content/105/21/1607.long.
- 65. Genomind. Genecept™ Assay. 2015. Available: http://genomind.com/.
- 66. Kloiber S, Czamara D, Karbalai N et al. ANK3 and CACNA1C--missing genetic link for bipolar disorder and major depressive disorder in two German case-control samples. J Psychiatr Res 2012; 46(8):973-9.
- 67. Zammit S, Spurlock G, Williams H et al. Genotype effects of CHRNA7, CNR1 and COMT in schizophrenia: interactions with tobacco and cannabis use. Br J Psychiatry 2007; 191:402-7.
- 68. American College of Obstetricians and Gynecologists (ACOG). Committee and Society for Maternal Fetal Medicine. Committee Opinion No. 682: Microarrays and Next-Generation Sequencing Technology: The Use of Advanced Genetic Diagnostic Tools in Obstetrics and Gynecology. Obstet Gynecol 2016;128:e262–8. Available: https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2016/12/microarrays-and-next-generation-sequencing-technology-the-use-of-advanced-genetic-diagnostic-tools-in-obstetrics-and-gynecology.
- 69. Schaefer GB, Mendelsohn NJ. Clinical genetics evaluation for the etiologic diagnosis of autism spectrum disorders. Genet Med. 2008 Jan;10(1):4-12.
- 70. Schaefer GB, Mendelsohn NJ; Professional Practice and Guidelines Committee. Clinical genetics evaluation in identifying the etiology of autism spectrum disorders. Genet Med. 2008 Apr;10(4):301-5.
- 71. Manning M, Hudgins L; Professional Practice and Guidelines Committee. Array-based technology and recommendations for utilization in medical genetics practice for detection of chromosomal abnormalities. Genet Med. 2010 Nov;12(11):742-5.
- 72. Schaefer GB, Mendelsohn NJ; Professional Practice and Guidelines Committee. Clinical genetics evaluation in identifying the etiology of autism spectrum disorders: 2013 guideline revisions. Genet Med. 2013 May;15(5):399-407.
- 73. National Institute for Health and Care Excellence (NICE). Autism in Children and Young People. Clinical Guideline. Updated December 2017. Available: http://guidance.nice.org.uk/CG128/Guidance/pdf/English.
- 74. Saam J, Gudgeon J, Aston E, Brothman AR. How physicians use array comparative genomic hybridization results to guide patient management in children with developmental delay. Genet Med. 2008;10(3):181-186.
- 75. Shen, Y, Dies, KA, Holm, IA, et al. Clinical genetic testing for patients with autism spectrum disorders. Pediatrics. 2010;125(4):e727-e735.

- 76. Reddy UM, Page GP, Saade GR, et al; NICHD Stillbirth Collaborative Research Network. Karyotype versus microarray testing for genetic abnormalities after stillbirth. N Engl J Med. 2012 Dec 6;367(23):2185-93.
- 77. New York State Department of Health Medicaid Program. Medicaid Update. October 2015. Volume 31. Number 11. Available: http://www.health.ny.gov/health_care/medicaid/program/update/2015/oct15_mu.pdf.
- 78. Schlade-Bartusiak K, Cox DW. Alpha-1 antitripsin deficiency. In Pagon RA, Bird TD, Dolan CR et al. (eds.). Gene Reviews (internet). Seattle (WA): University of Washington. http://www.ncbi.nlm.nih.gov/books/NBK1519/.
- 79. Alpha-1 Foundation. Testing for Alpha-1. https://www.alpha1.org/.
- 80. American Thoracic Society European Respiratory Society. American Thoracic Society/European Respiratory Society statement: standards for the diagnosis and management of individuals with alpha-1 antitrypsin deficiency. Am J Respir Crit Care Med. 2003;168(7):818-900.
- 81. U.S. Preventive Services Task Force. Published Recommendations. Colorectal Cancer Screening. Updated 2016. Available:
 http://www.uspreventiveservicestaskforce.org/BrowseRec/Index/browse-recommendations.
- 82. The National Comprehensive Cancer Network. NCCN. Clinical Practice Guidelines in Oncology. National Comprehensive Cancer Network. Available: www.nccn.org.
- 83. Nikiforov, Y. E., Carty, S. E., Chiosea, S. I., Coyne, C., Duvvuri, U., Ferris, R. L., Nikiforova, M. N. (2014). Highly accurate diagnosis of cancer in thyroid nodules with follicular neoplasm/suspicious for a follicular neoplasm cytology by ThyroSeq v2 next generation sequencing assay. Cancer, 120, 3627-3634.
- 84. Nikiforova, M. N., Wald, A. I., Roy, S., Durso, M. B., & Nikiforov, Y. E. (2013). Targeted next-generation sequencing panel (ThyroSeq) for detection of mutations in thyroid cancer. Journal of Clinical Endocrinology and Metabolism, 98, E1852-E1860).
- 85. Moses W, Weng J, Sansano I, et al. Molecular testing for somatic mutations improves accuracy of thyroid fine-needle aspiration biopsy. World J Surg 2010; 34(11):2589-2594.
- 86. Ohori NP, Nikiforova MN, Schoedel KE, et al. Contribution of molecular testing to thyroid fine-needle aspiration cytology of "follicular lesion of undetermined significance/atypia of undetermined significance." Cancer Cytopathol 2010; 118(1):17-23.

- 87. Cantara S, Capezzone M, Marchisotta S, et al. Impact of proto-oncogene mutation detection in cytological specimens from thyroid nodules improves the diagnostic accuracy of cytology. J Clin Endocrinol Metab 2010; 95(3):1365-1369.
- 88. Mathur A, Weng J, Moses W, et al. A prospective study evaluating the accuracy of using combined clinical factors and candidate diagnostic markers to refine the accuracy of thyroid fine needle aspiration biopsy. Surgery 2010; 148(6):1170-1177.
- 89. Ferraz C, Eszlinger M, Paschke R. Current state and future perspective of molecular diagnosis of fine-needle aspiration biopsy of thyroid nodules. J Clin Endocrinol Metab 2011; 96(7):2016-2026.
- 90. Haugen, B.R., et al. 2015 American Thyroid Association Management Guidelines for Adult Patients with Thyroid Nodules and Differentiated Thyroid Cancer: The American Thyroid Association Guidelines Task Force on Thyroid Nodules and Differentiated Thyroid Cancer. Thyroid. January 2016, 26(1): 1-133.
- 91. National Government Services. Local Coverage Determination (LCD) Genomic Sequence Analysis Panels in the Treatment of Non-Small Cell Lung Cancer (L36376) Original Effective Date: 04/01/16. Available: https://www.ngsmedicare.com/.
- 92. Centers for Medicare & Medicaid Services, Decision Memo for Next Generation Sequencing (NGS) for Medicare Beneficiaries with Advanced Cancer (CAG-00450N). March 16, 2018. Available: https://www.cms.gov.
- 93. American Medical Association CPT Codes.
- 94. American Society of Reproductive Medicine (ASRM). Preimplantation genetic testing: a Practice Committee opinion. Practice Committee of the Society for Assisted Reproductive Technology; Practice Committee of the American Society for Reproductive Medicine. Fertil Steril. ©2008 American Society for Reproductive Medicine. Fertil Steril. 2008j Nov;90(5 Suppl):S136-43.

Customer Product	Medical Management Requirements*
New York Products	•
НМО	Prior Auth
PPO in Plan	Prior Auth
PPO OOP	Prior Auth
POS in Plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Prior Auth
MVP Child Health Plus	Prior Auth
Harmonious Health Care Plan	Prior Auth
MVP Medicare Complete Wellness	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP Medicare WellSelect PPO	Prior Auth
MVP Medicare WellSelect Plus PPO	Prior Auth
MVP Medicare Patriot Plan PPO	Prior Auth
MVP DualAccess D-SNP HMO	Prior Auth
MVP DualAccess Complete D-SNP HMO	Prior Auth
MVP DualAccess Plus D-SNP HMO	Prior Auth
UVM Health Advantage Select PPO	Prior Auth
USA Care	Potential for Retrospective Review
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	Sec 31 B
POS in Plan	Prior Auth
POS OOP	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP VT HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD
730	JEE JED

[♦] Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Revision History

08/01/2022 - Added myChoiceCDx, FroundationOneCDx, Genecept Assay, GeneSight and NeuroIDgenetix to the pharmacogenomics testing section as exclusions to coverage based on either an NCCN category for low level evidence or lack of support or evidence in peer-reviewed literature.

12/01/2022- DecisionDX-Melenoma and PanGen Oncogene Panel moved to Oncotype DX Cancer Gene Expression Tests Medical Policy.

04/01/2023 – Removed prior authorization from 81229, 0022U, 0037U, 0048U. Medicare variations updated to match NCDs and LCDs. Added overview and coverage criteria for Targeted Genomic Sequence Analysis Panels consisting of 50 or fewer genes (CPT Code 81445). DNA-based prognostic testing proprietary tests, such as ScoliScore (CPT Code: 0004M) moved into this policy from Scoliosis bracing policy.

10/01/2023 – Added coverage for hematologic malignancies using CPT Code: 81450, 81451, added exclusions for genetic testing panels for inherited genetic conditions (CPT 81443) and Whole Genome Sequencing (WGS), Whole Exome Sequencing (WES) and Whole Mitochondrial Genome Sequencing. Expanded spinal muscular atrophy coverage for Medicaid plans.

08/01/2024 – Autoimmune disease genetic testing (0062U) now managed in the Biomarker Testing for Autoimmune Rheumatic Disease Payment Policy, HIV genetic testing (0219U) now managed in the Human Immunodeficiency Virus (HIV) Payment Policy, Tuberculosis genetic testing (81425, 81426) now managed through the Testing for Diagnosis of Active or Latent Tuberculosis Payment Policy, response to chemotherapy drugs genetic testing (0083U) now managed through the In Vitro Chemoresistance and Chemosensitivity Assays Payment Policy, Inflammatory bowel disease (IBD) genetic testing (81401, 0176U, 0203U) now managed through the Laboratory Testing for the Diagnosis of Inflammatory Bowel Disease Payment Policy, Alzheimer's Disease genetic testing (0206U, 0207U) now managed through the Biochemical Markers of Alzheimer Disease and Dementia Payment Policy.

09/15/2024 – 81470, 81471, 0063U removed and managed in the payment policy Testing for Autism Spectrum Disorder and Developmental Delay.

04/01/2025 – Medicare variation updated to align with Medicare criteria for psychotropic pharmacogenomics testing.



Ground Ambulance Services and Ambulette Services

Type of Policy: Medical

Prior Approval Date: 01/29/2024

Approval Date: 02/05/2024

Effective Date: 04/01/2024

Related Polices: Air Medical Transport

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

N/A

Codes Subject to Retrospective Review

N/A

Experimental/Investigational

N/A

Common Diagnosis Codes

N/A

Common Procedure Codes

HCPCS Codes: A0130, A0225, A0380, A0382, A0384, A0390, A0392, A0394, A0396, A0398, A0420, A0422, A0424, A0425, A0426, A0427, A0428, A0429, A0432, A0433, A0434, A0998, A0999

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy.

Overview

Use of ambulance services are rendered when the condition of the patient requires immediate transport to the appropriate medical facility and, at the time of transport, another means of transportation would be contraindicated. This includes inter-hospital emergency department transfers and trauma scene transports.

Ambulance services may also be used in non-emergent situations such as transporting a customer from a hospital to a skilled nursing facility (SNF) when the condition of the patient requires some medical care.

Ambulette services (a means of transportation for patients that do not need medical care) are not covered except for MVP Medicaid Managed Care. Refer to the MVP Medicaid Managed Care Variation section.

Indications/Criteria

Coverage of ground ambulance services is covered for customers who are nonambulatory and require transportation in order to receive necessary medical services.

Emergency Ambulance Transportation Services

Emergency ambulance transportation: Services are covered when a medical emergency exists and that lack of immediate medical attention may place the health of the person in serious jeopardy resulting in serious impairment to bodily functions, serious dysfunction to bodily organs or serious disfigurement to the customer.

Transport from one acute facility to the nearest acute facility capable of providing the necessary care related to the customer's condition (e.g., burn unit, cardiac care unit, trauma units, neonatal units).

A patient transport from one hospital to another hospital is covered only if the hospital to which the patient is transferred is the nearest one with appropriate facilities. Coverage is not available for transport from a hospital capable of treating the patient because the patient and/or the patient's family prefer a specific hospital or physician.

Types of Emergency Transport Services based on medical necessity include the following:

- Advanced Life Support Level 1 (ALS 1);
- Advanced Life Support Level 2 (ALS 2);
- Basic Life Support (BLS);
- Specialty Care Transport (SCT) (hospital to hospital transport of critically injured or ill
 patient requiring ongoing care during the transport time, beyond the scope of an
 EMT-Paramedic, furnished by one or more health professionals in an appropriate
 specialty area. This includes the provision of medically necessary supplies and
 services.); or

Paramedic Intercept (PI) Services are ALS services provided by an entity that does not provide the ambulance transport. This type of service is most often provided for an emergency ambulance transport in which a local volunteer ambulance can provide only basic life support (BLS) level of service is dispatched to transport the customer. If the customer needs ALS services such as EKG monitoring, chest decompressions, or I.V. therapy, another entity dispatches a paramedic to meet the BLS ambulance at the scene or once the ambulance is on the way to the hospital. The ALS paramedics then provide services to the customer. (For Air Emergency transport, see MVP's Air Medical Transport policy.)

Non-emergency Ambulance Transfer from Acute Facility to Acute Facility

Transport from one acute facility to the nearest acute facility capable of providing the necessary care related to the customer's condition (e.g., burn unit, cardiac care unit, trauma units, neonatal units, psychiatric center) is covered.

A patient transported from one hospital to another hospital is covered only if the hospital to which the patient is transferred is the nearest one with appropriate facilities. Coverage is not available for transport from a hospital capable of treating the patient because the patient and/or the patient's family prefer a specific hospital or physician.

Non-emergency Ambulance Transport

Non-emergency ambulance transport is covered when the customer's condition is such that the use of any other method of transportation is contraindicated such as when the customer is bed-confined before and after the ambulance trip. The customer is bed-confined if they are unable to get out of bed without assistance, unable to walk, and unable to sit in a chair or wheelchair.

The customer must need either Basic Life Support or Advanced Life Support to be transported.

Ambulance transport is covered (when the above requirements are met) only to the following destinations:

- hospital;
- critical access hospital (CAH);
- skilled nursing facility (SNF);
- customer's home;
- dialysis facility for end stage renal disease (ESRD) patient who requires dialysis; or
- return transport from a hospital, skilled nursing facility, critical access facility, or dialysis facility; or

Only local transportation by ambulance is covered, and therefore, only mileage to the nearest appropriate facility equipped to treat the patient is covered.

Ambulance service from an institution to the customer's home is covered when the home is within the locality of such institution or where the customer's home is outside the locality of such an institution but the institution, in relation to the home, is the nearest one with the appropriate facilities.

Items and services such as oxygen, drugs, extra attendants, supplies, EKG, night differential, and other miscellaneous ambulance services are considered global to the ambulance service. (A0420, A0422, A0424).

Exclusions

- Requests for non-emergency transport not meeting criteria.
- Ambulette services are not covered.

Medicare Variation

<u>Ambulance Treatment without Transport</u>

Ambulance treatment without transport (A0998) is not a covered benefit. The Medicare ambulance benefit is a transportation benefit and without transportation there is no payable service. The customer's condition must require both the ambulance transportation itself and the level of service provided in order for the service to be considered medically necessary.

Paramedic Intercept Services

Paramedic intercept services are covered when all Medicare requirements for paramedic intercept services are met.

When Medicare requirements for paramedic intercept service are not met, the benefit will be denied administratively.

See Publication 100-02, Medicare Benefit Policy Manual, Chapter 10 – Ambulance Services, section 30.1.1 – Ground Ambulance Services for coverage requirements for Paramedic Intercept benefit.

Available: https://www.cms.gov/Regulations-and-guidance/Guidance/Manuals/downloads/clm104c15.pdf

Non-emergency transportation is available for Medicare Advantage customers but varies by plan. If the non-emergency transportation benefit is available, it must be provided by the MVP vendor.

MVP Medicaid Managed Care Variation

Non-emergency transportation is not covered by MVP Health Care for MVP Medicaid Managed Care customers. Non-emergency transportation is provided by the NYS DOH transportation vendor, Medical Answering Services.

Emergency transportation is not covered by MVP. Emergency transportation is covered by Medicaid Fee-for-Service (FFS).

MVP Child Health Plus

Transportation Between Hospitals:

When a Child Health Plus enrollee is admitted to a hospital licensed under Article 28 of the Public Health Law, the reimbursement paid to the hospital includes all necessary transportation services for the inpatient. If the admitting hospital sends an inpatient round trip to another hospital for the purposes of obtaining a diagnostic test or therapeutic service, the original admitting hospital is responsible for the provision of the transportation services.

The following ambulance transports are considered emergency transports; therefore, prior authorization is not required:

- Transport from an Emergency Room to a Psychiatric Center
- Transport from an Emergency Room to a Trauma/Cardiac Care/Burn Center.
- Transportation from an Emergency Room to an Emergency Room.
- Transportation from an Emergency Room to Another Facility.

References (Reviewed 2024)

- Centers for Medicare and Medicaid Services. Medicare Benefit Policy Manual,
 Chapter 10 Ambulance Services. Available: www.cms.hhs.gov/center/ambulance.asp
- 2. Centers for Medicare and Medicaid Services Medicare Claims Processing, Chapter 15 Ambulance Available: <u>Medicare Claims Processing Manual (cms.gov)</u>
- 3. Centers for Medicare and Medicaid Services. Ambulances Services Center. Available: <u>Ambulances Services Center | CMS</u>
- 4. New York State Medicaid Program. Department of Health. Transportation Manual Policy Guidelines. Version 2019-1. February 1, 2019. Available: https://www.emedny.org/ProviderManuals/index.aspx
- 5. Insurance Law section 3221 (I) (15) for Article 42 Lines of Business.

Customer Product	Medical Management Requirements*
New York Products	
HMO	Potential for Retrospective Review
POS in Plan	Potential for Retrospective Review
POS OOP	Potential for Retrospective Review
Essential Plan	Potential for Retrospective Review
MVP Medicaid Managed Care	Carved out by Medicaid FFS
MVP Child Health Plus	Potential for Retrospective Review
MVP Harmonious Health Care Plan	Carved out by Medicaid FFS
MVP Medicare Complete Wellness	Potential for Retrospective Review
MVP Medicare Preferred Gold HMO POS	Potential for Retrospective Review
MVP Medicare Secure HMO POS	Potential for Retrospective Review
MVP Medicare Secure Plus HMO POS	Potential for Retrospective Review
MVP Medicare WellSelect PPO	Potential for Retrospective Review
MVP Medicare WellSelect Plus PPO	Potential for Retrospective Review
MVP Medicare Patriot Plan (PPO)	Potential for Retrospective Review
MVP DualAccess D-SNP HMO	Potential for Retrospective Review
MVP DualAccess Complete D-SNP HMO	Potential for Retrospective Review
MVP DualAccess Plus D-SNP HMO	Potential for Retrospective Review
UVM Health Advantage Select PPO	Potential for Retrospective Review
USA Care PPO	Potential for Retrospective Review
Healthy NY	Potential for Retrospective Review
MVP Premier	Potential for Retrospective Review
MVP Premier Plus	Potential for Retrospective Review
MVP Premier Plus HDHP	Potential for Retrospective Review
MVP Secure	Potential for Retrospective Review
MVP EPO	Potential for Retrospective Review
MVP EPO HDHP	Potential for Retrospective Review
MVP PPO	Potential for Retrospective Review
MVP PPO HDHP	Potential for Retrospective Review
Student Health Plans	Potential for Retrospective Review
ASO	See SPD
Vermont Products	
POS in Plan	Potential for Retrospective Review
POS Preferred OOP	Potential for Retrospective Review
MVP Medicare Preferred Gold HMO POS	Potential for Retrospective Review
MVP Medicare Secure Plus HMO POS	Potential for Retrospective Review
MVP VT HMO	Potential for Retrospective Review
MVP VT HDHP HMO	Potential for Retrospective Review
MVP VT Plus HMO	Potential for Retrospective Review
MVP VT Plus HDHP HMO	Potential for Retrospective Review
MVP Secure	Potential for Retrospective Review
ASO	See SPD
ASU	766 2hD

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Revision History:

02/01/2022 – added Emergency Triage, Treat, and Transport (ET3) model language to Commercial and Medicare coverage.

01/01/2023 – added coverage for non-emergency transportation and transportation between hospitals as part of Child Health Plus carve-in of benefits to managed care plans.

02/01/2024 – Annual review; removed coverage for Emergency Triage, Treat, and Transport (ET3) model language from Commercial and Medicare as CMS has discontinued the program. References reviewed and updated.



Habilitation Services (Individual and Small Group Products Only)

Type of Policy: Medical

Prior Approval Date: 09/14/2022

Approval Date: 10/07/2024

Effective Date: 12/01/2024

Related Polices: MVP Speech Therapy, Custodial Care Long

Term Placement in a Nursing Home for MVP

Medicaid Managed Care

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

Inpatient level of care requires prior authorization.

Codes Requiring Retrospective Review

N/A

Experimental/Investigational

N/A

Common Diagnosis Codes

ICD-10- CM Diagnosis Codes: N/A

Common Diagnosis Codes associated with this policy have been provided for informational purposes only. The list of codes may not be all-inclusive and may be updated to reflect any applicable revisions to the ICD-10 code set and/or medical necessity quidelines applied in this policy.

Common Procedure Codes

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Habilitation Services Page 1 of 8

Overview

This policy addresses MVP Health Care's medical management criteria and requirements for coverage of inpatient and outpatient habilitation services for individual and small group products only.

Habilitation Services are health care services that help a person keep, learn, or improve skills and functioning for daily living. Examples include therapy for a child who isn't walking or talking at the expected age. These services may include physical and occupational therapy, speech -language pathology and other services in a variety of inpatient and /or outpatient settings. Habilitation services are distinct from rehabilitation services in that they help a person attain a particular function as opposed to restoring it. Rehabilitation refers to recovery skills that were acquired at the appropriate age but have been lost or impaired. By contrast, habilitation services are designed to establish skills that have not yet been acquired at an age-appropriate developmental level.

Maintenance therapy is defined as activities that preserve present functional level and prevent regression.

Activities of daily living (ADLs) refer to such activities as bathing, getting dressed, using toilet facilities, eating, transferring into and out of a bed or chair, and ambulating/walking.

MVP Health Care will provide medically necessary habilitation services to meet the Customer's needs and safety in the most integrated and least restrictive setting.

Indications/Criteria

<u>Habilitation Services provided in Acute Inpatient Rehabilitation Facility (Inpatient level of care requires prior authorization.)</u>

A customer will be considered for habilitation services in an acute inpatient rehabilitation facility when all of the following criteria are met:

The customer requires at least three (3) hours per day, five (5) days per week, of a habilitation program that includes at least two (2) habilitation disciplines; and

- the "three-hour rule" should not be considered an inflexible rule of thumb; however, a patient receiving a less intensive schedule of therapy will require additional documentation to explain why he or she requires an inpatient habilitation facility level of care; and
- the customer has one or more persistent disabilities that require at least minimal assistance in mobility, basic activities of daily living, bowel or bladder control, cognition, emotional functioning, pain management, swallowing or communication; and

Habilitation Services Page 2 of 8

- the customer is medically stable, is able to fully participate in the habilitation program, and had the potential for significant measurable improvement in functional status. Measurable, practical improvement in the patient's functional condition is expected to be accomplished within a predetermined and reasonable period of time; and
- the customer has a discharge residence other than a Residential Health Care Facility, sufficient family/caregiver support to ensure personal and medical safety, and consensus among the patient, family/caregivers and health care team of discharge setting; and
- treatment precluded at a lower level of care due to clinical complexity; and
- a patient requires 24-hour a day access to a registered nurse with specialized training in habilitation; and
- a patient requires the 24-hour availability of a physician with specialized training or
 experience in habilitation, including face-to-face visits, at least three (3) days per
 week to assess the patient both medically and functionally, as well as to modify the
 course of treatment as needed to maximize the patient's capacity to benefit from the
 habilitation process; and
- meets the criteria listed in the Medical Record Documentation Requirements and Habilitation Services sections below.

<u>Habilitation Services provided in a Skilled Nursing Facility (SNF) (SNF level of care requires prior authorization.)</u>

A customer will be considered for habilitation services in a Skilled Nursing facility (SNF) when all of the following criteria are met:

The customer requires at least five (5) days per week, of a habilitation program

- Skilled nursing services or skilled rehabilitation services are required (performed or supervised by professional or technical personnel).
- Skilled services are required on a daily basis.
- The daily skilled services can be provided only on an inpatient basis based on economy and efficiency.
- Treatment precluded at a lower level of care due to clinical complexity.
- Meets the criteria listed in the Medical Record Documentation Requirements and Habilitation Services sections below.

Outpatient Habilitation

A customer will be considered for habilitation services in a physician office or an outpatient setting when all of the following are met:

Habilitation Services Page 3 of 8

- Habilitation services must be ordered by a physician and performed by a licensed physical therapist, occupational therapist, speech language pathologist, physician or other practitioner licensed to provide physical, occupational or speech therapy.
- Meets the criteria listed in the Medical Record Documentation Requirements and Habilitation Services sections below.

Medical Record Documentation Requirements

- Medical necessity must be documented in the medical record
- The medical record must document an ongoing, written plan of care. The written plan of care must include sufficient information to determine the medical necessity of treatment. The written plan of care must include:
 - o The date of onset or exacerbation of the disorder/diagnosis;
 - o Specific statements of long-term and short-term goals;
 - o Quantitative objectives measuring current age-adjusted level of functioning;
 - o A reasonable estimate of when the goals will be reached;
 - o The specific treatment techniques and/or exercises to be used in treatment; and
 - o The frequency and duration of treatment.
- The plan of care should be ongoing (i.e., updated as the patient's condition changes)
- The patient should be reevaluated weekly, and there should be documentation of progress made toward the goals of therapy.

Habilitation Services

Habilitation consisting of physical therapy, speech therapy and occupational therapy are covered when all the following criteria are met:

- The service is ordered by a physician; and
- The therapy is intended to maintain, develop, or improve skills needed to perform ADLs which have not (but normally would have) developed or which are at risk of being lost as a result of illness, injury, loss of a body part, or congenital abnormality; and
- The therapy is for a condition that requires the unique knowledge, skills, and judgment of a physical therapist for education and training that is part of an active skilled plan of treatment; and
- There is an expectation that the therapy will maintain or improve the level of functioning; and

Habilitation Services Page 4 of 8

- An individual would either not be expected to develop the function or would be expected to permanently lose the function without the habilitative service (not merely fluctuate); and
- The therapy documentation objectively verifies that, at a minimum, functional status is maintained; and
- The services are delivered by a qualified provider of physical therapy services, speech therapy, and occupational therapy services; and
- The services require the judgment, knowledge, and skills of a qualified provider of physical therapy speech therapy, and occupational therapy services due to the complexity and sophistication of the therapy and the medical condition of the individual.
- Any services received under the Habilitation benefit will not reduce the amount of services available under the Rehabilitation or Home Health Care services benefit.

Exclusions

- Any indication not listed in the Indications/Criteria section.
- The customer is not compliant with habilitation treatment or therapy.
- The customer skips or misses or absent from therapy sessions.
- Any therapy that is not delivered by a qualified provider of physical therapy services, speech therapy, and occupational therapy services
- The therapy is not aimed at developing, improving or maintaining functions, which would normally develop.
- The therapy is aimed at a function which would be permanently lost as a result of illness, injury, loss of a body part, or congenital abnormality whether or not therapy was provided.
- The therapy is for conditions for which therapy would be considered routine educational, training, conditioning, or fitness. This includes treatments or activities that require only routine supervision.
- The therapy is for custodial care, respite care, day care, therapeutic recreation, and vocational training.
- The expectation does not exist that the therapy will result in developing or maintaining the expected level of functioning within a reasonable and predictable period of time.
- The therapy documentation fails to objectively verify functional status is, at a minimum, maintained.

Habilitation Services Page 5 of 8

 Coverage is excluded for services beyond any visit limits, if any, if specified in the customer contract.

Duplicate habilitative therapy is considered not medically necessary. When individuals receive physical, occupational, or speech therapy, the therapists should provide different treatments that reflect each therapy discipline's unique perspective on the individual's impairments and functional deficits and not duplicate the same treatment. They must also have separate evaluations, treatment plans, and goals.

References (Reviewed 2024)

- 1. MVP Certificates of Coverage.
- 2. APTA Guide to Physical Therapist Practice 4.0. American Physical Therapy Association. Published 2023. Accessed October 24, 2023. https://guide.apta.org
- 3. The American Speech-Language-Hearing Association (ASHA). www.asha.org.
- 4. HealthCare.gov. Habilitative/Habilitation Services. Available at https://www.healthcare.gov/glossary/habilitative-habilitation-services/

Habilitation Services Page 6 of 8

Customer Product	Medical Management Requirements*
New York Products	
HMO	Not Covered
PPO in Plan	Not Covered
PPO OOP	Not Covered
POS in Plan	Not Covered
POS OOP	Not Covered
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Not Covered
MVP Child Health Plus	Not Covered
MVP Harmonious Health Care Plan	Not Covered
MVP Medicare Complete Wellness	Not Covered
MVP Medicare Preferred Gold HMO POS	Not Covered
MVP Medicare Secure HMO POS	Not Covered
MVP Medicare Secure Plus HMO POS	Not Covered
MVP Medicare WellSelect PPO	Not Covered
MVP Medicare WellSelect Plus PPO	Not Covered
MVP Medicare Patriot Plan PPO	Not Covered
MVP DualAccess D-SNP HMO	Not Covered
MVP DualAccess Complete D-SNP HMO	Not Covered
MVP DualAccess Plus D-SNP HMO	Not Covered
UVM Health Advantage Select PPO	Not Covered
USA Care	Not Covered
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	
POS in Plan	Not Covered
POS OOP	Not Covered
MVP Medicare Preferred Gold HMO POS	Not Covered
MVP Medicare Secure Plus HMO POS	Not Covered
MVP VT HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD
	OUD products are the same as the base product (e.g.

[♦] Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

MVP Health Care Medical Policy Revision History:

12/01/2022 – Annual review; added clarification that services received under the Habilitation benefit will not reduce the amount of services available under the Rehabilitation or Home Health Care services benefit.

12/01/2024 – Annual review with no changes to indications or criteria. Made minor changes to overview for clarity and added references.

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Hearing Aid Services

Type of Policy: Medical

Prior Approval Date: 07/12/2021

Approval Date: 09/11/2023

Effective Date: 12/01/2023

Related Polices: Cochlear Implants & Osseointegrated Devices

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

N/A

Codes Requiring Retrospective Review

N/A

Experimental/Investigational

N/A

Common Diagnosis Codes

N/A

Common Procedure Codes

CPT Codes: 92590, 92591, 92592, 92593, 92594, 92595

HCPCS Codes: V5010, V5011, V5014, V5020, V5030, V5040, V5050, V5060, V5095, V5100, V5120, V5130, V5140, V5170, V5180, V5210, V5220, V5242, V5243, V5244, V5245, V5246, V5247, V5248, V5249, V5250, V5251, V5252, V5253, V5254, V5255, V5256, V5257, V5258, V5259, V5260, V5261, V5262, V5263, V5264, V5265, V5266, V5268, V5269, V5270, V5271, V5272, V5273, V5274, V5275, V5281, V5282, V5283, V5286, V5287, V5288, V5289, V5290, S0618

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are

Hearing Aid Services Page 1 of 6

subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

Hearing aid services and products encompass a range of offerings aimed at addressing hearing-related challenges. These include audiology services, audiometric screening and use of a hearing aid when medically necessary to mitigate disability caused by the loss or impairment of hearing.

Hearing aid devices include behind-the-ear (BTE) devices, in-the-ear (ITE) devices, in-the-ear canal (ITC) devices and completely in the canal (CIC) devices. These devices are specifically designed to enhance hearing capabilities by amplifying and making sounds audible to individuals with hearing loss. Incorporating advanced technology, modern hearing aid devices function as computerized electroacoustic systems that transform environmental sound to make it audible.

For cochlear implants and bone-anchored prosthetic devices see the MVP Cochlear Implants & Osseointegrated Devices Medical Policy.

Indications/Criteria

- Medically necessary hearing aids and audiology services are covered if the benefit is listed in the patient's base contract or certificate of coverage.
- Any applicable benefit plan exclusions and limitations for coverage of hearing aids would apply to hearing aid devices. Please check benefit plan descriptions for details.
- Audiology services include audiometric examination or testing (e.g., screening test, pure tone, air only), conformity evaluation, and hearing aid prescription, if indicated. Services may be rendered in an office setting or at an approved participating speech or hearing center. A conformity evaluation is a hearing aid check performed following the receipt of a hearing aid for the purpose of evaluating the performance of the hearing and its benefit to the wearer to ensure that the unit and its benefit meet expectations. A referral for a conformity evaluation is not required.

Exclusions

- Disposable hearing aids and extended wear hearing aids do not provide a superior long-term solution for the hearing impaired. Alternative permanent solutions are available. Disposable hearing aids and extended wear hearing aids are, therefore, considered not medically necessary.
- Disposable ear molds are not covered.
- Repairs/replacements covered under warranty.
- Batteries for use in hearing aids are not a covered benefit.

Hearing Aid Services Page 2 of 6

- Assistive Listening Devices are non-covered as they are not considered part of the hearing benefit or plan contracts.
- Replacements require proof of loss or damage through documentation such as a police report, picture, or corroborating statement should be submitted.

MVP Medicaid Managed Care Variation

Medical Record Documentation

The medical record must document medical necessity for hearing aids. A statement ((psycho/social assessment) that the patient is alert, oriented and able to utilize their aid appropriately.

Hearing Aid Coverage Indications/Criteria

Hearing aid is covered when all of the following criteria are met:

- Monaural Hearing Aid
 - Hearing loss in the better ear of 30 dBHL or greater (re ANSI 1969) for the pure tone average of 500, 1000 and 2000Hz.
 - A spondee threshold in the better ear of 30 dBHL or greater when pure tone thresholds cannot be established.
 - Hearing loss in each ear is less than 30 dBHL at the frequencies below 2,000 Hz and thresholds in each ear are greater than 40 dBHL at 2,000 Hz and higher
- Binaural Hearing Aid
 - Must meet the same criteria for Monaural Hearing Aid (above), and in addition must meet one or more of the following:
 - significant vocational or educational demands;
 - previous user of binaural hearing aids within the past five (5) years supported by written documentation of medical need;
 - significant visual impairment, i.e. severe low vision as defined by the AMA best corrected visual of 20/200 or below or a visual acuity score of < 50; or
 - children (less than 21 years of age.
- Replacement Hearing Aid
 - A replacement hearing aid is a device that is recommended because the original device was:
 - Lost, stolen or damaged and is outside the manufacturer's warranty
 - in disrepair with a history of excessive repairs
 - no longer providing adequate benefit

Hearing Aid Services Page 3 of 6

FM Systems, Assisted Listening Devices and Tinnitus Maskers are not reimbursable for Medicaid Managed Care plans.

Audiology examinations and hearing aids services, products, and supplies (including batteries) are covered.

Ear molds are covered.

Batteries for use in hearing aids are covered.

For full coverage and exclusion details refer to the New York State Medicaid Program. Hearing Aid/Audiology Services Policy Guidelines. Available:

https://www.emedny.org/ProviderManuals/HearingAid/PDFS/HearingAid Policy Guidelines.pdf

MVP Child Health Plus Variation

The following criteria pertain to MVP Child Health Plus:

- one hearing examination per calendar year is covered. If an auditory deficiency requires additional hearing exams and follow-up exams, these exams will be covered;
- hearing aids, including batteries and repairs, are covered. If medically necessary, more than one hearing aid will be covered;
- ear mold/inserts are covered

MVP Medicare Variation

MVP Medicare Advantage (MA) plans allows coverage for hearing exams and hearing aids. Hearing aid coverage is only available through TruHearing. Hearing aid copayment is dependent on the specific plan contract.

There is no Medicare/CMS National or Local Determination for Hearing Aids.

References (Reviewed 2023)

- 1. MVP Contracts
- 2. New York State Medicaid Program. eMedNY. Provider Manuals. Hearing Aid. Version 2014 1 (08/01/2014). I Available: https://www.emedny.org/ProviderManuals/HearingAid/index.aspx
- 3. Medicare Benefit Policy Manual. Chapter 16: General Exclusions From Coverage. Rev. 198, 11/06/17. Available: https://www.cms.gov/Regulations-and-Guidance/Manuals/downloads/bp102c16.pdf

Hearing Aid Services Page 4 of 6

Customer Product	Medical Management Requirements*
New York Products	
HMO	Potential for Retrospective Review
PPO In Plan	Potential for Retrospective Review
PPO OOP	Potential for Retrospective Review
POS in Plan	Potential for Retrospective Review
POS OOP	Potential for Retrospective Review
Essential Plan	Potential for Retrospective Review
MVP Medicaid Managed Care	Potential for Retrospective Review
MVP Child Health Plus	Potential for Retrospective Review
MVP Harmonious Health Care Plan	Potential for Retrospective Review
MVP Medicare Complete Wellness	Potential for Retrospective Review
MVP Medicare Preferred Gold HMO POS	Potential for Retrospective Review
MVP Medicare Secure HMO POS	Potential for Retrospective Review
MVP Medicare Secure Plus HMO POS	Potential for Retrospective Review
MVP Medicare WellSelect PPO	Potential for Retrospective Review
MVP Medicare WellSelect Plus PPO	Potential for Retrospective Review
MVP Medicare Patriot Plan PPO	Potential for Retrospective Review
MVP DualAccess D-SNP HMO	Potential for Retrospective Review
MVP DualAccess Complete D-SNP HMO	Potential for Retrospective Review
MVP DualAccess Plus D-SNP HMO	Potential for Retrospective Review
UVM Health Advantage Select PPO	Potential for Retrospective Review
USA Care PPO	Potential for Retrospective Review
Healthy NY	Potential for Retrospective Review
MVP Premier	Potential for Retrospective Review
MVP Premier Plus	Potential for Retrospective Review
MVP Premier Plus HDHP	Potential for Retrospective Review
MVP Secure	Potential for Retrospective Review
MVP EPO	Potential for Retrospective Review
MVP EPO HDHP	Potential for Retrospective Review
MVP PPO	Potential for Retrospective Review
MVP PPO HDHP	Potential for Retrospective Review
Student Health Plans	Potential for Retrospective Review
ASO	See SPD
Vermont Products	
POS in Plan	Potential for Retrospective Review
POS OOP	Potential for Retrospective Review
MVP Medicare Preferred Gold HMO POS	Potential for Retrospective Review
MVP Medicare Secure Plus HMO POS	Potential for Retrospective Review
MVP VT HMO	Potential for Retrospective Review
MVP VT HDHP HMO	Potential for Retrospective Review
MVP VT Plus HMO	Potential for Retrospective Review
MVP VT Plus HDHP HMO	Potential for Retrospective Review
MVP Secure	Potential for Retrospective Review
ASO	See SPD

[♦] Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Hearing Aid Services Page 5 of 6

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Revision History:

10/01/2021 – Updated criteria and indications for replacement of hearing aids based on the commercial customer contract for commercial plans. Added that FM Systems, Assisted Listening Devices and Tinnitus Maskers are not reimbursable for Medicaid Managed Care plans based on NYS Medicaid.

12/1/2023 – Annual review with updates to the overview and language around batteries.

Hearing Aid Services Page 6 of 6



High Frequency Chest Wall Oscillation Devices

Type of Policy: DME

Prior Approval Date: 02/06/2023

Approval Date: 12/02/2024

Effective Date: 04/01/2025

Related Polices: N/A

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

HCPCS Code	Description
E0483	High frequency chest wall oscillation system, with full anterior and/or posterior thoracic region receiving simultaneous external oscillation, includes all accessories and supplies, each
E0469	Lung expansion airway clearance, continuous high frequency oscillation, and nebulization device

Codes Subject to Retrospective Review

N/A

Experimental/Investigational

E0469 - Lung expansion airway clearance, continuous high frequency oscillation, and nebulization device

Common Diagnosis Codes

ICD-10-CM Diagnosis Codes: E84.0, E84.9, J47.0, J47.1, J47.9, Q33.4

Common Procedure Codes

HCPCS Codes: A7025, A7026

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-

authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy.

Overview

High Frequency Chest Wall Oscillation Device is an inflatable vest that fits over a patient's entire thorax and is connected by flexible hoses to an air pulse delivery generator. The vest utilizes a technology called high-frequency chest wall oscillation (HFCWO) to decrease the viscoelastic properties of pulmonary secretions and produces cough-like shear forces to increase mucus mobilization.

Indications

High frequency chest wall oscillation devices (HFCWO) are covered for customers who meet all the following criteria:

- Requires request from a qualified specialist (e.g., Pulmonologist); and
- The customer has one of the following:
 - there is a diagnosis of cystic fibrosis; or
 - o there is a diagnosis of bronchiectasis:
 - characterized by daily productive cough for at least six (6) continuous months or frequent (i.e., more than two/year) exacerbations requiring antibiotic therapy; and
 - confirmed by high resolution, spiral, or standard CT scan; or
 - the customer has one (1) of the following neuromuscular disease diagnoses: post-polio, acid maltase deficiency, anterior horn cell diseases, multiple sclerosis, quadriplegia, hereditary muscular dystrophy, myotonic disorders, other myopathies, paralysis of the diaphragm;
- And, there must be well-documented failure, intolerance or contraindication of standard treatments to adequately mobilize retained secretions (e.g., pharmacotherapy, postural drainage, daily chest percussion, vibration, mechanical percussors, positive expiratory pressure device); and
- Medical record documentation should demonstrate the inability of a primary care giver to perform daily chest percussion or no available parent/partner to perform daily chest percussion.
- The device is cleared and used according to US Food and Drug Administration (FDA) approved indications (e.g., age restrictions);
- Rentals for a trial period of three (3) months will be considered upon the initial request; and

 At the end of the three-month trial period, review of physician documentation regarding compliance with prescribed therapy and stable or improved respiratory status will be required. If it is determined that continued therapy is medically necessary, device rental may be extended until the contract purchase price is reached.

Exclusions

- Not meeting criteria under Indications/Criteria in this policy.
- High frequency chest compression device replacement or upgrade is considered not medically necessary when requested for convenience or to upgrade to newer technology when the current components remain functional.
- The Volara System Oscillation & Lung Expansion (OLE) therapy device for the treatment of asthma, cystic fibrosis, middle lobe syndrome, and other respiratory disorders is experimental and investigational because there is insufficient evidence supporting its effectiveness.

Medicare Variation

There is a Local Coverage Determination (LCD): High Frequency Chest Wall Oscillation Devices (L33785) Medicare Local Coverage Determination for Medicare Customers. Please refer to the Noridian Healthcare Solutions, LLC Local Coverage Determination (LCD): High Frequency Chest Wall Oscillation Devices (L33785). Available:

https://www.cms.gov/medicare-coverage-database

There is no National Coverage Determination (NCD) or Local Coverage Determination (LCD) for The Volara System, therefore the above exclusion would apply to Medicare plans.

Medicaid Variation

High frequency chest wall oscillation devices (HFCWO) are covered for Medicaid customers who meet all the following criteria:

- The underlying medical condition(s) causing the accumulation of pulmonary secretions and the specific diagnosis supporting such equipment (e.g., neuromuscular disease(s); chronic pulmonary disease, bronchiectasis, cystic fibrosis)
- The need for the requested equipment and the treatment plan, with frequency of use and settings included on the fiscal order.
- The training given to the customer or caregiver on the use of the equipment.

References (Updated 2024)

1. Clinkscale D, Spihlman K, Watts P, et al. A randomized trial of conventional chest physical therapy versus high frequency chest wall compressions in intubated and non-intubated adults. Respir Care. 2012; 57(2):221-228.

- 2. Cystic Fibrosis Foundation (CFF). Cystic fibrosis pulmonary guidelines: airway clearance therapies. https://www.cff.org. Published April 2009.
- 3. Flume PA, Robinson KA, O'Sullivan BP, et al. Cystic fibrosis pulmonary guidelines: airway clearance therapies. Respir Care. 2009; 54(4):522-537.
- 4. Gokdemir Y, Kardag-Saygi E, Erdem E, et al. Comparison of conventional pulmonary rehabilitation and high frequency chest wall oscillation in primary ciliary dyskinesia. Pediatr Pulmonol. 2014; 49(6):611-616.
- 5. HAYES Medical Technology Directory™. High Frequency Chest Wall Compression for Diseases other than Cystic Fibrosis. Lansdale, PA: HAYES, Inc.; ©Winifred S. Hayes, Inc. August 11, 2016. Available: www.hayesinc.com/.
- 6. Hayes, Inc. Evidence Analysis Research Brief. Volara (Hillrom) for respiratory therapy. https://evidence.hayesinc.com. Published August 14, 2023.
- 7. Irwin RS, Baumann MH, Bolser DC, Boulet LP, Braman SS, Brightling CE, Brown KK, Canning BJ, Chang AB, Dicpinigaitis PV, Eccles R, Glomb WB, Goldstein LB, Graham LM, Hargreave FE, Kvale PA, Lewis SZ, McCool FD, McCrory DC, Prakash UB, Pratter MR, Rosen MJ, Schulman E, Shannon JJ, Smith Hammond C, Tarlo SM; American College of Chest Physicians (ACCP). Diagnosis and management of cough executive summary: ACCP evidence-based clinical practice guidelines. Chest. 2006 Jan;129(1 Suppl):1S-23S.
- 8. Kempainen RR, Milla C, Dunitz J, et al. Comparison of settings used for high-frequency chest-wall compression in cystic fibrosis. Respir Care. 2010; 55(6):695-701.
- 9. Lee AL, Burge AT, Holland AE Airway clearance techniques in bronchiectasis. Cochrane. Published: November 22, 2015.
- 10. Leemans G, Belmans D, Van Holsbeke C, Becker B, et al. The effectivenss of a mobile high-frequency chest wall oscillation (HFCWO) device for airway clearance. Pediatr Pulmonol. 2020; 55(8): 1984-1992.
- 11. McCool FD, Rosen MJ. Non-pharmacologic airway clearance therapies: ACCP evidence-based clinical practice guidelines. *Chest.* 2006; 129(1 Suppl):250S-259S.
- 12. Morrison, L, Agnew J. Oscillating devices for airway clearance in people with cystic fibrosis. Cochrane Database Systematic Review. 2014 Jul 20;7:CD006842.
- 13. New York State Department of Health eMedNY DME Manual Available: eMedNY.org
- 14. Nicolini A, Cardini F, Landucci N, et al. Effectiveness of treatment with high-frequency chest wall oscillation in patients with bronchiectasis. BMC Pulm Med. 2013; 13:21.
- 15. Nicolini A, Cardini F, Landucci N, Lanata S, Ferrari-Bravo M, Barlascini C. Effectiveness of treatment with high-frequency chest wall oscillation in patients with bronchiectasis. BMC Pulm Med. 2013 Apr 4;13:21.

- 16. Nicolini A, Grecchi B, Ferrari-Bravo M, Barlascini C. Safety and effectiveness of the highfrequency chest wall oscillation vs intrapulmonary percussive ventilation in patients with severe COPD. Int J Chron Obstruct Pulmon Dis. 2018 Feb 16;13:617-625.
- 17. SmartVest® System. Airway Clearance System. Electromed, Inc. Available: http://www.smartvest.com/.
- 18. Sontag MK, Quittner AL, Modi AC, et al. Lessons learned from a randomized trial of airway secretion clearance techniques in cystic fibrosis. *Pediatr Pulmonol*. 2010; 45(3):291-300.
- 19. Strickland SL, Rubin BK, Drescher GS, et al. American Association for Respiratory Care (AARC) clinical practice guideline: Effectiveness of nonpharmacologic airway clearance therapies in hospitalized patients. Respir Care. 2013; 58(12):2187-2193.
- 20. The inCourage® System. Airway Clearance Therapy. RespirTech®. Respiratory Technologies, Inc. Available: <u>InCourage | RespirTech</u>
- 21. The Vest® Airway Clearance System. Hill-Rom Services, Inc. Available: http://www.thevest.com/.
- 22. Varekojis, S.M., et al. A comparison of the therapeutic effectiveness of and preference for postural drainage and percussion, intrapulmonary percussive ventilation, and high frequency chest wall compression in hospitalized cystic fibrosis patients. Respiratory Care. 2003; 48(1):24-28.
- 23. Yuan N, Kane P, Shelton K, Matel J, Becker BC, Moss RB. Safety, Tolerability, and Efficacy of High-Frequency Chest Wall Oscillation in Pediatric Patients With Cerebral Palsy and Neuromuscular Diseases: An Exploratory Randomized Controlled Trial. J Child Neurol. 2010 Mar 31.

Customer Product	Medical Management Requirements*
New York Products	
HMO	Prior Auth
PPO in Plan	Prior Auth
PPO OOP	Prior Auth
POS in Plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Prior Auth
MVP Child Health Plus	Prior Auth
MVP Harmonious Health Care Plan	Prior Auth
MVP Medicare Complete Wellness	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP Medicare WellSelect PPO	Prior Auth
MVP Medicare WellSelect Plus PPO	Prior Auth
MVP Medicare Patriot Plan	Prior Auth
MVP DualAccess D-SNP HMO	Prior Auth
MVP DualAccess Complete D-SNP HMO	Prior Auth
MVP DualAccess Plus D-SNP HMO	Prior Auth
UVM Health Advantage Select PPO	Prior Auth
USA Care PPO Healthy NY	Potential for Retrospective Review Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	
ASO	Prior Auth See SPD
	See SPD
Vermont Products	Dries Auth
POS in Plan POS OOP	Prior Auth
	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP VT HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD

[♦] Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Revision History:

04/01/2021 – annual review; no change to the indications or criteria for coverage.

04/01/2023 – Annual review; Added Medicaid variation, updated code description and references.

04/01/2025 – Medical Policy Task Force (MPTF) annual review. Added Volaro System lung expansion airway clearance to exclusions, added exclusion for upgrades, updated references and websites.



MVP Health Care Behavioral Health Medical Necessity Criteria

Home and Community Based Services - Adult

Type of Policy: Behavioral Health

Prior Approval Date: 04/04/2022

Approval Date: 03/04/2024

Effective Date: 06/01/2024

Related Polices: Assertive Community Treatment (ACT)

Personalized Recovery Oriented Services

(PROS)

Codes Requiring Authorization

Authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

Home and Community Based Services for adults require authorization for MVP Harmonious Health Care Plan.

Code:	Description:	
T2017	Habilitation, residential, waiver; 15 minutes	
T2015	5 Habilitation prevocational, waiver; per hour	
T2019	Habilitation, supported employment, waiver; per 15 minutes	
H2023	Supported employment, per 15 minutes	
H2025	H2025 Ongoing support to maintain employment, per 15 minutes	
T2013	Habilitation, educational, waiver; per hour	

Codes Requiring Retrospective Review

N/A

Common Procedure Codes

CPT Codes: N/A

HCPCS Codes: A0160 - Non-emergency transportation: per mile - case worker or social

worker

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has

been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

Home and Community Based Services (HCBS) provide opportunities for Medicaid beneficiaries with mental illness and/or substance use disorders who are enrolled in a Health and Recovery Plan (HARP) to receive services in their own home or community. Implementation of HCBS will help to create an environment where managed care plans (Plans), Health Home care managers, service providers, plan customers and their chosen supporters/caregivers, and government partners help customers prevent, manage, and ameliorate chronic health conditions and recover from serious mental illness and substance use disorders.

The review guidelines provide a framework for discussion between HCBS providers and MVP Health Care (MVP). The review process is a collaboration between all pertinent participants including but not limited to the Health Home care manager, HCBS provider, MVP, and customer to review progress and identify barriers or challenges that may be interfering with a reasonable expectation of progress towards the customer's chosen goals. These conversations will focus on the customer's needs, strengths, and history in determining the best and most appropriate fit of the services. These review guidelines are applied to determine appropriate care for all customers. In general, services will be authorized if they meet the specific criteria for a particular service. The individual's needs, choice, and characteristics of the local service delivery system and social supports are also taken into consideration.

HCBS eligibility will be determined using a standard needs assessment tool, typically administered by the individual's Health Home care manager. Provision of Home and Community Based Services requires a person-centered approach to care planning, service authorizations, and service delivery.

MVP's utilization management for HCBS must conform to guidelines listed in the NYS HCBS Provider Manual. This manual outlines how HCBS care planning and utilization management emphasizes attention to customer strengths, goals, and preferences; and also ensures customer choice of service options and providers.

NYS has developed an expedited workflow for accessing HCBS. The State has provided this suggested workflow to promote enrollee access to Adult Behavioral Health Home and Community Based Services (BH HCBS). This expedited workflow is designed to keep the individual engaged during the BH HCBS assessment process and address service needs as soon as they are identified. Refer to NYS guidance on "Suggested Workflow Focused on Initial Engagement for HARP customers Enrolled in Health Home."

Home and Community Bases Services (HCBS)

The following is a description of the various HCBS services.

1. Vocational Services

Many of the HCBS services are designed to be provided in clusters that promote recovery along a spectrum and as such, Employment Support Services are grouped as a cluster and include Pre-vocational Services, Transitional Employment, Intensive Supported Employment, and Ongoing Supported Employment.

a. Pre-vocational Services:

Pre-vocational services are time-limited services that prepare a participant for paid or unpaid employment. This service specifically provides learning and work experiences where the individual with mental health and/or disabling substance use disorders can develop general, non-job-task-specific strengths and soft skills that contribute to employability in competitive work environment as well as in the integrated community settings. Pre-vocational services occur over a defined period of time and with specific person-centered goals to be developed and achieved, as determined by the individual and his/her employment specialist and support team and ongoing person-centered planning process as identified in the individual's person-centered plan of care. Pre-vocational services provide supports to individuals who need ongoing support to learn a new job and/or maintain a job in a competitive work environment or a self-employment arrangement. The outcome of this pre-vocational activity is documentation of the participant's stated career objective and a career plan used to guide individual employment support.

b. Transitional Employment (TE):

This service is designed to strengthen the participant's work record and work skills toward the goal of achieving assisted or unassisted competitive employment at or above the minimum wage paid by the competitive sector employer. This service is provided, instead of individual supported employment, only when the person specifically chooses this service and may only be provided by clubhouse, psychosocial club program certified provider or recovery center. This service specifically provides learning and work experiences where the individual with behavioral health and/or substance use disorders can develop general, non-job-task-specific strengths and soft skills that contribute to employability in the competitive work environment in integrated community settings paying at or above minimum wage. The outcome of this activity is documentation of the participant's stated career objective and a career plan used to guide individual employment support.

c. Intensive Supported Employment (ISE):

ISE services that assist individuals with MH/SUD to obtain and keep competitive employment. These services consist of intensive supports that enable individuals to obtain and keep competitive employment at or above the minimum wage. This service will follow the evidence-based principles of the Individual Placement and Support (IPS) model. This service is based on Individual Placement Support (IPS)

model which is an evidence-based practice of supported employment. It consists of intensive supports that enable individuals for whom competitive employment at or above the minimum wage is unlikely, absent the provision of supports, and who, because of their clinical and functional needs, require supports to perform in a regular work setting. Individual employment support services are individualized, person-centered services providing supports to participants who need ongoing support to learn a new job and maintain a job in a competitive employment or selfemployment arrangement. Participants in a competitive employment arrangement receiving Individual Employment Support Services are compensated at or above the minimum wage and receive not less than the customary wage and level of benefits paid by the employer for the same or similar work performed by individuals without disabilities. The outcome of this activity is documentation of the participant's stated career objective and a career plan used to guide individual employment support. Services that consist of intensive supports that enable participants for whom competitive employment at or above the minimum wage is unlikely, absent the provision of supports, and who, because of their disabilities, need supports to perform in a regular work setting.

d. Ongoing Supported Employment

This service is provided after a participant successfully obtains and becomes oriented to competitive and integrated employment. Ongoing follow-along is support available for an indefinite period as needed by the participant to maintain their paid employment position. Individual employment support services are individualized, person centered services providing supports to participants who need ongoing support to learn a new job and maintain a job in a competitive employment or self-employment arrangement. Participants in a competitive employment arrangement receiving Individual Employment Support Services are compensated at or above the minimum wage and receive not less than the customary wage and level of benefits paid by the employer for the same or similar work performed by individuals without disabilities. The outcome of this activity is documentation of the participant's stated career objective and a career plan used to guide individual employment support.

2. Education Support Services

Education Support Services are provided to assist individuals with mental health or substance use disorders who want to start or return to school or formal training with a goal of achieving skills necessary to obtain employment. Education Support Services may consist of general adult educational services such as applying for and attending community college, university, or other college-level courses. Services may also include classes, vocational training, and tutoring to receive a Test Assessing Secondary Completion (TASC) diploma, as well as support to the participant to participate in an apprenticeship program. Participants authorized for Education Support Services must relate to an employment goal or skill development documented in the service plan.

Education Support Services must be specified in the service plan as necessary to enable the participant to integrate more fully into the community and to ensure the health, welfare, and safety of the participant. Examples of these goals would include, but not be limited to: tutoring or formal classes to obtain a Test Assessing Secondary Completion (TASC) diploma, vocational training, apprenticeship program or formal classes to improve skills or knowledge in a chosen career, community college, university or any college-level courses or classes.

3. Habilitation / Residential Support Services

Habilitation services are typically provided on a 1:1 basis and are designed to assist participants with a behavioral health diagnosis (i.e. SUD or mental health) in acquiring, retaining and improving skills such as communication, self-help, domestic, self-care, socialization, fine and gross motor skills, mobility, personal adjustment, relationship development, use of community resources and adaptive skills necessary to reside successfully in home and community-based settings. These services assist participants with developing skills necessary for community living and, if applicable, to continue the process of recovery from an SUD disorder. Services include things such as: instruction in accessing transportation, shopping, and performing other necessary activities of community and civic life including self-advocacy, locating housing, working with landlords and roommates and budgeting. Services are designed to enable the participant to integrate full into the community and ensure recovery, health, welfare, safety, and maximum independence of the participant.

Transition of HCBS to Community Oriented Recovery & Empowerment (CORE) Services

To improve access to services, on February 1, 2022, New York State transitioned four HCBS to a new service array called Community-Oriented Recovery and Empowerment (CORE) Services. These services include Community Psychiatric Support and Treatment (CPST); Psychosocial Rehabilitation (PSR); Family Support and Training (FST); and Empowerment Services-Peer Support (Peer Support). In addition, HCBS Short-term and Intensive Crisis Respite Services were transitioned to the Crisis Intervention Benefit Crisis Residence services.

HCBS Admission Criteria:

All of the following criteria must be met:

- 1. The customer must be deemed eligible to receive HCBS using the HCBS Eligibility Assessment tool.
- 2. Where the customer has been deemed eligible to receive services, a Level of Service Determination is made to ensure recommended HCBS are appropriate for meeting the customer's identified goals, and appropriate HCBS provider(s) are identified in a conflict-free manner.

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- 3. Upon receipt of notification from the HCBS provider(s), up to 3 visits over 14 days is authorized for intake and evaluation.
- 4. The BH Prior and/or Continuing Authorization Request Form is submitted by the HCBS provider(s) for Prior Authorization and includes service scope, duration, and frequency.
- 5. The service request must support the customer's efforts to manage their condition(s) while establishing a purposeful life and sense of membership in a broader community.
- 6. The customer must be willing to receive home and community-based services.
- 7. There is no alternative level of care or co-occurring service that would better address the customer's clinical needs.

HCBS Continued Stay Criteria:

All of the following criteria must be met:

- 1. Customer continues to meet admission criteria and an alternative service would not better serve the customer.
- 2. Interventions are timely, need based as per the CMHA (Full Assessment), consistent with evidence based/best practice, and provided by a designated HCBS provider.
- 3. Customer is making measurable progress towards a set of clearly defined goals; Or There is evidence that the service plan is modified to address the barriers in treatment progression; Or Continuation of services is necessary to maintain progress already achieved and/or prevent deterioration.
- 4. There is care coordination with physical and behavioral health providers, State, and other community agencies.
- 5. Family/guardian/caregiver is participating in treatment where appropriate. In addition, determination of progress and modifications to goals/objectives are made by reviewing the BH HCBS Prior and/or Continuing Authorization Request Form and/or with a telephonic review with the provider.

HCBS Discharge Criteria:

Criteria #1, 2, 3, 4, or 5 are suitable; criteria #6 is recommended, but optional:

- 1. Customer no longer meets admission criteria and/or meets criteria for another more appropriate service, either more or less intensive.
- 2. Customer or parent/guardian withdraws consent for treatment.
- 3. Customer does not appear to be participating.
- 4. Customer's needs have changed, and current services are not meeting these needs. Customer's self-identified recovery goals would be better served with an

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alternate service and/or service level. As a component of the expected discharge, alternative services are being explored in collaboration with the customer, the customer's family members (if applicable), Health Home, HCBS provider, and MVP.

- 5. Customer's goals have been met.
- 6. Customer's support system is in agreement with the aftercare service plan.

References (Updated 2024)

 New York State Office of Mental Health Office of Alcoholism and Substance Abuses Services – Home and Community Based Services – Review Guidelines and Criteria December 2, 2016 Available: https://www.omh.ny.gov/omhweb/bho/docs/hcbs-utilization-man-guide.pdf

New York State Office of Mental Health Office of Alcoholism and Substance Abuses Services – Community Oriented Recovery and Empowerment Services Benefit and Billing Guidance, Updated April 1, 2022 Available: https://omh.ny.gov/omhweb/bho/core/core-benefit-and-billing-guidance.pdf

Customer Product	Management Requirements*
New York Products	
HMO	Not a Covered Benefit
PPO in Plan	Not a Covered Benefit
PPO OOP	Not a Covered Benefit
POS in Plan	Not a Covered Benefit
POS OOP	Not a Covered Benefit
Essential Plan	Not a Covered Benefit
MVP Medicaid Managed Care	Not a Covered Benefit
MVP Child Health Plus	Not a Covered Benefit
MVP Harmonious Health Care Plan	Prior Authorization
MVP Medicare Complete Wellness	Not a Covered Benefit
MVP Medicare Preferred Gold HMO POS	Not a Covered Benefit
MVP Medicare Secure HMO POS	Not a Covered Benefit
MVP Medicare Secure Plus HMO POS	Not a Covered Benefit
MVP Medicare WellSelect PPO	Not a Covered Benefit
MVP Medicare WellSelect Plus PPO	Not a Covered Benefit
MVP Medicare Patriot Plan	Not a Covered Benefit
MVP DualAccess D-SNP HMO	Not a Covered Benefit
MVP DualAccess Complete D-SNP HMO	Not a Covered Benefit
MVP DualAccess Plus D-SNP HMO	Not a Covered Benefit
UVM Health Advantage Select PPO	Not a Covered Benefit
USA Care	Not a Covered Benefit
Healthy NY	Not a Covered Benefit
MVP Premier	Not a Covered Benefit
MVP Premier Plus	Not a Covered Benefit
MVP Premier Plus HDHP	Not a Covered Benefit
MVP Secure	Not a Covered Benefit
MVP EPO	Not a Covered Benefit
MVP EPO HDHP	Not a Covered Benefit
MVP PPO	Not a Covered Benefit
MVP PPO HDHP	Not a Covered Benefit
Student Health Plans	Not a Covered Benefit Not a Covered Benefit
ASO	Not a Covered Benefit Not a Covered Benefit
Vermont Products	Not a Covered Bellent
	Net - Coursed Barrefit
POS in Plan	Not a Covered Benefit
POS OOP	Not a Covered Benefit
MVP Medicare Preferred Gold HMO POS	Not a Covered Benefit
MVP Medicare Secure Plus HMO POS	Not a Covered Benefit
MVP VT HMO	Not a Covered Benefit
MVP VT HDHP HMO	Not a Covered Benefit
MVP VT Plus HMO	Not a Covered Benefit
MVP VT Plus HDHP HMO	Not a Covered Benefit
MVP Secure	Not a Covered Benefit
ASO	Not a Covered Benefit

[♦] Note: Prior authorization requirements for HDHP products are the same as the base product (e.g., HDHP HMO auth requirements are the same as listed for HMO).

*Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

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Revision History:

12/01/2021 - Annual Review with no changes to the indications or criteria.

05/02/2022 - Policy updated to reflect HCBS benefits regulated by NYS.

06/01/2024 – Annual Review. Policy updated to reflect transition of Community Rehabilitation Services, Psychosocial Rehabilitation (PSR), Community Psychiatric Support and Treatment (CPST), Short-Term Crisis Respite Services, Empowerment Services, and Family Support and Training to core services.



MVP Health Care Behavioral Health Medical Necessity Criteria

Home and Community Based Services (HCBS) - Children's

Type of Policy: Behavioral Health

Prior Approval Date: 08/03/2024

Provisional Approval 06/25/2025

Date:

Provisional Effective 06/01/2025

Date:

Related Polices: Assertive Community Treatment (ACT)

Home and Community Based Services

Children's Family Treatment and

Support Services (CFTSS)

Personalized Recovery Oriented

Services (PROS)

Codes Requiring Authorization

Authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

Home and Community Based Services (HCBS) require authorization for Medicaid Managed Care and Child Health Plus Plans for children ages 0-20 only.

90832, TJ- Psychotherapy, 30 minutes with patient

97124, TJ - Therapeutic procedure, 1 or more areas, each 15 minutes; massage, including effleurage, petrissage and/or tapotement (stroking, compression, percussion)

99347, TJ - Home or residence visit for the evaluation and management of an established patient

H2014, HA, UK, UN, UP - Skills training and development, per 15 minutes

H2015, HA, UN, UP - Comprehensive community support services, per 15 minutes

H2023, HA - Supported employment, per 15 minutes

T2015, HA, UN, UP - Habilitation, prevocational, waiver; per hour

T2020, HA, UN, UP - Day habilitation, waiver; per diem

S5150, HA, HQ - Unskilled respite care, not hospice; per 15 minutes S5151, HA - Unskilled respite care, not hospice; per diem

Codes Requiring Retrospective Review

N/A

Common Procedure Codes

CPT Codes: N/A

HCPCS Codes: N/A

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

Children's Home and Community Based Services (CHCBS) are community-based services to prevent the need for institutional care such as psychiatric hospitalization, residential treatment, or nursing home admission, or to assist the participant to return to their home and community after discharge from an institutional level of care. To be eligible for Children's Waiver HCBS, participants must have a medical condition, developmental disability, and/or serious mental health disorder that impacts their daily functioning and that places them at imminent risk of hospitalization or institutionalization, or results in the need for supports to return safely home and to their community after discharge from an institutional level of care. All services must be provided based on the participant's assessed needs and goals and must be necessary to assist a waiver participant to avoid institutionalization and function in the community.

CHCBS services include:

- Day Habilitation
- Caregiver/Family Advocacy and Supports Services
- Respite
 - o Planned
 - Crisis
- Prevocational Services
- Supported Employment
- Non-Medical Transportation
- Adaptive and Assistive Technology

- Vehicle Modifications
- Environmental Modifications
- Community Habilitation
- Palliative Care
 - Expressive Therapy (art, music, and play)
 - Massage Therapy
 - Counseling and Support Services
 - Pain and Symptom Management

Limitations/Exclusions

MVP utilizes the NYS eligibility guidelines for medical necessity and continuously updates requirements and assessment processes based on those guidelines.

Waiver services complement and/or supplement the services that are available through the Medicaid State plan and other federal, state and local public programs, as well as the supports that families and communities provide to individuals, and when applicable, third-party insurance coverage. HCBS cannot duplicate or replace services otherwise available to the participant, including services available through the Medicaid State Plan, Section 110 of the Rehabilitation Act of 1973 (Rehabilitation Act), the Individuals with Disabilities Education Act (IDEA), private insurance, or Medicare. HCBS are not an appropriate substitute for medically necessary care covered under the state plan such as Early Intervention (EI), Applied Behavior Analysis (ABA) therapy, mental health assessment and treatment, physical therapy, occupational therapy, speech therapy, personal care assistance, and private duty nursing.

Rehabilitation services, which are services intended to restore and improve skills and function that have been lost or impaired, are available as State Plan services. Habilitation Services available under the Children's Waiver, which are intended to help individuals with intellectual/developmental disabilities acquire, retain, and improve skills are not appropriate substitutes for rehabilitation services authorized under the State Plan.

Children's HCBS is not billable when provided while another billable Medicaid service is provided, except in limited circumstances. Services that are substantively equivalent but cover care gaps because the procedures or form of that service is different in parameters such as time, quantity or acuity of service may be an exception. This is only permissible when HCBS is not duplicative in any way of the other services being provided. For example, it is not appropriate for Respite to be provided while the participant is receiving another service that includes general supervision of the child in the caregiver's absence, such as applied behavior analysis, or personal care assistance. It is not appropriate for habilitation services to be provided/billed at the same time that a child is receiving some form of medically necessary therapy. However, it may be

appropriate for a child to receive palliative care while also receiving private duty nursing services. HCBS providers must coordinate with the care manager and family to ensure services are coordinated to avoid duplication and ensure appropriate scheduling of services. When it is necessary for the participant to receive more than one service simultaneously, the rationale must be documented in the member's record or plan of care, explaining the need for a combination of services and how the services complement each other.

When appropriate and necessary during HCBS delivery, direct care workers may attend to the participant's medical and non-medical needs and other ADLs which would ordinarily be performed by a caregiver or family member. However, unlicensed direct care workers are not permitted to utilize medical equipment, administer medications, or utilize medical devices without appropriate training by a licensed professional. If requested by the family, determined appropriate by a clinician, and approved by the designated HCBS agency, an appropriately licensed professional such as a registered nurse, physical therapist, or occupational therapist may provide training to the direct care staff member to provide limited medical supports that do not require licensure. Documentation of staff training must be maintained in the participant/staff record. All services must be provided in alignment with the service definition.

Some HCBS allow for both an Individual and Group modality. Group and Individual billing for the same service cannot overlap.

Services cannot be provided during school hours to participants attending school. Additionally, Children's HCBS is not a substitute for parenting, babysitting, childcare, or generalized supervision. HCBS must be provided in a professional capacity with a clearly defined need that exceeds general childcare needs. HCBS does not replace the role of the parent/caregiver in fostering skill development essential to typical child development.

Children's HCBS cannot duplicate or replace the role of the participant's care manager. Additional details on limitations/exclusions and utilization are provided in each of the service-specific sections below. The anticipated utilization ranges in each of the service-specific sections below are provided as a guideline to assist in developing the HCBS Service Plan and is not a guaranteed or appropriate for all HCBS participants. Frequency of services may be different for participants in school versus participants who have graduated/aged out of school settings and must take into consideration the participant's age, development, and condition, along with the participant's other appointments and activities. MVP case manager and children's medical director will follow NYS guidelines to determine medical necessity. Please see NYS Children's Waiver Home and Community-Based Services (HCBS) Service Definitions and Necessity Criteria Policy to determine certification/provider qualifications and individual staff qualifications.

Service Admission Requirements

HCBS may only be provided when the following criteria are met:

- The participant was found HCBS eligible by a Health Home Care Manager (HHCM), Children and Youth Evaluation Service (C-YES) assessor, or an allowed Office of Mental Health Single Point of Access through conducting the HCBS Eligibility Determination. The HCBS Eligibility Determination is active within 365 days from being completed.
 - o The Participant has active K-codes.
 - o The participant is enrolled in care management either through HHCM or C-YES.
- The need for the service has been assessed, determined, and authorized in alignment with the service definition as part of the person-centered planning process.
- The service is identified in the participant's Service Plan and Plan of Care and is associated with specific attainable goal(s) and outcome(s) to enhance the participant's ability to remain in the home/community. 12
- A referral for HCBS that outlines the assessed needs and goals of the participant and the requested service, has been made to a designated HCBS provider from a HHCM/C-YES.

When making a referral for HCBS, the care manager must explain the types of services recommended and provide the participant/family with the applicable HCBS Service Information Sheet. The care manager must document in the participant's record that this information was provided.

Service Necessity Documentation

Prior to any HCBS delivery, the HCBS provider must receive a referral from the participant's HH/C-YES care manager. It is the responsibility of the HCBS provider to evaluate the referral for appropriateness and confirm the participant's eligibility prior to delivery of any HCBS. After determining appropriateness, the HCBS provider can provide HCBS for the Initial Service Period. The Initial Service Period is the period of time after accepting an HCBS referral but prior to submitting an HCBS Authorization Request lasting up to 96 units/24 hours or 60 days (whichever comes first). The Initial Service Period begins on the first date of billable service for the participant and is service specific. The Initial Service Period is used to complete an intake assessment, to finalize service goals and objectives, and determine Frequency/Scope/Duration (F/S/D) for the service. If the service is needed beyond the Initial Service Period, an HCBS Authorization is needed.

The HCBS provider must maintain documentation that clearly substantiates the need for services to support the participant remaining in the home/community and must support the proposed frequency, scope, and duration of the service. The HCBS provider should

work with the participant's other involved care professionals and the care manager to obtain documentation to support the proposed level of service provision and appropriateness for the type and amount of service being offered to meet the participant's identified need and goals. This may include assessments completed by the HCBS provider or a licensed professional, applicable evaluations conducted by a licensed practitioner, test results, diagnoses from licensed practitioners, school information, documentation of presenting problem(s), and/or demonstration of functional limitations. Documentation may vary by service and by participant but may include any intake evaluation/assessments completed by the provider, documentation from a licensed professional working with the participant indicating the need for services, and/or other evaluations outlining the participant's needs. Ongoing service progress notes should illustrate service necessity by outlining interventions utilized to meet the goals/objectives, responses from the participant/family, progress made towards goals, and ongoing communication with the care manager and other service providers.

Service utilization that exceeds the service limits (i.e., annual, monthly, daily, dollar amount) is expected to be rare, temporary, and must be necessary to prevent institutionalization and support the participant remaining in the home/community. As outlined in the Documentation Policy, service authorization requests in excess of the service limits must be justified by documentation from a third-party involved in the member's care demonstrating this need. Third-party entities are entities external to the HCBS provider, the care management agency, and the Health Home, or if this documentation is provided by a clinician within the same organization as the HCBS provider or care manager, there are firewalls between the HCBS/care management functions and the clinician, consistent with the principles of Conflict-Free Case Management (CFCM). Additionally, there must be documentation in the case record that the multidisciplinary care team has determined a need for HCBS in excess of the service limits to prevent institutionalization, determined whether other services are appropriate, and has established a plan to monitor the participant's progress.

HCBS providers must develop and maintain a Service Plan for all HCBS provided. If a participant receives multiple HCBS, the goals for each service must be distinctly different from goals associated with other HCBS provided. Additional details about Service Plan and documentation requirements can be found in the Provider Service Delivery Documentation Policy for Children's HCBS.

HCBS providers should maintain documentation in the record to justify ongoing delivery of HCBS. This includes documentation of goals that have been accomplished through services so far, what is still needed to be accomplished, and what barriers are impacting participant outcomes, if applicable, as well as how these barriers are/will be resolved. The Service Plan must be updated to modify ongoing goals and timeframe and the care

manager/HCBS provider is responsible for maintaining documentation that ongoing services are necessary.

Continued Stay and Discharge Criteria

Ongoing delivery of HCBS is appropriate when the participant remains Waiver eligible and either of the following criteria are met:

- the participant/family is making progress but has not fully reached established service goals and there is a reasonable expectation that continued services will increase the likelihood of the participant meeting the service goals, or
- the participant is at risk of losing skills gained if the service is not continued. Discharge from an HCBS is appropriate when any of the following apply:
- Participant/family has successfully met their specific goal outlined in their Service Plan and no longer needs the service, OR
- Participant no longer meets Children's Waiver eligibility criteria, transitions to OPWDD waiver services, or is admitted to an excluded residential or institutional setting, OR
- Participant/family no longer wishes to receive the service or withdraws consent for the service, or transitions to other more appropriate services, OR
- Participant is no longer engaged in the service despite multiple attempts on the part of the provider to apply reasonable engagement strategies.

MVP will use the HCBS Eligibility Determination within the Uniform Assessment System (UAS) to confirm HCBS eligibility. In addition, Health Home Care Managers will continue to use the comprehensive Child and Adolescent Needs and Strengths New York (CANS-NY) assessment tool to support person-centered service planning for HCBS eligible children/youth. The following is a description of the various CHCBS services:

1) Day Habilitation:

Assistance with acquisition, retention or improvement in self-help, socialization and adaptive skills necessary to support age-appropriate Activities of Daily Living (ADLs), Instrumental Activities of Daily Living (IADLs) including communication, and travel that regularly takes place in a non-residential setting, separate from the person's private residence or other residential arrangement. Activities and environments are designed to foster the acquisition of skills, appropriate behavior, greater independence, community inclusion, relationship building, self-advocacy, and informed choice. Day Habilitation (DH) services are provided **only** at locations certified by OPWDD to provide site-based Day Habilitation typically between the hours of 9am and 3 pm. Day Habilitation Without Walls (i.e. Day Habilitation that takes place outside of a site-based setting) is not a component of Children's Waiver Day Habilitation.

Limitations/Exclusions

Group and Individual DH cannot be billed as overlapping services. Any child receiving HCBS under this waiver may receive this service. Service necessity criteria for this service requires that the child must have a developmental delay justifying the need for the provision of Day Habilitation, but the child may meet NF, ICF/IID, or Hospital LOC.

Day Habilitation services will not include funding for direct, hands-on physical therapy, occupational therapy, speech therapy, nutrition, or psychology services.

Children have a maximum daily amount of services that are available to individuals based upon their residence. Individuals residing in certified settings are limited to a maximum of six hours of non-residential services (or its equivalent) which must commence no later than 3 pm on weekdays. Day Habilitation Services are limited to 6 hours (24 units) per day (all Day Habilitation combined), 12 hours (48 Units) per month (all Day Habilitation Combined), and 144 hours (576 Units) per calendar year (all Day Habilitation Combined). However, not all participants will require this level of support. Frequency, scope, and duration of the service must be necessary to support the participant remaining in the home or community.

Supplemental DH services are those services provided on weekends and/or on weekdays with a service start time after 3 pm. Supplemental DH services are not available to individuals residing in certified residential settings with paid, professional staff, because the certified residential habilitation provider is responsible for the habilitation needs of the individual on weekday evenings and anytime on weekends.

Ages 0 through 6

• Anticipated Utilization: 0 hours (0 units) per month (all Day Habilitation combined), 25 At this age skill building needs are typically met through parental support/natural caregivers and use of services such as Early Intervention (EI), Preschool Supportive Health services, School Supportive Health services, or other educational/school programs. Services necessary at this age typically are provided by licensed practitioners including Licensed Behavior Analyst, Occupational Therapists, Physical Therapist, and Speech Therapists.

Ages 7 through 13

• Anticipated Utilization: 0-6 hours (24 units) per month (all Day Habilitation Combined) At this age, Day Habilitation typically involves reinforcing skills, behaviors, or lessons taught in other settings, supporting skill development and retention. It may include reinforcing or practicing skills and abilities associated with physical, occupational, or speech therapies, if the direct support provider is appropriately trained. It may also include supports with time management, hygiene, and organization for school and home life or supports for developmentally

appropriate independence, when not available through BOCES, or other school/community programming.

Ages 14 through 20

• Anticipated Utilization: 0-12 hours (48 units) per month (all Day Habilitation Combined) At this age, Day Habilitation typically involves skill development, with a focus on independence/life skills (not to replace prevocational service), when not available through BOCES, or other school/community programming. It may also include supports with time management, hygiene, and organization for school and home life.

Authorization

Authorization is not required for assessment visits within 60 days of the initial visit (up to 96 units or 24 total hours of service). Authorization is required for services after the assessment visits.

2) Caregiver/Family Advocacy and Support Services:

Caregiver/Family Advocacy and Support Services enhance the child/youth's ability, regardless of disability (developmental, physical, and/or behavioral), to function as part of a caregiver/family unit and enhance the caregiver/family's ability to care for the child/youth in the home and/or community. Family is broadly defined, and can include families created through birth, foster care, adoption, or a self-created unit.

Caregiver/Family Advocacy and Support Services (CFASS) are short-term interventions to train, coach, and educate the enrolled participant's caregivers and family related to the medical, physical, developmental, or behavioral health condition that puts them at risk of institutionalization. These temporary services develop and implement strategies and interventions that will result in the reduction of stress associated with caring for the child/youth's complex needs while building resilience to better care for the child/youth. These services will also assist the participant, family/caregiver, and collateral contacts in understanding and addressing the participant's needs related to their condition(s) or disability(ies) that put them at risk of institutionalization.

Caregiver/Family Advocacy and Support Services enhance the participant's ability to function as part of a caregiver/family unit and community at-large; and enhance the caregiver/family's ability to care for the participant in the home and/or community and provides the participant, family, caregivers, and collateral contacts (family members, caregivers, and other stakeholders identified on the participant's POC) with techniques and information so that they can better respond to the needs of the participant and reduce the risk of institutionalization.

Note: this service is not the State Plan service of Family Peer Support Services which must be delivered by a certified/credentialed Family Peer with lived experience.

Limitations/Exclusions

- This service cannot be delivered nor billed while an enrolled child is in an ineligible setting, including hospitalization
- Special education and related services that are otherwise available to the individual through a local educational agency, under the provisions of the Individuals with Disabilities Education Act (IDEA)
- Caregiver/Family Advocacy and Support Services (CFASS) is limited to 6 hours (24 units) per day (all CFASS combined), 12 hours (48 Units) per month (all CFASS combined), and 144 hours (576 Units) per calendar year (all CFASS combined).
 However, not all participants will require this level of support. Frequency, scope, and duration of the service must be necessary to support the participant remaining in the home or community.

Ages 0 through 8

• Anticipated Utilization: 0-12 hours (48 units) per month (all CFASS combined) At this age, CFASS typically involves training, education, and coaching to the caregivers, family members, collaterals regarding the specific needs of the participant. CFASS goals/objectives should be specific to the caregivers', family members', and collaterals' education and training regarding the identified needs. This type of training and support provided to a participant is not generally appropriate for children under the age of 9.

Ages 9 through 20

• Anticipated Utilization: 0-12 hours (48 units) per month (all CFASS combined) At this age, CFASS may involve training, education, and coaching of the caregivers, family members, collaterals, or the participant regarding the specific needs of the participant.

Authorization

Authorization is not required for assessment visits within 60 days of the initial visit (up to 96 units or 24 total hours of service). Authorization is required for services after the assessment visits.

3) Respite:

This service provides short-term assistance to families of participants because of the absence of or need for relief of the participant or the participant's family caregiver. HCBS respite provides short-term relief for primary caregivers who are responsible for parenting participants with significant medical, physical, developmental, or behavioral health needs that put the participant at risk of institutionalization. Respite enhances the family or primary caregiver's ability to support the participant's functional, developmental, behavioral health, and/or health care needs. Additionally, respite helps

build stability in the family unit by avoiding disruptions in a participant's home environment and supporting the family in being able to care for the participant at home.

Respite workers provide appropriate temporary care and supervision to protect the participant's safety in the absence of family members or caregivers and engage the participant in participant-centered care directly related to the participant's unique abilities and circumstances. It is important that the respite worker has a knowledge of and understanding of the participant's particular needs and abilities to provide activities that support his/her and/or primary caregiver/family's constructive interests and abilities. Respite providers regularly communicate with other providers to maintain familiarity with the participant's goals.

Planned

Planned Respite services provide planned short-term relief for the child or family/primary caregivers to enhance the family/primary caregiver's ability to support the child/youth's functional, developmental, behavioral health, and/or health care needs. The service is direct care for the child/youth by individuals trained to support the child/youth's needs. This support may occur in short-term increments of time (usually during the day) or on an overnight or longer-term increment. Planned Respite activities support the POC goals and include providing supervision and activities that match the child/youth's developmental stage and continue to maintain the child/youth health and safety.

Crisis

Crisis Respite is a short-term care and intervention strategy for children/youth and their families that helps to alleviate the risk for an escalation of symptoms, a loss of functioning, and/or a disruption in a stable living environment. It may be used when challenging behavioral or situational crises occur that the child/youth and/or family/caregiver is unable to manage without intensive assistance and support. Crisis Respite can also be used for crisis intervention or from visiting the emergency room.

Crisis Respite should be included on the POC to the extent that it is an element of the crisis plan or risk mitigation strategy.

Crisis Respite services may be delivered in a home or residence by qualified practitioners, out-of-home/residence by staff in community-based sites, or in allowable facilities. Services offered may include site-based crisis residence, monitoring for high-risk behavior, health and wellness skill building, wellness activities, family/caregiver support, conflict resolution, and other services as needed.

Ongoing communication between child/youth or the family/primary caregiver receiving crisis respite for their child, the crisis respite staff, and the child/youth's established behavioral health and health care providers is required to assure

collaboration and continuity in managing the crisis situations and identifying subsequent support and service needs.

At the conclusion of a Crisis Respite period, crisis respite staff, together with the child/youth and family/primary caregiver, and his or her established behavioral health or health care providers when needed, will make a determination as to the continuation of necessary care and make recommendations for modifications to the child's POC. Children are encouraged to receive Crisis Respite in the most integrated and cost-effective settings appropriate to meet their respite needs. Out-of-home Crisis Respite is not intended as a substitute for permanent housing arrangements.

• Overnight Respite

Overnight Respite is defined as Respite services provided to a person on two consecutive days when Respite staff are providing supervision of a participant during nighttime hours. Overnight Respite may be used to enhance the family/primary caregiver's ability to support the participant's functional, developmental, behavioral health, and/or health care needs or to help alleviate the risk for an escalation of symptoms, a loss of functioning, and/or a disruption in a stable living environment by giving the caregiver a break for caring for a child with complex needs.

HCBS providers must have clear documentation for the need of overnight respite and the risk being alleviated by overnight respite. 37 Note: Utilization of overnight respite for supervision "in case" there is a situation or if the participant has elopement concerns is not an appropriate use of overnight respite.

Limitations/Exclusions

Services to participants in foster care must comply with Part 435 of 18 NYCRR. When HCBS respite is provided for the relief of a foster care provider, foster care respite services may not also be billed for the same time period. However, should additional respite in excess of foster care respite be necessary to meet needs of the participant or caregiver, due to the child's complex condition, HCBS respite may be utilized. Respite is not an allowable substitute for permanent housing arrangements. Participants living independently are not eligible to receive Respite. Respite is not a substitute for routine childcare. In scenarios where the parent/caregiver otherwise routinely needs childcare (e.g., during their workday if they work apart from their child), respite is not permitted. If provided before and/or after school, the need for Respite must be documented: why the service will be provided in the morning (before school) and in the afternoon (after school). Respite cannot be connected to the caregiver's work schedule. Respite is not an allowable substitute for medically necessary care or treatment in a residential or institutional setting. For instance, although an OMH licensed Children's Crisis Residence can be used for HCBS Respite services, HCBS respite should only be billed if a child does not otherwise meet admission criteria for the Crisis Residence service. If the child meets

the admission criteria for the Crisis Residence, they must be admitted to the Crisis Residence and the service must be billed under the Crisis Residence benefit. Respite workers may attend to the participant's medical and non-medical needs and other ADLs which would ordinarily be performed by a caregiver or family member. However, unlicensed Respite workers are not permitted to utilize medical equipment, administer medications, or utilize medical devices without appropriate training by a licensed professional. If requested by the family, determined appropriate by a clinician, and approved by the designated Respite agency, an appropriately licensed professional such as a registered nurse, physical therapist, or occupational therapist may provide training to the Respite staff member to provide limited medical supports that do not require licensure. Documentation of staff training must be maintained in the participant/staff record. Some examples of care that Respite workers for medically fragile participants can provide include turning and repositioning youth with limited mobility, and assistance with home exercise plan as guided by a therapist (OT, PT, ST, etc.). These activities are only permissible if provided for the sole purpose of supporting the participant's needs while providing a break to the primary caregiver. 40 Payment may not be made for Respite provided at the same time when other services that include care and supervision are provided. For example, a provider may not bill for community habilitation and respite provided to the same participant at the same time. Both services can be billed on the same date, but only if they are provided at different times that do not overlap during the day. Respite Services are limited to 28 hours per month (all Respite combined), and 336 hours per calendar year (all Respite combined). However, not all participants will require this level of support. Frequency, scope, and duration of the service must be necessary to support the participant remaining in the home or community. When Respite is provided simultaneously to another Medicaid service, documentation must be present in the record to indicate the rationale/justification for service delivery in this manner.

Ages 0 through 6

• Anticipated Utilization: 0-6 hours per month (all Respite combined). At this age, Respite services typically involve provision of a planned break to assist in managing an identified need for relief from stressors of caring for a child with complex needs.

Ages 7 through 17

• Anticipated Utilization: 0-28 hours per month (all Respite combined). At this age, Respite services typically involve provision of a planned break to assist in managing an identified need for relief from stressors of caring for a child with complex needs who requires supervision.

Ages 18 through 21

• Anticipated Utilization: 0-15 hours per month (all Respite combined). At this age, Respite services typically involve provision of a planned break to assist in managing

an identified need for relief from stressors of caring for a youth with complex needs who requires supervision.

Authorization

- Planned: Authorization is required after 7 consecutive days of service.
- Crisis: Authorization is not required for Crisis Respite.

4) Prevocational Services:

Prevocational Services are individually designed to prepare a youth (age 14 up to 21) to engage in paid work, volunteer work, or career exploration. Prevocational Services are not job-specific, but rather are geared toward facilitating success in any work environment for youth whose disabilities do not permit them access to other prevocational services. The service will be reflected in youth's POC and must be directed to teaching skills rather than explicit employment objectives. In addition, Prevocational Services assist with facilitating appropriate work habits, acceptable job behaviors, and learning job production requirements.

Prevocational Services may include volunteer work, such as learning and training activities that prepare a person for entry into the paid workforce. Prevocational Services should enable each participant to attain the highest level of work in the most integrated setting and with the job matched to the participant's interests, strengths, priorities, abilities, and capabilities, while following applicable federal wage guidelines from the U.S. Department of Labor. Services are intended to develop and teach general skills. Examples include, but are not limited to:

- Ability to communicate effectively with supervisors, co-workers, and customers
- Generally accepted community workplace conduct and dress
- Ability to follow directions
- Ability to attend to and complete tasks
- Punctuality and attendance
- Appropriate behaviors in and outside the workplace
- Workplace problem solving skills and strategies
- Mobility training
- Career planning
- Proper use of job-related equipment and general workplace safety

Prevocational Services include activities that are not primarily directed at teaching skills to perform a particular job, but at underlying habilitative goals (e.g., attention span, motor skills, interpersonal relations with co-workers and supervisors) that are associated with building skills necessary to perform work and optimally to perform competitive, integrated employment.

Resume writing, interview techniques, role play, and job application completion

- Exploring career options, facilitating appropriate work habits, acceptable job behaviors, and learning job production requirements
- Assisting in identifying community service opportunities that could lead to paid employment
- Helping the youth to connect their educational plans to future career/vocational goals
- Helping youth to complete college, technical school, or other applications to continue formal education/training
- Helping youth to apply for financial aid or scholarship opportunities

Documentation is maintained that the service is not available under a program funded under Section 110 of the Rehabilitation Act of 1973 or the IDEA (20 U.S.C. 1401 et seq.).

Limitations/Exclusions

Documentation is maintained that the service is not available under a program funded under Section 110 of the Rehabilitation Act of 1973 or the IDEA (20 U.S.C. 1401 et seq.).

Prevocational services will not be provided to an HCBS participant if:

- Special education and related services that are otherwise available to the individual through a local educational agency, under the provisions of the Individuals with Disabilities Education Act (IDEA)
- Vocational rehabilitation services that are otherwise available to the individual through a program funded under section 110 of the Rehabilitation Act of 1973 (Access VR)
- Vocational services that are provided in facility-based work settings that are not integrated settings in the general community workforce.

Prevocational Services are limited to 2 hours (8 units) per day, 10 hours (40 units) per month, and 120 hours (480 units) per calendar year (all Prevocational combined). However, not all participants will require this level of support. Frequency, scope and duration of the service must be necessary to support the participant remaining in the home or community.

Ages 0 through 13

• Anticipated Utilization: 0 hours (0 units) (all Prevocational combined). This service is not billable for individuals in this age group.

Ages 14 through 20

• Anticipated Utilization: 0-10 hours (40 units) per month (all Prevocational combined). At this age, Prevocational services typically involve provision of curriculum-based services geared toward assisting the participant in obtaining employment.

Authorization

Authorization is not required for assessment visits within 60 days of the initial visit (up to 96 units or 24 total hours of service). Authorization is required for services after the assessment visits.

5) Supported Employment:

Supported Employment services are individually designed to prepare youth with disabilities (age 14 up to 21) to engage in paid work. Supported Employment services provide assistance to participants with disabilities as they perform in a work setting.

Supported Employment provides ongoing supports to participants who, because of their disabilities, need intensive on-going support to obtain and maintain an individual job in competitive or customized employment, or self-employment, in an integrated work setting in the general workforce for which an individual is compensated at or above the minimum wage, but not less than the customary wage and level of benefits paid by the employer for the same or similar work performed by individuals without disabilities. The outcome of this service is sustained paid employment at or above the minimum wage in an integrated setting in the general workforce, in a job that meets personal and career goals.

Supported Employment services are individualized and may include any combination of the following services: vocational/job-related discovery or assessment, person-centered employment planning, job placement, job development, negotiation with prospective employers, job analysis, job carving, training and systematic instruction, job coaching, benefits support, training and planning, transportation, career advancement services, and other workplace support services including services not specifically related to job skill training that enable the participant to successfully integrate into the job setting.

Supported Employment services may also include services and supports that assist the participant in achieving self-employment through the operation of a business including home-based self-employment. However, Medicaid funds are not used to defray the expenses associated with starting up or operating a business.

In addition to the need for an appropriate job match that meets the individual's skills and interests, individuals may also need long term employment support to successfully maintain a job due to the ongoing nature of the HCBS participant's support needs, changes in life situations, or evolving and changing job responsibilities.

Limitations/Exclusions

Medicaid funds may not be used to defray the expenses associated with starting up or operating a business.

Supported Employment service will not be provided to an HCBS participant if:

- Special education and related services that is otherwise available to the individual through a local educational agency, under the provisions of the Individuals with Disabilities Education Act (IDEA).
- Vocational rehabilitation services that are otherwise available to the individual through a program funded under section 110 of the Rehabilitation Act of 1973.
- Supported employment does not include facility based, or other similar types of vocational services furnished in specialized facilities that are not a part of the general workplace.
- Supported employment does not include payment for supervision, training, support, and adaptations typically available to other workers without disabilities filling similar positions in the business.
- Supported employment does not include volunteer work. Such volunteer learning and unpaid training activities that prepare a person for entry into the paid workforce are addressed through Pre-Vocational services.

Medicaid funding cannot be claimed for incentive payments, subsidies, or unrelated vocational training expenses such as the following:

- Incentive payments made to an employer to encourage or subsidize the employer's participation in supported employment; or
- Payments that are passed through to users of supported employment services.

Supported employment is limited to three hours per day.

Authorization

Authorization is not required for assessment visits within 60 days of the initial visit (up to 96 units or 24 total hours of service). Authorization is required for services after the assessment visits.

6) Non-Medical Transportation:

Non-Medical Transportation services are offered, in addition to any medical transportation furnished under the 42 CFR 440.17(a) in the State Plan. Non-Medical Transportation services are available for individuals to access authorized HCBS and destinations that are related to a goal included on the child/youth's POC.

Examples where this service may be requested include transportation to: HCBS that a child/youth was determined eligible to receive, a job interview, college fair, a wellness seminar, a GED preparatory class, etc. This service will be provided to meet the child/youth's needs as determined by an assessment performed in accordance with the State's requirements and as outlined in the child/youth's POC.

The care manager must document a need for transportation to support an individual's identified goals. The Health Home Care Manager will include justification for this service within the Person-Centered POC. For individuals not enrolled in a Health Home, the Independent Entity or MCO Care Manager will be responsible for completing

documentation of which goals in an individual's POC to which the trips will be tied. For each participant utilizing Non-Medical Transportation, the Transportation Manager will provide a monthly report of authorized trips to the State.

Limitations/Exclusions

Generally, the same rules used to determine reimbursement of trips to medical appointments should be followed when considering reimbursement of non-medical trips for eligible participants. Only those services not reimbursable under the Community First Choice Option (CFCO) State Medicaid Plan will be reimbursable under the HCBS Waiver.

The following guidelines apply to Non-Medical Transportation:

- Transportation must be tied to a goal in the POC
- Transportation is available for a specified duration
- Individuals receiving residential services are ineligible for Non-Medical Transportation
- Use transportation available free of charge
- Use the medically appropriate mode of transportation
- Travel within the common marketing area
- When possible, trips should be combined
- Justify need for travel outside the common marketing area

Vouchers submitted for personal vehicle mileage reimbursement must be submitted within 90 days of the date of service. Only when there are extenuating circumstances, will the Department allow payment for trips that are submitted after the 90-day time-period. These requests will be considered on a case-by-case basis provided valid justification is given.

Reimbursement for travel can be denied when the destination does not support the participant's integration into the community.

A participant's POC outlines the general parameters of his or her Non-Medical Transportation needs. However, these needs can change or be amended based upon the participant's stated goals and/or successful ongoing integration into the community.

7) Adaptive and Assistive Technology (AT):

Adaptive and Assistive Technology includes but is not limited to: direct selection communicators, alphanumeric communicators, scanning communicators, encoding communicators, speech amplifiers, electronic speech aids/devices; voice activated, light activated, motion activated, and electronic devices; standing boards/frames and therapeutic equipment for the purpose of maintaining or improving the participant's strength, mobility, or flexibility to perform activities of daily living; adaptive switches/devices, meal preparation and eating aids/devices/appliances, specially adapted locks, motorized wheelchairs; guide dogs, hearing dogs, service dogs (as

defined in New York Civil Rights Law Article 47-b(4)), electronic, wireless, solar-powered, or other energy powered devices that demonstrate to the satisfaction of the commissioner, or designee, that the device(s) will significantly enable the participant to live, work, or meaningfully participate in the community with less reliance on paid staff supervision or assistance. Such devices may include computers, observation cameras, sensors, telecommunication screens, and/or telephones and/or other, telecare support services/systems that enable the participant to interact with remote staff to ensure health and safety. Such devices cannot be used for surveillance, but to support the person to live with greater independence including devices to assist with medication administration, including tele-care devices that prompt, teach, or otherwise assist the participant to independently self-administer medication routinely, portable generators necessary to support equipment, or devices needed for the health or safety of the person including stretcher stations.

Limitations/Exclusions

The adaptive and assistive technology available through the HCBS authorities including both CFCO and the HCBS authorities cannot duplicate equipment and/or technology otherwise available through the Medicaid State Plan under 1905(a) of the Social Security Act or other federal/state funding streams. Equipment must be beyond the scope of Durable Medical Equipment (DME).

Adaptive Devices are expected to be a one-time only purchase. Replacements, repairs, upgrades, or enhancements made to existing equipment will be paid if documented as necessary and approved by the State or its designee. Ongoing monitoring associated with telecare support services or other approved systems authorized under this definition may be provided if necessary, for health and safety and documented to the satisfaction of the State or designee. The HHCM, IE or MCO care manager will ensure, that where appropriate, justification from physicians, or other specialists or clinicians has been obtained.

Warranties, repairs, or maintenance on assistive technology only when most cost effective and efficient means to meet the need and are not available through the Medicaid State Plan 1905(a), CFCO, or third-party resources

Cost Limits

The prior authorization review, payment and approval of all Adaptive and Assistive Technology (AT) requests will be managed by the Children's Health Home of Upstate NY (CHHUNY), who will serve as the designated FMS provider, in conjunction with the New York State Department of Health (NYS DOH). Adaptive and Assistive Technology is subject to a \$15,000 per calendar year limit.

8) Vehicle Modifications (VMod)

Modifications include but are not limited to: portable electric/hydraulic and manual lifts, ramps, foot controls, wheelchair lock downs, deep dish steering wheel, spinner knobs, hand controls, parking break extension, replacement of roof with fiberglass top, floor cut outs, extension of steering wheel column, raised door, repositioning of seats, wheelchair floor, dashboard adaptations and other ancillary equipment or modifications necessary to guarantee full access to, and safety in, a motor vehicle.

Limitations/Exclusions

Exclusions may include the purchase, installation, or maintenance of items such as cellular phones, global positioning/tracking devices, or other mobile communication devices; repair or replacement of modified equipment damaged or destroyed in an accident; alarm systems; auto loan payments; insurance coverage; costs related to obtaining a driver's license, title/registration, license plates, emergency road service, or rental vehicles when a vehicle modification is in process.

In most instances a specific type of Vehicle Modification is a one-time benefit to motor vehicles used by the child.

Vehicle Modifications are limited to the primary means of transportation for the child. The vehicle may be owned by the child or by a family member or non-relative who provides primary, consistent, and ongoing transportation for the child. Costs may not exceed current market value of vehicle.

Modification Limits & Authorization

Only those services not reimbursable under the Medicaid State Plan under 1905(a) of the Social Security Act, or other federal/state funding streams will be reimbursable under the HCBS Waiver.

The prior authorization review, approval and payment of all Vehicle Modifications (VMod) will be managed by the Children's Health Home of Upstate NY (CHHUNY), who will serve as the designated Financial Management Services (FMS) provider, in conjunction with the New York State Department of Health (NYS DOH). Contracts for Vehicle modifications may not exceed \$15,000 per calendar year.

9) Environmental Modifications (EMod)

Modifications include but are not limited to: installation of ramps, hand rails, and grab bars; widening of doorways (but not hallways); modifications of bathroom facilities; installation of specialized electric and plumbing systems that are necessary to accommodate the medical equipment and supplies needed for the welfare of the recipient; lifts and related equipment; elevators when no feasible alternative is available; automatic or manual door openers/bells; modifications of the kitchen necessary for the participant to function more independently in his/her home; medically necessary air conditioning; Braille identification systems; tactile orientation systems; bed shaker alarm

devices; strobe light smoke detection and alarm devices; small area drive-way paving for wheel-chair entrance/egress from van to home.

Safe environment modifications for behaviorally challenged participants require the prior review of a behavioral specialist and include window protections, reinforcement of walls, durable wall finishes, open-door signal devices, fencing, video monitoring systems, and shatter-proof shower doors; and future technology devices that allow the participant to live more safely and independently to avoid possible institutional placement or placement in a more restrictive living environment, which are available at a reasonable cost in comparison to living in a more restrictive residential setting. The scope of environmental modifications will also include necessary assessments to determine the types of modifications needed.

Limitations/Exclusions

Excluded are those adaptations or improvements to the home that are of general utility and are not of direct medical or remedial benefit to the child. Adaptations that add to the total square footage of the home's footprint are excluded from this benefit except when necessary to complete an adaptation (e.g., in order to improve entrance/egress to a residence or to configure a bathroom to accommodate a wheelchair). Also excluded are pools and hot tubs and associated modifications for entering or exiting the pool or hot tub.

Modification Limits & Authorization

Prior authorization review, approval and payment for all Environmental Modifications (EMod) will be managed by the Children's Health Home of Upstate NY (CHHUNY), who will serve as the designated Financial Management Services (FMS) provider, in conjunction with the New York State Department of Health (NYS DOH). Contracts for Environmental Modifications may not exceed \$15,000 per calendar year.

10) Community Habilitation:

Community Habilitation covers face-to-face services and supports related to the child's acquisition, maintenance, and enhancement of skills necessary to perform Activities of Daily Living (ADLs), Instrumental Activities of Daily Living (IADLs), and/or Health Related Tasks delivered in the community (non-certified) settings.

Acquisition is described as the service available to a child who is seeking greater independence by learning to perform the task for him or herself. There should be a reasonable expectation that the individual will acquire the skills necessary to perform that task within the authorization period.

Maintenance is described as the service available to prevent or slow regression in the child's skill level and to prevent loss of skills necessary to accomplish the identified task. Enhancement activities are provided to the child through training and demonstration to

promote growth and independence with an already acquired skill level and to support the child's goal outside of the training environment.

ADL, IADL, skill acquisition, maintenance, and enhancement are face-to-face services that are determined by the person-centered planning process and must be identified in the child's Plan of Care (POC) on an individual or group basis. These identified services will be used to maximize personal independence and integration in the community, preserve functioning, and prevent the likelihood of future institutional placement. Skill acquisition, maintenance, and enhancement services are appropriate for children who have the capacity to learn to live in the community, with or without support. Community Habilitation may be delivered in individual or group modality.

Limitations/Exclusions

Please note that this service cannot be substituted for vocational rehabilitation services provided under the Rehabilitation Act of 1973 or other Children's HCBS. Approved settings do not include an OPWDD certified residence, congregate or institutional settings, a social day care or health care setting in which employees of the particular setting care for or oversee the child. Foster Care children meeting LOC may receive these services in a home or community-based setting where they reside that is not an institution. OCFS Licensed Institutions are defined in New York State Social Services law section 427.2(f) as a facility established for the 24-hour care and maintenance of 13 or more children and operated by a childcare agency (Voluntary Foster Care Agency). Only those services not reimbursable under the Community First Choice Option (CFCO) State Medicaid Plan will be reimbursable under this HCBS Waiver.

Children living in certified settings may only receive this service on weekdays with a start time prior to 3 pm. And are limited to a maximum of six (6) hours of non-residential services (or its equivalent) daily. For school-age children, this service cannot be provided during the school day when a child/youth is participating or enrolled in a school program. Time spent receiving another Medicaid service cannot be counted toward the Community Habilitation billable service time. This service cannot be delivered nor billed while a child is in an ineligible setting, such as in a hospital, ICF/IID, or skilled nursing facility. Community Habilitation services provided under this waiver cannot be duplicative or delivered at the same time as services otherwise available to a child through a local educational agency including those services available under the Individuals with Disabilities Education Act (IDEA) or Rehabilitation Act of 1973.

Community Habilitation is limited to 6 hours (24 Units) per day (all Community Habilitation combined), 12 hours (48 Units) per month (all Community Habilitation combined), and 144 hours (576 Units) per calendar year (all Community Habilitation combined). However, not all participants will require this level of support. Frequency, scope, and duration of the service must be necessary to support the participant remaining in the home or community.

Ages 0 through 6

• Anticipated Utilization: (0 units) per month (all Community Habilitation combined), At this age, skill building is typically met through parental support/natural caregivers and use of services such as Early Intervention (EI) and daycare/preschool services. If Habilitative services are necessary at this age, they are typically provided by licensed practitioners including Occupational Therapy, Physical Therapy, and Speech Therapy, not Community Habilitation.

Ages 7 through 13

• Anticipated Utilization: 0-6 hours (24 units) per month (all Community Habilitation combined), At this age, Community Habilitation typically involves reinforcing skills, behaviors, or lessons taught in other settings, supporting skill development and retention when not available through BOCES, or other school/community programming. It may include reinforcing or practicing skills and abilities associated with physical, occupational, or speech therapies, if the direct support provider is appropriately trained, or supports with time management, hygiene, and organization for school and home life, supporting a developmentally appropriate level of independence,

Ages 14 through 20

• Anticipated Utilization: 0-12 hours (48 units) per month (all Community Habilitation combined) 19 At this age, Community Habilitation typically involves supports with time management, hygiene, and organization for school and home life and/or supports for developmentally appropriate independence, including transition into adulthood/independent living, when not available through BOCES, or other school/community programming.

Authorization

Authorization is not required for assessment visits within 60 days of the initial visit (up to 96 units or 24 total hours of service). Authorization is required for services after the assessment visits.

11) Palliative Care Counseling and Support Services

Palliative care is specialized medical care focused on providing relief from the symptoms and stress of a chronic condition or life-threatening illness. The goal is to improve quality of life for both the child and the family. Palliative care is provided by a specially trained team of doctors, nurses, social workers, and other specialists who work together with a child's doctors to provide an extra layer of support. It is appropriate at any stage of a chronic condition or life-threatening illness and can be provided along with curative treatment.

Children must meet LOC functional criteria and suffer from the symptoms and stress of chronic medical conditions OR illnesses that put individuals at risk for death before age 21.

Palliative Care Services include:

- **Expressive Therapy** (art, music, and play) helps children better understand and express their reactions through creative and kinesthetic treatment.
- Massage Therapy To improve muscle tone, circulation, range of motion and address physical symptoms related to their illness as well as provide physical and emotional comfort, pain management, and restore the idea of healthy touch for children/youth who are dealing with treatments that may involve painful interventions and ongoing and/or past trauma.
- Counseling and Support Services Provide help for participants and their families to cope with grief related to the participant's chronic condition or lifethreatening illness. Children/youth with chronic or life-threatening illness, and their families, cope with grief and loss in a variety of ways and may need various kinds of support over time, including counseling, support groups, and other services. Counseling and Support Services can be inclusive for those participants who are receiving services with a hospice care provider, if the services are not duplicative.
- Pain and Symptom Management Relief and/or control of the child's suffering related to their illness or condition. The goal is to improve quality of life for both the child/youth and the family. Palliative care is provided by a specially trained team of doctors, nurses, social workers, and other specialists who work together with a child/youth's doctors to provide an extra layer of support. It is appropriate at any stage of a chronic condition or life-threatening illness and can be provided along with curative treatment.

Limitations/ Exclusions

Palliative care benefits may not duplicate Hospice or other State Plan benefits accessible to participants.

Expressive Therapy: Expressive Therapy is limited to the lesser of (4 hours/16 units) per month or 48 hours (192 units) per calendar year. However, not all participants/families will require this level of support. Frequency, scope, and duration of the service must be necessary to support the participant remaining in the home or community. This limit can be exceeded when medically necessary.

Massage Therapy: Service is limited to 1.5 hours (6 units) per month or 18 hours (72 units) per calendar year. However, not all participants/families will require this level of support. Frequency, scope and duration of the service must be necessary to support the

participant remaining in the home or community. This limit can be exceeded when medically necessary.

Counseling and Support Services: When Counseling and Support Services are provided prior to the passing of an HCBS participant, frequency, scope and duration of the service must be necessary to support the participant remaining in the home or community. When provided during the participant's lifetime, this service is limited to five 5 hours (10 Units) per month or 60 hours (120 Units) per calendar year.

Authorization

Authorization required to validate child is medically fragile.

References (Updated 2025)

- New York State Department of Health Office of Mental Health Children's Health and Behavioral Health Medicaid System Transformation; Children's Home and Community Based Service Provider Manual; Version 2023-1 March 2023 Available: https://www.health.ny.gov/health_care/medicaid/redesign/behavioral_health/children/docs/hcbs_manual.pdf
- 2. HCBS Settings Final Rule Compliance Policy: https://www.health.ny.gov/health-care/medicaid/redesign/behavioral_health/children/docs/hcbs-settings-final-rule-compliance.pdf
- 3. Centers for Medicare and Medicaid Services 1915(c) Home and Community Based Waiver Instructions: Instructions Technical Guide and Review Criteria
- 4. Provider Service Delivery Documentation Policy for Children's HCBS: https://www.health.ny.gov/health-care/medicaid/redesign/behavioral_health/children/2-024/docs/cw0017 prov del doc child hcbs.pdf
- 5. Children's Waiver Home and Community-Based Services (HCBS) Service Definitions and Necessity Criteria Policy; January 2024

 https://www.health.ny.gov/health_care/medicaid/redesign/behavioral_health/children/2_024/docs/2024-01-23_hcbs_elig-enroll_policy.pdf

Customer Product	Management Requirements*
New York Products	
НМО	Not A Covered Benefit
PPO in Plan	Not A Covered Benefit
PPO OOP	Not A Covered Benefit
POS in Plan	Not A Covered Benefit
POS OOP	Not A Covered Benefit
Essential Plan	Not A Covered Benefit
MVP Medicaid Managed Care	Authorization
MVP Child Health Plus	Authorization
MVP Harmonious Health Care Plan	Not A Covered Benefit
MVP Medicare Complete Wellness	Not A Covered Benefit
MVP Medicare Preferred Gold HMO POS	Not A Covered Benefit
MVP Medicare Secure HMO POS	Not a Covered Benefit
MVP Medicare Secure Plus HMO POS	Not a Covered Benefit
MVP Medicare Wellselect PPO	Not a Covered Benefit
MVP Medicare WellSelect Plus PPO	Not A Covered Benefit
MVP Medicare Patriot Plan PPO	Not a Covered Benefit
MVP DualAccess D-SNP HMO	Not a Covered Benefit
MVP DualAccess Complete D-SNP HMO	Not a Covered Benefit
MVP DualAccess Plus D-SNP HMO	Not a Covered Benefit
UVM Health Advantage Select PPO	Not a Covered Benefit
USA Care	Not a Covered Benefit
Healthy NY	Not A Covered Benefit
MVP Premier	Not A Covered Benefit
MVP Premier Plus	Not A Covered Benefit
MVP Premier Plus HDHP	Not A Covered Benefit
MVP Secure	Not A Covered Benefit
MVP EPO	Not A Covered Benefit
MVP EPO HDHP	Not A Covered Benefit
MVP PPO	Not A Covered Benefit
MVP PPO HDHP	Not A Covered Benefit
Student Health Plans	Not A Covered Benefit
ASO	Not A Covered Benefit
Vermont Products	Not it covered benefit
POS in Plan	Not A Covered Benefit
POS OOP	Not A Covered Benefit
MVP Medicare Preferred Gold HMO POS	Not A Covered Benefit
MVP Medicare Secure Plus HMO POS	Not A Covered Benefit
MVP VT HMO	Not A Covered Benefit
MVP VT HDHP HMO	Not A Covered Benefit
MVP VT Plus HMO	Not A Covered Benefit
MVP VT Plus HDHP HMO	Not A Covered Benefit
MVP Secure	Not A Covered Benefit
ASO	Not A Covered Benefit
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[♦] Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

*Management Requirements

Potential for Retrospective Review Retro Review Not Covered See SPD Authorization Required
No Authorization Required. May be subject to Retrospective Review
Retrospective Review Required
Service is not a covered benefit.
See Specific Plan Design

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Revision History:

04/01/2022 - Annual Review. Updated to match version 2020-2 Children's Home and Community Based Service Provider Manual.

09/01/2022 - Updated to match version 2020-2 Children's Home and Community Based Service Provider Manual.

07/01/2024 - The prior authorization review, payment and approval of all Adaptive and Assistive Technology (AT), Environmental Modifications (EMod), and Vehicle Modifications (VMod) requests will be managed by the Children's Health Home of Upstate NY (CHHUNY), who will serve as the designated Financial Management Services (FMS) provider, in conjunction with the New York State Department of Health (NYS DOH).

06/01/2025 – Medical necessity review criteria updated according to NYS Medicaid.



MVP Health Care Medical Policy

Home Care Services

Type of Policy: Medical

Prior Approval Date: 11/17/2022

Approval Date: 11/04/2024

Effective Date: 02/01/2025

Related Polices: Private Duty Nursing

Personal Care and Consumer-Directed Service

Pharmacy Programs Administration

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

HCPCS Codes:

G0299, - Direct skilled nursing services of a registered nurse (RN) in the home health or hospice setting, each 15 minutes

G0300 - Direct skilled nursing services of a licensed practical nurse (LPN) in the home health or hospice setting, each 15 minutes

Medicare Products require Prior Auth through naviHealth

All LOB require prior authorization for out-of-network services through MVP

Codes Subject to Retrospective Review

N/A

Experimental/Investigational

N/A

Common Diagnosis Codes

ICD-10- CM Diagnosis Codes: Z74.2

Common Procedure Codes

Home Care Services Page 1 of 7

G0151, G0152, G0153, G0155, G0156, G0157, G0158, G0162, G0299, G0300, G0493, G0494

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy.

Overview

Home care services include professional nursing care, home health aide services, short-term physical and/or speech therapy, occupational therapy, medical social work, and related supplies provided in the home to customers who are homebound. A homebound customer is normally unable to leave the home and leaving the home requires a major effort. If the customer does leave the home, the customer may nevertheless be considered homebound if the absences from the home are infrequent or for short duration (e.g., attending a religious service), or are attributable to the need to receive health care treatment.

A visit is personal contact in the place of the customer's residence for the purpose of providing a covered service by a health worker employed or under contracted arrangement with a home health agency.

Medical Record Documentation

The medical record documents the physician certifies the patient is homebound. The customer is homebound when the following conditions are met:

The customer must either:

- because of illness or injury, need the aid of supportive devices such as crutches, canes, wheelchairs, and walkers; the use of special transportation; or the assistance of another person to leave their place of residence; or
- have a condition such that leaving his or her home is medically contraindicated.

If the customer meets either one of the criteria above, the customer must also meet the following:

• there must exist a normal inability to leave home and leaving home must require a considerable and taxing effort.

If the patient does, in fact, leave the home, the patient may nevertheless be considered homebound if the absences from the home are infrequent or for periods of short duration, or are attributable to the need to receive health care treatment. Absences attributable to the need to receive health care treatment include, but are not limited to:

attendance at adult day centers to receive medical care;

Home Care Services Page 2 of 7

- ongoing receipt of outpatient kidney dialysis; or
- the receipt of outpatient chemotherapy or radiation therapy.

Indications/Criteria

Home care services is a covered benefit when medically necessary or in accordance with Medicare guidelines for skilled services to be rendered in the home. Coverage includes:

- part-time (skilled services on a per visit basis not to exceed eight (8) hours per day/or 28 hours per week) home nursing care provided by or supervised by a Registered Nurse;
- intermittent (less than daily, not to exceed eight (8) hours per day or 28 hours per week) home nursing care provided by or supervised by a Registered Nurse;
- part-time or intermittent home health aide services to provide patient care.
 Custodial care, as defined under exclusions, is not included;
- short-term physical, occupational and/or speech therapy if provided by the home health agency personnel; and
- coverage for home visits also includes the following:
 - o up to two (2) visits for women who stay in the hospital less than 48 hours after a normal vaginal delivery or less than 96 hours after a c-section; and
 - o services must be provided by a qualified nurse within 48 hours after discharge.

Home care is covered when the following are met:

- a skilled service that meets criteria; and
- the customer is homebound;

Consideration for home care approval is based on the following:

- the customer's diagnosis;
- caregiver availability;
- the customer can learn and assume their own care; and
- additional support services (Occupational Therapy, Physical Therapy, Speech Therapy, Medical Social work, home health aides) are needed.

Services must be provided by a certified private or public home care agency.

Variations

Most contracts limit the duration of visits (refer to specific contract limits).

The customer may be responsible for co-payments/co-insurances per contract.

Exclusions

- Not meeting criteria under Indications/Criteria in this policy.
- Patients requiring the intensity or the frequency of service beyond the capacity of the home care service and the Primary Care Physician are excluded from coverage.
- Home care services are not a substitute for patients clearly requiring acute inpatient or outpatient on-site services.
- The following are not usually considered a benefit under this policy:
 - services that are not benefits:
 - services which necessitate extensive continuous monitoring;
 - private duty nursing services (for private duty nursing coverage refer to the Private Duty Nursing Medical Policy);
 - self-administered medications are not covered under the home care benefit (for self-administered medication coverage refer to the MVP Pharmacy Programs Administration policy; and
 - custodial care is any service which can be learned and provided by an average individual who does not have medical training such as assistance with feeding, dressing, personal hygiene, administration of oral medications, routine dressing changes, preparation of special diets, assistance in walking or getting out of bed, or childcare. Custodial care is considered not medically necessary. (For MVP Medicaid Managed Care refer to MVP Medicaid Managed Care Variation above)

MVP Medicaid Managed Care Variation

Home health care is covered for medically necessary intermittent skilled nursing care, including home health aide services and rehabilitation services. Also includes non-Medicare covered home health services (e.g., home health aide services with nursing supervision to medically unstable individuals) as required with an approved plan of care developed by a certified home health agency.

Medicaid customers are not required to be homebound.

For services that provide partial or total assistance with personal hygiene, dressing, feeding and nutrition, and environmental support functions refer to the MVP Personal Care and Consumer Directed Services for MVP Medicaid Managed Care medical policy.

References (Reviewed 2025)

- 1. CMS Manual System. Pub 100-02 Medicare Benefit Policy. Transmittal 192. Change Request 8818. August 1, 2014. Available: http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R192BP.pdf
- 2. Medicare Program Manual: Home Care; https://www.cms.gov/Regulations-and-guidance/Manuals/downloads/bp102c07.pdf

Home Care Services Page 4 of 7

- 3. MVP Contracts
- 4. New York State Department of Health, Office of Managed Care. Medicaid Managed Care and Family Health Plus Model Contract. January 2011. Available: https://www.health.ny.gov/health-care/managed-care/docs/medicaid-advantage-model-contract.pdf
- 5. Vermont Law Title 8 Banking and Insurance Chapter 107 Health Insurance Home Health Care §4096 Rule 91-4B

Home Care Services Page 5 of 7

Customer Product	Medical Management Requirements*
New York Products	•
HMO	Potential for Retrospective Review
PPO in Plan	Potential for Retrospective Review
PPO OOP	Potential for Retrospective Review
POS In plan	Potential for Retrospective Review
POS OOP	Potential for Retrospective Review
Essential Plan	Potential for Retrospective Review
MVP Medicaid Managed Care	Potential for Retrospective Review
MVP Child Health Plus	Potential for Retrospective Review
MVP Harmonious Health Care Plan	Potential for Retrospective Review
MVP Medicare Complete Wellness	Prior Auth naviHealth
MVP Medicare Preferred Gold HMO POS	Prior Auth naviHealth
MVP Medicare Secure HMO POS	Prior Auth naviHealth
MVP Medicare Secure Plus HMO POS	Prior Auth naviHealth
MVP Medicare WellSelect PPO	Prior Auth naviHealth
MVP Medicare WellSelect Plus PPO	Prior Auth naviHealth
MVP Medicare Patriot Plan PPO	Prior Auth naviHealth
MVP DualAccess D-SNP HMO	Prior Auth naviHealth
MVP DualAccess Complete D-SNP HMO	Prior Auth naviHealth
MVP DualAccess Plus D-SNP HMO	Prior Auth naviHealth
UVM Health Advantage Select PPO	Prior Auth naviHealth
USA Care	Prior Auth naviHealth
Healthy NY	Potential for Retrospective Review
MVP Premier	Potential for Retrospective Review
MVP Premier Plus	Potential for Retrospective Review
MVP Premier Plus HDHP	Potential for Retrospective Review
MVP Secure	Potential for Retrospective Review
MVP EPO	Potential for Retrospective Review
MVP EPO HDHP	Potential for Retrospective Review
MVP PPO	Potential for Retrospective Review
MVP PPO HDHP	Potential for Retrospective Review
Student Health Plans	Potential for Retrospective Review
ASO	See SPD
Vermont Products	
POS in Plan	Potential for Retrospective Review
POS OOP	Potential for Retrospective Review
MVP Medicare Preferred Gold HMO POS	Prior Auth naviHealth
MVP Medicare Secure Plus HMO POS	Prior Auth naviHealth
MVP VT HMO	Potential for Retrospective Review
MVP VT HDHP HMO	Potential for Retrospective Review
MVP VT Plus HMO	Potential for Retrospective Review
MVP VT Plus HDHP HMO	Potential for Retrospective Review
MVP Secure	Potential for Retrospective Review
ASO	See SPD

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g., HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Home Care Services Page 6 of 7

Revision History

02/01/2023 – Annual review with no changes to indications or criteria.

02/01/2025 - Annual review with no changes to indications or criteria.

Home Care Services Page 7 of 7



MVP Health Care Medical Policy

Hospice Care

Type of Policy: Medical

Prior Approval Date: 03/07/2022

Approval Date: 03/04/2024

Effective Date: 06/01/2024

Related Polices: MVP Utilization Management Policy and

Procedure Manual for Hospice

MVP Utilization Management Policy and Procedure Manual for Palliative Care

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

N/A

Codes Subject to Retrospective Review

N/A

Experimental/Investigational

N/A

Common Revenue Codes

Revenue Codes: 0650, 0651, 0652, 0654, 0655, 0656, 0659

Common Procedure Codes

N/A

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy.

Hospice Care Page 1 of 6

Overview

Hospice is an interdisciplinary program of supportive care and services addressing the physical, spiritual, social, and economic needs of terminally ill patients and their families provided in the home, inpatient, or a hospice center.

For the purpose of this policy, the palliative care program includes supportive services for customers that have a prognosis of more than six months and may be pursuing curative interventions. This type of care is focused on providing relief from the symptoms and stress of the illness. The goal is to provide services to customers to improve quality of life.

Coverage for hospice care is subject to the terms, conditions, and limitations of the applicable benefit plan. Please refer to the applicable benefit plan document [certificate of coverage (COC), summary of plan description (SPD)] to determine benefit availability and the terms, conditions, and limitations of coverage.

Documentation Requirements

Medical record documentation must contain medical justification for home hospice and inpatient hospice care.

Indications/Criteria

Hospice service provided in the home, inpatient, or a hospice center is a covered benefit subject to the customer meeting the following admission criteria:

- customer must have a terminal illness with a life expectancy of less than six months; and
- all aggressive forms of treatment for their illness must have stopped, except for radiation therapy which is used for palliative measures; and
- hospice services must be administered by an approved hospice agency certified pursuant to Article 40 of the New York Public Health Law.

Coverage shall include home care and outpatient services provided by the hospice.

Coverage includes drugs and medical supplies related to the hospice care and use of durable medical equipment (DME).

All durable medical equipment (DME) must be obtained through a qualified vendor or hospice provider.

Exclusions

- Not meeting criteria under Indications/Criteria in this policy.
- Hospice services are not covered if not medically necessary or not a covered benefit.

Hospice Care Page 2 of 6

- Funeral arrangements, pastoral, financial, or legal counseling
- Homemaker, caretaker, or respite care

Over-the-counter medications are not covered. **Variations**

Refer to the specific contract language regarding hospice care. Most contracts limit the duration and number of visits for hospice care.

Most contracts allow up to five visits for bereavement counseling service to the family, either before or after the customer's death. Routine pastoral care visits will not be covered.

MVP Medicaid Managed Care Variation

Hospice care provides support services and some medical services to patients who are ill and expect to live for one year or less.

For children less than 21 years of age, medically necessary curative services are covered while receiving hospice care.

Over-the-counter medications may be covered for MVP Medicaid Managed Care Products.

The following Medicaid services/programs are not allowed in combination with the hospice benefit:

- Private Duty Nursing; and
- · Certified Home Health Agency Services; and
- Adult Day Health Care Services.

MVP Child Health Plus Variation

For children less than 21 years of age, medically necessary curative services are covered while receiving hospice care.

Over-the-counter medications may be covered for MVP Child Health Plus.

The following Medicaid services/programs are not allowed in combination with the hospice benefit:

- Private Duty Nursing; and
- Certified Home Health Agency Services; and
- Adult Day Health Care Services.

Medicare Variation

Drugs traditionally covered under Part B and Part D are covered under the Medicare Part A per-diem payment to the hospice program. For prescription drugs to be covered

Hospice Care Page 3 of 6

outside of the Part A per diem and under the customer's Part D benefit, the hospice provider must provide documentation identifying why the drug is unrelated to the terminal illness or related condition. Prescribers who are unaffiliated with the hospice provider should also attest that they have coordinated with the hospice provider and the hospice provider confirmed that the drug is unrelated to the terminal illness or related condition.

Based on review, hospice is not addressed in a Medicare National or Local Coverage Determinations or policies.

References (Updated 2024)

- 1. MVP New York Contracts
- 2. MVP Vermont Contracts
- 3. MVP Medicaid Managed Care Member Guide
- 4. National Hospice and Palliative Care Organization (NHPCO). Standards of practice for hospice programs: professional development and resource series. 2022.
- 5. New York State Department of Health. eMedNY. Provider Manuals. Hospice. New York State Medicaid Program. Hospice Program Policy Guidelines. Available: https://www.emedny.org/ProviderManuals/index.aspx
- 6. Medicare Benefit Policy Manual: Hospice. Available: www.cms.hhs.gov/manuals/Downloads/bp102c07.pdf
- 7. Centers for Medicare & Medicaid Services. Prospective Payment Systems. Hospice. https://www.cms.gov/medicare/payment/fee-for-service-providers/hospice
- 8. Centers for Medicare & Medicaid Services. Prescription Drug Coverage. Part D Benefits Manual. Chapter 6, Section 20.2 Drugs Covered Under Medicare Part A or B. Available: https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/part-d-benefits-manual-chapter-6.pdf

Hospice Care Page 4 of 6

Customer Product	Medical Management Requirements*
New York Products	•
НМО	Potential for Retrospective Review
PPO in Plan	Potential for Retrospective Review
PPO OOP	Potential for Retrospective Review
POS in Plan	Potential for Retrospective Review
POS OOP	Potential for Retrospective Review
Essential Plan	Potential for Retrospective Review
MVP Medicaid Managed Care	Potential for Retrospective Review
MVP Child Health Plus	Potential for Retrospective Review
MVP Harmonious Health Care Plan	Potential for Retrospective Review
MVP Medicare Complete Wellness	Covered by Original Medicare
MVP Medicare Preferred Gold HMO POS	Covered by Original Medicare
MVP Medicare Secure HMO POS	Covered by Original Medicare
MVP Medicare Secure Plus HMO POS	Covered by Original Medicare
MVP Medicare WellSelect PPO	Covered by Original Medicare
MVP Medicare WellSelect Plus PPO	Covered by Original Medicare
MVP Medicare Patriot Plan PPO	Covered by Original Medicare
MVP DualAccess D-SNP HMO	Covered by Original Medicare
MVP DualAccess Complete D-SNP HMO	Covered by Original Medicare
MVP DualAccess Plus D-SNP HMO	Covered by Original Medicare
UVM Health Advantage Select PPO	Covered by Original Medicare
USA Care	Covered by Original Medicare
Healthy NY	Potential for Retrospective Review
MVP Premier	Potential for Retrospective Review
MVP Premier Plus	Potential for Retrospective Review
MVP Premier Plus HDHP	Potential for Retrospective Review
MVP Secure	Potential for Retrospective Review
MVP EPO	Potential for Retrospective Review
MVP EPO HDHP	Potential for Retrospective Review
MVP PPO	Potential for Retrospective Review
MVP PPO HDHP	Potential for Retrospective Review
Student Health Plans	Potential for Retrospective Review
ASO	See SPD
Vermont Products	See Si D
POS in Plan	Potential for Retrospective Review
POS OOP	Potential for Retrospective Review
MVP Medicare Preferred Gold HMO POS	Covered by Original Medicare
MVP Medicare Secure Plus HMO POS	Covered by Original Medicare
MVP VT HMO	Potential for Retrospective Review
MVP VT HDHP HMO	Potential for Retrospective Review
MVP VT Plus HMO	Potential for Retrospective Review
MVP VT Plus HDHP HMO	Potential for Retrospective Review
MVP Secure	Potential for Retrospective Review
ASO	See SPD
7100	300 31 D

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g., HDHP HMO auth requirements are the same as listed for HMO).

*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit
See SPD See Specific Plan Design

Hospice Care Page 5 of 6

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Revision History:

06/01/2022 – Annual Review with no changes to the indications or criteria. Eliminated references to visit limits as these are contract specific.

06/01/2024 – Annual Review. Edited for format and grammar, updated and added references, added Medicaid one year indication.

Hospice Care Page 6 of 6



Hospital Beds

Type of Policy: DME

Prior Approval Date: 12/02/2024

Provisional Approval 03/27/2025

Date:

Provisional Effective 04/01/2025

Date:

Related Polices: N/A

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

MVP list of Durable Medical Equipment (DME) that requires Prior Authorization, go to https://www.mvphealthcare.com/providers/reference-library/#utilization

Codes Requiring Retrospective Review

None

Experimental/Investigational

None

Common Diagnosis Codes

Common Diagnosis Codes associated with this policy have been provided for informational purposes only. The list of codes may not be all-inclusive and may be updated to reflect any applicable revisions to the ICD-10 code set and/or medical necessity quidelines applied in this policy.

Common Procedure Codes

HCPCS Codes:

E0250, E0251, E0255, E0256, E0260, E0261, E0280, E0290, E0291, E0292, E0293, E0294, E0295, E0301, E0302, E0303, E0304, E0910, E0911, E0912, E0940

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has

Hospital Beds Page 1 of 9

been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

A fixed height hospital bed allows for manual adjustments to head and leg elevation but not height.

Variable height hospital beds allow manual adjustments to height as well as head and leg elevation.

Semi-electric beds allow manual adjustments to height and electric adjustments to head and leg elevation.

Totally electric beds allow electric adjustment to height, leg and head elevation.

Indications/Criteria

A **fixed height hospital bed** (E0250, E0251, E0290, E0291) is covered if one or more of the following criteria (1-4) are met:

- 1. The customer has a medical condition which requires positioning of the body in ways not feasible with an ordinary bed. Elevation of the head/upper body less than 30 degrees does not usually require the use of a hospital bed, **or**
- 2. The customer requires positioning of the body in ways not feasible with an ordinary bed in order to alleviate pain, **or**
- 3. The customer requires the head of the bed to be elevated more than 30 degrees most of the time due to congestive heart failure, chronic pulmonary disease, or problems with aspiration, **or**
- 4. The customer requires traction equipment, which can only be attached to a hospital bed.

A **variable height hospital bed** (E0255, E0256, E0292, and E0293) is covered if the customer meets one of the criteria for a fixed height hospital bed and:

• requires a bed height different than a fixed height hospital bed to permit transfers to chair, wheelchair or standing position.

A **semi-electric hospital bed** (E0260, E0261, E0294, E0295) is covered if the customer meets one of the criteria for a fixed height bed and:

 requires frequent changes in body position and/or has an immediate need for a change in body position.

A **heavy duty extra wide hospital bed** (E0301, E0303) is covered if the customer meets one of the criteria for a fixed height hospital bed and:

Hospital Beds Page 2 of 9

• the beneficiary's weight is more than 350 pounds but does not exceed 600 pounds.

An **extra heavy-duty hospital bed** (E0302, E0304) is covered if the customer meets one of the criteria for a fixed height hospital bed and:

• the beneficiary's weight exceeds 600 pounds.

Enclosed Pediatric Hospital bed (E0328) with 360-degree side enclosure is covered when criteria is met:

- 1. The customer has a medical condition which requires positioning of the body in ways not feasible with an ordinary bed. Elevation of the head/upper body less than 30 degrees does not usually require the use of a hospital bed, **or**
- 2. The customer requires positioning of the body in ways not feasible with an ordinary bed in order to alleviate pain, **or**
- 3. The customer requires the head of the bed to be elevated more than 30 degrees most of the time due to congestive heart failure, chronic pulmonary disease, or problems with aspiration, **or**
- 4. The customer requires traction equipment, which can only be attached to a hospital bed.

AND

- 5. The patient has a diagnosis-related cognitive or communication impairment or a severe behavioral disorder (a behavioral management plan is required) that results in risk for safety in bed; **and**
- 6. There is evidence of mobility that puts the patient at risk for injury while in bed (more than standing at the side of the bed), or the patient has had an injury relating to bed mobility; **and**
- 7. Less costly alternatives have been tried and were unsuccessful or contraindicated (e.g., putting a mattress on the floor, padding added to ordinary beds or hospital beds, transparent plastic shields, medications, helmets); **and**
- 8. The ordering practitioner has ruled out physical and environmental factors as reasons for patient behavior, such as hunger, thirst, restlessness, pain, need to toilet, fatigue due to sleep deprivation, acute physical illness, temperature, noise levels, lighting, medication side effects, over- or under-stimulation, or a change in caregivers or routine.

Safety enclosure frame (E0316) for use with a hospital bed is covered when customer meets above criteria for enclosed pediatric hospital bed (E0328) and:

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- 1. The customer's bed mobility results in risk for safety in bed that cannot be accommodated by an enclosed pediatric manual hospital bed (E0328); **and**
- 2. A monitoring plan that documents how customer will be managed in the enclosed bed, **and**
- 3. A successful trial in the home has been completed.

Accessories:

Trapeze equipment (E0910, E0940) is covered if the customer needs this device to sit up because of a respiratory condition, to change body position for other medical reasons, or to get in or out of bed.

Heavy duty trapeze equipment (E0911, E0912) is covered if the customer meets the criteria for regular trapeze equipment and the beneficiary's weight is more than 250 pounds.

A bed cradle (E0280) is covered when it is necessary to prevent contact with the bed coverings.

Exclusions

A **total electric hospital bed** (E0265, E0266, E0296, and E0297) is not covered; the height adjustment feature is a convenience feature.

Sleep Safe Beds / Courtney Bed /Haven Bed / Vail Enclosed Bed (using miscellaneous codes) – These devices are considered safety equipment as they are not primarily medical in nature, and therefore not medically necessary.

Medicaid Variation

Total Electric Hospital bed (E0266) is covered if customer meets the criteria for a Semi Electric Bed (E0260, E0261, E0294, E0295) and requires the ability to adjust the bed height for independent transfers.

Special Needs Bed (E1399)

To meet the definition of a special needs bed it must have one of the following features:

- A fixed foundation (articulation or height)
- Foundations with electric adjustability
- Side rails greater than 24 inches above the mattress
- Integrated full enclosure (360-degree enclosure with a top)

A fully enclosed special needs bed is met when documentation includes all of the following:

 The customer has a diagnosis-related cognitive or communication impairment or a severe behavioral disorder that results in risk for safety in bed; and

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- There is evidence of mobility that puts the customer at risk for injury while in bed (more than standing at the side of the bed), or the customer has had an injury relating to bed mobility; and
- Less costly alternatives have been tried and were unsuccessful, or contraindicated (e.g. putting a mattress on the floor, padding added to ordinary beds or hospital beds, transparent plastic shields, medication, helmets); and
- The ordering practitioner has ruled out physical and environmental factors as reasons for patient behavior, such as hunger, thirst, restlessness, pain, need to toilet, fatigue due to sleep deprivation, acute physical illness, temperature, noise levels, lighting, medication side effects, over- or under- stimulation, or a change in caregivers or routine. (For customers with behavioral disorder, a behavioral management plan is required.)
- The customer should be evaluated by a qualified practitioner (PT/OT/MD) who has specific training and/or experience in ordering of complex durable medical equipment and /or enclosed bed evaluation and ordering. The evaluation and/or letter of medical necessity should include at minimum:
 - Height and weight
 - Medical history
 - Current functional status
 - Upper and lower extremity range of motion and strength
 - Cognitive status
 - Skin integrity
 - Transfer status
 - Ambulation
 - Bed mobility, including specifically how it results in risk for safety in bed that cannot be accommodated by an enclosed pediatric manual hospital bed (e0328)
 - Any additional information that supports the medical need for the bed;
 and
- A written monitoring plan approved by the ordering and all treating practitioners has been completed which describes:
 - o When the bed will be used
 - How the customer will be monitored at specified time intervals
 - How the member needs will be met while using the enclosed bed (including eating, hydration, skin care, toileting, and general safety)
 - Identification by relationship of all caregivers providing care to the member and explanation of how any medical conditions (e.g. seizures) will be managed while the customer is in the enclosed bed; and
 - A statement confirming that the requested bed system will not be used as a restraint; and

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• There is evidence of mobility that puts the customer at risk for an injury while in a hospital bed with high-sides (E0328) and a full enclosure (E0316).

For customers that reside in an Office for People with Developmental Disabilities (OPWDD) certified residence, documentation of the approval as a restraint meets with the agency's Human Rights Committee.

Supporting documentation should include:

- A list of comparable, less costly beds that have been explore (from multiple manufacturers) and why they would not meet the member's needs; and
- Medical justification for each accessory requested that is an additional cost.

Only twin-size beds are considered.

Please note: Electronic components that do not adjust the position of the bed (such as camera/video/speaker/mic, sound/light machine etc.) are considered assistive technology and are not within the scope of NYS Medicaid program.

Medicare Variation

Enclosed Pediatric Hospital bed (E0328) with 360-degree side enclosure is covered when criteria is met:

- 1. The customer has a medical condition which requires positioning of the body in ways not feasible with an ordinary bed. Elevation of the head/upper body less than 30 degrees does not usually require the use of a hospital bed, **or**
- 2. The customer requires positioning of the body in ways not feasible with an ordinary bed in order to alleviate pain, **or**
- 3. The customer requires the head of the bed to be elevated more than 30 degrees most of the time due to congestive heart failure, chronic pulmonary disease, or problems with aspiration, **or**
- 4. The customer requires traction equipment, which can only be attached to a hospital bed.

A **semi-electric pediatric hospital bed** (E0329) is covered if the customer meets one of the criteria for a fixed height bed and:

 requires frequent changes in body position and/or has an immediate need for a change in body position.

Side rails (E0305, E0310) or **safety enclosures** (E0316) are covered when they are required by the beneficiary's condition and they are an integral part of, or an accessory to, a covered hospital bed.

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MVP uses the Medicare Local Coverage Policy on Hospital Beds and Accessories criteria for these items. For coverage criteria, go to Active LCDs - JA DME - Noridian (noridianmedicare.com).

References (Updated 2025)

- Centers for Medicare and Medicaid Services (CMS). Local Coverage
 Determination (LCD) Hospital Beds And Accessories (L33820). Accessed October
 21, 2024. Available at URL address: LCD Hospital Beds And Accessories (L33820)
- 2. U.S. Food and Drug Administration (FDA). Medical devices. Hospital Beds. Page Last Updated: August 23, 2018. Accessed October 21, 2024. Available at URL address: Hospital Beds | FDA
- U.S. Food and Drug Administration (FDA). Medical devices. Class 1 Device Recall. Vail 500 Enclosed Bed System. Vail 1000 Enclosed Bed System. June 30, 2005. Accessed October 21, 2024. Available at URL addresses: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRes/res.cfm?id=39027
- 4. U.S. Food and Drug Administration (FDA). Information on Pediatric Medical Cribs and Medical Bassinets Used in Homes, Child Care Settings and Traditional Health Care Facilities Accessed October 21, 2024. Available at URL address: <a href="Information on Pediatric Medical Cribs and Medical Bassinets Used in Homes, Child Care Settings and Traditional Health Care Facilities | FDA
- 5. New York State Department of Health. Provider Manual. DME Manual. Procedure Codes. 2022. Available: https://www.emedny.org/ProviderManuals/DME/index.aspx

Customer Product Medical Management Requirements*

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New York Products	
НМО	Prior Auth
PPO in Plan	Prior Auth
PPO OOP	Prior Auth
POS in Plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Prior Auth
MVP Child Health Plus	Prior Auth
MVP Harmonious Health Care Plan	Prior Auth
MVP Medicare Complete Wellness	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP Medicare WellSelect PPO	Prior Auth
MVP Medicare WellSelect Plus PPO	Prior Auth
MVP Medicare Patriot Plan PPO	Prior Auth
MVP DualAccess D-SNP HMO	Prior Auth
MVP DualAccess Complete D-SNP HMO	Prior Auth
MVP DualAccess Plus D-SNP HMO	Prior Auth
UVM Health Advantage Select PPO	Prior Auth
USA Care PPO	Potential for Retrospective Review
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	300 9. 5
POS in Plan	Prior Auth
POS OOP	Prior Auth
MVP Medicare Preferred Gold HMO POS POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP VT HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
A Note: Prior outh oriention requirements for UDUD a	See SPD

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Auth Potential for Retrospective Review Retro Review

Not Covered See SPD Prior Authorization Required

No Prior Authorization Required. May be subject to Retrospective Review.

Retrospective Review Required Service is not a covered benefit. See Specific Plan Design

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Revision History

04/01/2023 – New policy effective date.

02/01/2025 – Annual review with no changes to the indications or criteria. References updated.

04/01/2025 -Updated Medicaid variation in accordance with Medicaid regulatory update.

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Hospital Inpatient Level of Care

Type of Policy: Medical

 Prior Approval Date:
 02/05/2024

 Approval Date:
 02/03/2025

 Effective Date:
 04/01/2025

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

N/A

Codes Requiring Retrospective Review

N/A

Experimental/Investigational

N/A

Common Diagnosis Codes

N/A

Common Procedure Codes

N/A

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

The decision to admit a customer to an inpatient level of care is often complex requiring consideration of customer's severity of illness, intensity of care needed, and individual customer circumstances. The individual circumstances that should be considered when

making a decision to admit to an inpatient level of care include comorbidities, complications, age, social situation, progress of treatment, and availability of alternative levels of care. Although InterQual criteria are guidelines used by MVP Health Care to assist in making utilization review determinations for levels of care, InterQual guidelines are not to be rigid. There are times when InterQual criteria are not met but the customer is appropriate for an inpatient status. Likewise, there are times when InterQual criteria are met but there are alternatives to inpatient level of care. In these circumstances an inpatient level of care is not necessary.

Medical Record Documentation Requirements

The medical record document should include the following: physician order for inpatient admission, time and date, reason for hospitalization for inpatient medical treatment, estimated time the patient will remain in hospital, severity of illness (e.g. condition, history, and physical), co-morbidities, complications and contributing factors, treatment received prior to being hospitalized, initial hospital treatment plan, documentation substantiating medical necessity and appropriateness.

Indications/Criteria

MVP requires the use of InterQual® Subsets or SmartSheets to obtain prior authorization for the following levels of care:

- Acute Inpatient
- Long Term Acute Care
- Subacute SNF
- Inpatient Acute Rehabilitation

In addition to considering InterQual criteria as a guideline for determining if inpatient level of care is medically necessary, the following apply:

- For diagnoses that frequently can be evaluated and treated as outpatient or at an alternative level of care, the medical record must support that alternative levels of care are inappropriate. (e.g. Failure to respond to outpatient treatment and a clear deterioration of the patient's clinical status).
- Time in the hospital resulting from delays in obtaining appropriate care including availability of diagnostic testing or scheduling delays in performing procedures or obtaining consultations is not medically necessary.
- If an alternative level of care such as observation, ambulatory surgery, skilled nursing facility, or home care is appropriate for the customer, a hospital level of care is not medically necessary.
- If appropriate care can be provided in a less intense level of care setting, then a higher level of care is considered not medically necessary.
- Delays in discharge for reasons other than the customer's medical condition do not support the need for acute inpatient level of care.

Interfacility transfers (acute-to-acute hospital) are considered medically necessary when one or more of the following criteria are met:

- The individual requires a medically necessary diagnostic or therapeutic service (for example, organ transplantation) which is not available at the originating facility; or
- The individual requires a level of care (for example, neonatal care unit or level 1 trauma center) which is not available at the originating facility; or
- The individual requires the services of a specialist to evaluate, diagnose or treat their condition when that specialist is not available in a timely manner at the originating facility (Note: Timeliness of care is a case/individual specific attribute. It may be appropriate for a medically stable individual to await availability of a specialist for several days while a medically unstable individual may require care more quickly); or
- The individual has received care at a specific prior institution for a condition not normally managed at the originating facility (for example, organ transplant recipient) and return to that prior institution is needed to diagnose, manage, or treat a complication or other acute issue; or
- The individual has been diagnosed with advanced cancer without probability of reversal, with fewer than sixty days expected to live and requires acute care services specializing in the treatment of terminally ill patients (End-of-Life Care). The individual's attending health care provider, in consultation with the Medical Director of the receiving facility, must submit an attestation that the individual's care can be best provided by the requested facility.

Exclusions

Not meeting criteria listed under the Indications/Criteria of this policy.

Interfacility transfers (acute-to-acute hospital) between an originating facility and a receiving facility are considered not medically necessary when the transfer is primarily for the convenience of the individual, the individual's family, the physician or the originating facility.

References (Updated 2024)

- InterQual clinical Decision Support Criteria. Change Healthcare LLC, Copyright 2022 Change Healthcare.
- 2. Medicare Claims Processing Manual Chapter 3 Inpatient Hospital Billing Section 20.1.2.4 Medicare Claims Processing Manual (cms.gov)
- 3. Centers for Medicare and Medicaid Services. Administration. Code of Federal Regulations. Chapter IV, Part 412.4. Prospective payment systems for inpatient hospital services. Discharges and transfers. Available at:

http://www.gpo.gov/fdsys/pkg/CFR-2011-title42-vol2/pdf/CFR-2011-title42-vol2-sec412-4.pdf. Accessed on September 12, 2022.

- 4. New York Consolidated Laws, Public Health Law PBH § 4406-e. Access to end-of-life care
- 5. New York Consolidated Laws, Insurance Law ISC § 4805. Access to end-of-life care

Customer Product	Medical Management Requirements*
New York Products	
НМО	Prior Auth
PPO in Plan	Prior Auth
PPO OOP	Prior Auth
POS in Plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Prior Auth
MVP Child Health Plus	Prior Auth
MVP Harmonious Health Care Plan	Prior Auth
MVP Medicare Complete Wellness	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
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MVP Medicare WellSelect Plus PPO	Prior Auth
MVP Medicare Patriot Plan PPO	Prior Auth
MVP DualAccess D-SNP HMO	Prior Auth
MVP DualAccess Complete D-SNP HMO	Prior Auth
MVP DualAccess Plus D-SNP HMO	Prior Auth
UVM Health Advantage Select PPO	Prior Auth
USA Care PPO	Potential for Retrospective Review
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	
POS in Plan	Prior Auth
POS OOP	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP VT HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review.

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Revision History

08/01/2022 – Annual review with no changes.

04/01/2024 – Added coverage criteria for Interfacility transfers (acute-to-acute hospital).

04/01/2025 – Added coverage criteria for interfacility transfers for treatment of terminally ill patients.



Hyperbaric Oxygen Therapy (HBO) and Topical Oxygen Therapy

Type of Policy: Medical

Prior Approval Date: 02/06/2023

Approval Date: 07/03/2023

Effective Date: 10/01/2023

Related Polices: Negative Pressure Wound Therapy Pumps

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

CPT/HCPCS	Description:
Codes	
99183	Physician or other qualified health care professional attendance and
	supervision of hyperbaric oxygen therapy, per session
E0446	Topical oxygen delivery system, not otherwise specified, includes all
	supplies and accessories
G0277	Hyperbaric oxygen under pressure, full body chamber, per 30
	minute interval
A4575	Topical hyperbaric oxygen chamber, disposable

Experimental/Investigational Codes Subject to Retrospective Review

N/A

Common Diagnosis Codes

N/A

Common Procedure Codes

N/A

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy.

Overview

Hyperbaric oxygen therapy is a medical treatment in which the patient is entirely enclosed in a pressurized chamber breathing 100% oxygen at >1.4 times atmospheric pressure. This increased atmospheric pressure allows the blood to absorb large amounts of oxygen thereby creating hyper-oxygenation and increasing the amount of oxygen in the tissues. Hyperbaric oxygen therapy is considered as a treatment for certain diseases or injuries of the skin or bone, decompression sickness, or for certain toxic inhalations.

Documentation Requirements

Medical records must contain documentation to support medical necessity.

- For the treatment of non-healing wounds, in addition to the wound criteria listed below, documentation must indicate that for customers who meet criteria for negative pressure wound therapy, the customer has tried and failed negative pressure wound therapy prior to requesting hyperbaric oxygen therapy (HBO). (See the MVP Medical Policy Negative Pressure Wound Therapy Pumps).
- The medical record must contain documentation that the customer is non-smoking during hyperbaric oxygen therapy.
- Wounds must be evaluated after every 15 treatments and/or at least every 30 days during administration of HBOT. Continued treatment with HBOT is not considered medically necessary if measurable signs of healing have not been demonstrated within any 30 day period of treatment.

Indications/Criteria

Coverage will be considered with supporting medical documentation for the following conditions:

- air or gas embolism: an iatrogenic introduction of air into the circulatory system (e.g., during cardiovascular procedures, lung biopsy, hemodialysis, central line placement) and resulting in neurologic symptoms which do not immediately resolve;
- carbon monoxide exposure with any of the following: unconsciousness, new neurologic deficit, or mental status change, end organ ischemia, or CO-Hgb >40% (pregnant woman with CO-Hgb > 20%);
- cyanide poisoning;
- decompression sickness: also known as caisson disease, or the bends, occurs after ascent from diving or in rapid ascent in altitude during flight when decompression guidelines are not followed;
- crush injury, compartment syndrome, acute traumatic ischemia documented by history and physical findings, including physical or angiographic evidence of absence of arterial perfusion and technical inability to re-perfuse, or lack of response to

restoration of perfusion;

- necrotizing soft tissue infections (fascia, muscle) documented by culture of organisms known to cause this (e.g., clostridium), resulting in progressive necrosis, and unresponsive to antibiotics and wide surgical debridement;
- chronic refractory osteomyelitis must meet <u>all</u> the following:
 - localized disease;
 - systemic or local compromise;
 - systemic compromise (e.g., malnutrition, diabetes mellitus, immunosuppression, renal failure, hepatic failure, chronic hypoxia, immune disease, extremes of age); or
 - local compromise (e.g., chronic lymphedema, radiation fibrosis, loss of local sensation, venous stasis, major vessel compromise, arteritis, extensive scarring, radiation fibrosis, small vessel disease, neuropathy, tobacco abuse); and
 - o refractory to optimal medical and surgical treatment;
- radiation necrosis /osteoradionecrosis (ORN) documented by a history of intense radiation therapy, and radiologic evidence of osteonecrosis or soft tissue necrosis, e.g. radiation enteritis, cystitis, proctitis.
- skin grafts and flaps documented local ischemic compromise or a systemically compromised host and a history of previous graft failures;
- actinomycosis only as an adjunct to conventional therapy when the disease process is refractory to antibiotics and surgical treatment;
- acute peripheral arterial insufficiency.
- Idiopathic sudden sensorineural hearing loss (ISSHL) is covered when the following criteria are met:
 - o diagnosed by a specialist (e.g., otolaryngologist); and
 - o an adjunctive treatment to systemic or intratympanic steroid therapy; and
 - o initiated within four (4) weeks of symptom onset

For the treatment of non-healing wounds, in addition to the wound criteria listed below, documentation must indicate that for customers who meet criteria for negative pressure wound therapy, the customer has tried and failed negative pressure wound therapy prior to requesting hyperbaric oxygen therapy (HBO). (See the MVP Medical Policy Negative Pressure Wound Therapy Pumps).

• diabetic wounds of the lower extremities in patients who meet all the following three criteria:

- o patient has Type I or Type II diabetes and has a lower extremity wound;
- o patient has a wound classified as Wagner grade III or higher (deep ulcer with abscess or osteomyelitis or gangrene); and
- patient has failed an adequate course of standard wound therapy (minimum of 30 consecutive days).
- The use of hyperbaric oxygen therapy is covered as adjunctive therapy only after there are no measurable signs of healing for at least 30 days of treatment with standard wound therapy and must be used in addition to standard wound care. Standard wound care in patients with diabetic wounds includes: assessment of a patient's vascular status and correction of any vascular problems in the affected limb. If possible, optimization of nutritional status, optimization of glucose control, debridement by any means to remove devitalized tissue, maintenance of a clean, moist bed of granulation tissue with appropriate moist dressings, appropriate offloading, and necessary treatment to resolve any infection that might be present. Failure to respond to standard wound care occurs when there are no measurable signs of healing for at least 30 consecutive days. Wounds must be evaluated at least every 30 days during administration of hyperbaric oxygen therapy. Continued treatment with hyperbaric oxygen therapy is not covered if measurable signs of healing have not been demonstrated within any 30-day period of treatment.

Customers must be non-smoking during the hyperbaric oxygen therapy treatment period.

Exclusions

- Any other indication not listed in the Indications/Criteria section
- Enhancement of healing in selected problem wounds (e.g., cutaneous, decubitus, and stasis ulcer
- Chronic peripheral vascular insufficiency
- Senility
- Myocardial infarction
- Cardiogenic shock
- Sickle cell anemia
- Acute or chronic cerebral vascular insufficiency
- Hepatic necrosis
- Anaerobic septicemia and infection other than clostridial
- Aerobic septicemia

- Non-vascular causes of chronic brain syndrome (Pick's disease, Alzheimer's disease, Korsakoff's disease)
- Tetanus
- Thermal (skin) burns
- Acute thermal and chemical pulmonary damage (i.e., smoke inhalation with pulmonary insufficiency)
- Systemic aerobic infection
- Organ transplantation
- Organ storage
- Pulmonary emphysema
- Exceptional blood loss anemia
- Multiple Sclerosis
- Arthritic diseases
- Prevention of osteoradionecrosis in relation to tooth extraction in the absence of active osteoradionecrosis
- Treatment of hemorrhagic cystitis
- Treatment of edema, erythema, and pain related to breast irradiation
- Acute cerebral edema
- Home units for hyperbaric oxygen therapy are considered not medically necessary

Topical Oxygen Wound Therapy (TOWT) (E0446, A4575) has not been proven in the medical literature to improve health outcomes over standard wound care and, therefore, is considered investigational.

- Topical oxygen delivery systems (E0446) including all supplies and accessories, have not been proven in the medical literature to improve health outcomes over standard wound care and, therefore, are considered investigational.
- Topical hyperbaric oxygen chambers (A4575) have not been proven in the medical literature to improve health outcomes over standard wound care and, therefore, are considered investigational.

Contraindications for Hyperbaric Oxygen Therapy include:

- untreated pneumothorax; or
- concurrent treatment with doxorubicin, cisplatin, disulfiram, or premature infants.

MVP Medicaid Managed Care and MVP Child Health Plus Variation

Indications/Criteria for Topical Oxygen Wound Therapy (TOWT) (E0446, A4575):

I. General Definitions

- 1. 18 NYCRR 505.5, states that durable medical equipment (DME) are devices and equipment, other than prosthetic or orthotic appliances, which have been ordered by a practitioner in the treatment of a specific medical condition and which have all the following characteristics:
 - Can withstand repeated use for a protracted period of time;
 - Are primarily and customarily used for medical purposes;
 - Are generally not useful in the absence of an illness or injury;
 - Are not usually fitted, designed or fashioned for a particular individual's use;
 - Where equipment is intended for use by only one beneficiary, it may be
 - either custom-made or customized.
- 2. **TOWT** is the controlled application of 100% oxygen directly to an open moist wound at slightly higher then atmospheric pressure. An oxygen concentrator is connected to a FDA approved O2 boot and/or O2 sacral device that are for onetime use and disposable, therefore reducing the risk of cross contamination. Studies indicate that concentration of oxygen at the wound site increases the local cellular oxygen tension, which in turn promotes wound healing.
- 3. The staging of **pressure ulcers** used in this policy is as follows:
 - **Stage I**: nonblanchable erythema of intact light toned skin or darker or violet hue in darkly pigmented skin.
 - **Stage II**: partial thickness skin loss involving epidermis and/or dermis.
 - Stage III: full thickness skin loss involving damage or necrosis of
 - subcutaneous tissue that may extend down to, but not through, underlying fascia.
 - **Stage IV**: full thickness skin loss with extensive destruction, tissue necrosis or damage to muscle, bone, or supporting structures.
- 4. **Wound healing** is defined as improvement occurring in either surface area or depth of the wound. Lack of improvement of a wound is defined as a lack of progress in these quantitative measurements.

II. Criteria for Coverage

TOWT (A4575 with E1390) is covered when criteria 1 and any of criteria 2-6 are met:

- 1. A complete wound therapy program as applicable, depending on the type of wound, has been attempted prior to application of TOWT, including:
 - a. Documentation in the patient's medical record of evaluation, care, compliance and wound measurements by the treating physician, and
 - b. Application of dressings to maintain a moist wound environment, and
 - c. Debridement of necrotic tissue if present, and
 - d. Evaluation of and provision for adequate nutritional status, and
 - 2. Stage IV pressure ulcers:
 - a. The patient has been appropriately turned and positioned, and
 - b. The patient has used a support surface for pressure ulcers on the posterior trunk or pelvis (not required if the ulcer is not on the trunk or pelvis), and
 - c. The patient's moisture and incontinence have been appropriately managed, or
 - 3. Neuropathic (for example, diabetic) ulcers:
 - a. The patient has been on a comprehensive diabetes management program, and
 - b. Reduction in pressure on a foot ulcer has been accomplished with appropriate modalities, or
 - 4. Venous insufficiency ulcers:
 - a. Compression bandages and/or garments have been consistently applied, and
 - b. Leg elevation and ambulation have been encouraged, or
 - For non-healing surgically created or traumatic wounds, documentation of medical necessity for accelerated formation of granulated tissue as a result of which cannot be achieved by other topical wound treatments,

or

6. A chronic (being present for at least 30 days) ulcer of mixed etiology.

III. Non-covered Indications

TOWT is considered **investigational**, **not medically necessary**, **medically contraindicated** and **not covered** for all other indications, including but not limited to, the following:

 The presence in the wound of necrotic tissue with eschar, if debridement is not attempted;

- Untreated osteomyelitis within the vicinity of the wound;
- Cancer present in the wound;
- The presence of a fistula to an organ or body cavity within the vicinity of the wound;
- Stage I, II or III pressure ulcers.

The New York State Medicaid Topical Oxygen Wound Therapy Guidelines which describe general definitions, criteria for coverage, non-covered indications, and general requirements, please refer to the following link:

https://www.emedny.org/ProviderManuals/DME/PDFS/2008-

<u>4 New%20York%20State%20Medicaid%20Topical%20Oxygen%20Wound%20Therapy%20Guidelines.pdf</u>

Medicare

There is a Medicare National Coverage Determination (NCD) for Hyperbaric Oxygen Therapy. For full coverage details refer to: Centers for Medicare & Medicaid Services National Coverage Determination for Hyperbaric Oxygen Therapy (20.29). Effective Date June 19, 2006. Available: Available: MCD Search (cms.gov)

Medicare Variation (HCPCS E0446 and A4575)

Topical oxygen delivery systems (E0446) will be denied as not reasonable and necessary. (IOM 100-03 20.29(C)).

Topical hyperbaric oxygen chambers (A4575) will be denied as not reasonable and necessary. (IOM 100-03 20.29(B) & (C)).

Refer to Noridian healthcare Solutions, LLC. Local Coverage Determination (LCD): Oxygen and Oxygen Equipment (L33797). Revision Effective date: 01/01/2023. Available: MCD Search (cms.gov)

References (Updated 2023)

- 1. Undersea and Hyperbaric Medical Society (UHMS). Indications for hyperbaric oxygen therapy. 2014. Available: https://www.uhms.org/resources/hbo-indications.html
- 2. Centers for Medicare & Medicaid Services National Coverage Determination for Hyperbaric Oxygen Therapy (20.29). Effective Date April 3, 2017. Available: National Coverage Determination (NCD) for Hyperbaric Oxygen Therapy (20.29) (cms.gov)
- 3. Carek, PJ, et al. Diagnosis and management of osteomyelitis (2001) American Family Physician 2001; 63(12): 2413-2420.
- 4. Hailey, D Hyperbaric oxygen-recent findings on evidence for its effectiveness. Alberta Heritage Foundation for Medical Research Health Technology Assessment. 2003.
- 5. McDonagh, MS., et al. Hyperbaric oxygen therapy for brain injury, cerebral palsy, and

- stroke. Agency for Healthcare Research and Quality (AHRQ) Evidence Reports 2003 Publication No. 04-E003.
- 6. Oral complications of cancer therapies: diagnosis, prevention, and treatment. NIH Consensus Statement 1989; 7(7):1-11.
- 7. Tibbles, PM and Edelsberg, JS. Hyperbaric-oxygen therapy. New England Journal of Medicine 1996; 334:1642-1648.
- 8. Magnant, CM, Milzman, DP, Dhindsa, H Hyperbaric medicine for outpatient wound care Emergency Medicine Clinics of North America 1992; 10(4): 847-860.
- 9. State of New York Department of Health. DME Provider Manual: New York State Medicaid Topical Oxygen Wound Therapy Guidelines 2008. Available: https://www.emedny.org/providermanuals/DME/PDFS/2008-4 <a href="https://www.emedny.org/providermanuals/DME/PDFS/2008-4 <a href="https://www.emedny.org/providermanuals/DME/PDFS/2008-4 <a href="https://www.emedn
- 10. State of New York Department of Health. eMedNY June 26, 2017:

 <a href="https://www.google.com/url?client=internal-element-cse&cx=002102995624522195956:9ighjut50f8&q=https://www.emedny.org/Notice/ma_update_towt_continues_to_be_covered_06-26-17_approved.pdf&sa=U&ved=2ahUKEwi52qiuleX7AhV3EVkFHdpGDo4QFnoECAgQAg&usg=AOvVaw0GA_Al1qvzG6ZsXzoZ3NVR
- 11. Raman, G, A horizon scan: Uses of hyperbaric oxygen therapy. Technology Assessment Report. Prepared by the Tufts-New England Medical Center Evidence Based Practice Center for the Agency for Healthcare Research and Quality (AHRQ). Rockville, MD: AHRQ; October 5, 2006. Available: www.cms.hhs.gov/determinationprocess/downloads/id42TA.pdf
- 12. Kranke P, et al., Hyperbaric oxygen therapy for chronic wounds. Cochrane Database Syst Rev. 2004; (1):CD004123.
- 13. Villanueva E, et al. Hyperbaric oxygen therapy for thermal burns. Cochrane Database Syst Rev. 2004; (2):CD004727.
- 14. Ubbink DT, et al. Topical negative pressure for treating chronic wounds. Cochrane Database Syst Rev. 2008; (3):CD001898.
- 15. Feldmeier JJ, et al., UHMS position statement: Topical oxygen for chronic wounds. Undersea Hyperb Med. 2005; 32(3):157-168.
- 16. Eskes A, et al. Hyperbaric oxygen therapy for treating acute surgical and traumatic wounds. Cochrane Database Syst Rev. 2010; (10):CD008059.
- 17. Boudreau R, et al. Hyperbaric oxygen therapy for difficult wound healing: Systematic review of clinical effectiveness and cost-effectiveness. Ottawa: Canadian Agency for Drugs and Technologies in Health; 2010. available at:

- https://cadth.ca/hyperbaric-oxygen-therapy-difficult-wound-healing-systematic-review-clinical-effectiveness-and-cos-0
- 18. Smith J. Cutaneous manifestations of smoking. E-Medicine. January 2007. Available: http://www.emedicine.com/derm/topic629.htm
- 19. Bartsch RH, Weiss G and Kästenbauer T et al. Crucial aspects of smoking in wound healing after breast reduction surgery. J Plast Reconstr Aesthet Surg. 2007; 60(9):1045-9. Available: Crucial aspects of smoking in wound healing after breast reduction surgery PubMed (nih.gov)
- 20. Petschke FT, Engelhardt TO and Ulmer H et al. [Effect of cigarette smoking on skin perfusion of the hand]. Chirurg. 2006 Nov; 77(11):1022-6. Available: [Effect of cigarette smoking on skin perfusion of the hand] PubMed (nih.gov)
- 21. Chan LK, Withey S and Butler PE. Smoking and wound healing problems in reduction mammaplasty: is the introduction of urine nicotine testing justified? Ann Plast Surg. 2006 Feb; 56(2):111-5. Erratum in: Ann Plast Surg. 2006 Apr; 56(4):358. Available: Smoking and wound healing problems in reduction mammaplasty: is the introduction of urine nicotine testing justified? PubMed (nih.gov)
- 22. Sorensen LT, Karlsmark T and Gottrup F et al. Abstinence from smoking reduces incisional wound infection: a randomized controlled trial. Ann Surg. 2003 Jul; 238(1):1-5. Available: The effect of cigarette smoking on wound healing PubMed (nih.gov)
- 23. Gallego Vilar D, García Fadrique G, Povo Martín IJ, et al. Hyperbaric oxygen therapy for the management of hemorrhagic radio-induced cystitis. Arch Esp Urol. 2011;64(9):869-874.
- 24. Parra C, Gómez R, Marchetti P, et al. Management of hemorrhagic radiation cystitis with hyperbaric oxygen therapy. Actas Urol Esp. 2011; 35(3):175-179.
- 25. Shao Y, Lu GL, Shen ZJ. Comparison of intravesical hyaluronic acid instillation and hyperbaric oxygen in the treatment of radiation-induced hemorrhagic cystitis. BJU Int. 2012; 109(5):691-694.
- 26. Freiberger JJ. Utility of hyperbaric oxygen in treatment of bisphosphonate-related osteonecrosis of the jaws. J Oral Maxillofac Surg. 2009; 67(5 Suppl):96-106.
- 27. Vescovi P, Nammour S. Bisphosphonate-Related Osteonecrosis of the Jaw (BRONJ) therapy. A critical review. Minerva Stomatol. 2010; 59(4):181-203, 204-213.
- 28. Hayes Search & Summary. Hyperbaric Oxygen Therapy for Treatment for Sudden Sensorineural Hearing Loss. Lansdale, PA: ©2020 TractManager, Inc.September 29, 2016. Annual Review: December 12, 2019 Available: https://www.hayesinc.com/

- 29. Hayes Health Technology Assessment. Hyperbaric Oxygen Therapy for Diabetes-Related Foot Ulcers: A Review of Reviews. ©2020 TractManager, Inc. October 5, 2017 Annual Review: January 7, 2020 Available: https://www.hayesinc.com/
- 30. Hayes Health Technology Assessment. Topical Oxygen Therapy For Chronic Wound Healing. ©2020 TractManager, Inc. November 21, 2017 Annual Review: March 4, 2020. Available: https://www.hayesinc.com/
- 31. New York State Department of Health Medicaid Update June 2017. Volume 33 |
 Number Attention: Topical Oxygen Wound Therapy Continues to be Covered Until
 Further Notice. Available:
 https://www.health.ny.gov/health_care/medicaid/program/update/2017/jun17_mu.pdf
- 32. Mechem CC, Manaker S. Hyperbaric oxygen therapy. UpToDate [online serial]. Waltham, MA: UpToDate; Reviewed October 2016
- 33. Bennett MH, Feldmeier J, Hampson N, et al. Hyperbaric oxygen therapy for late radiation tissue injury. Cochrane Database Syst Rev. 2005;(3):CD005005.
- 34. Schoen PJAU, Raghoebar GMAU, Bouma JAU, Reintsema HAU, Vissink AAU, Sterk WAU, et al. Rehabilitation of oral function in head and neck cancer patients after radiotherapy with implant-retained dentures: effects of hyperbaric oxygen therapy. *Oral Oncology* 2007;43(4):379-88.
- 35. Mendenhall WM et al: Mandibular Osteoradionecrosis. Journal of Clinical Oncology, Vol 22, No 24 (December 15), 2004: pp.4867-4868
- 36. Sultan A et al: The Use of Hyperbaric Oxygen for the Prevention and Management of Osteoradionecrosis of the Jaw: A Dana-Farber/Brigham and Women's Cancer Center Multidisciplinary Guideline. Oncologist. 2017 Mar;22(3):343-350.doi:10.1634/theoncologist.2016-0298.Epub 2017 Feb 16. Review.
- 37. Chandrasekhar SS, Tsai Do BS, Schwartz SR, et al. Clinical Practice Guideline: Sudden Hearing Loss (Update). Otolaryngology–Head and Neck Surgery. 2019;161(1_suppl): S1-S45.
- 38. Undersea and Hyperbaric Medicine Society (UHMS). Idiopathic sudden sensorineural hearing loss (ISSHL). 2011.
- 39. Undersea and Hyperbaric Medicine Society (UHMS). Indications for hyperbaric oxygen therapy, 14 ed. 2021. Available: https://www.uhms.org

Customer Product	Medical Management Requirements*
New York Products	-
HMO	Prior Auth
PPO in Plan	Prior Auth
PPO OOP	Prior Auth
POS in Plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Prior Auth
MVP Child Health Plus	Prior Auth
MVP Harmonious Health Care Plan	Prior Auth
MVP Medicare Complete Wellness	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP Medicare WellSelect PPO	Prior Auth
MVP Medicare WellSelect Plus PPO	Prior Auth
MVP Medicare Patriot Plan PPO	Prior Auth
MVP DualAccess D-SNP HMO	Prior Auth
MVP DualAccess Complete D-SNP HMO	Prior Auth
MVP DualAccess Plus D-SNP HMO	Prior Auth
UVM Health Advantage Select PPO	Prior Auth
USA Care PPO	Potential for Retrospective Review
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	
POS In Plan	Prior Auth
POS OOP	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP VT HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD

[♦] Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Revision History:

04/01/2020 – No changes to the criteria or indication for all plans. Policy format changes completed.

04/01/2023 – Annual review; updated documentation requirements and references with no changes to the indications or criteria, added prior authorization to A4575.

10/01/2023 – added criteria for sudden hearing loss.



Hyperhidrosis Treatments

Type of Policy: Medical/DME

Prior Approval Date: 06/07/2021

Approval Date: 05/03/2023

Effective Date: 08/01/2023

Related Polices: Durable Medical Equipment

Botulinum Toxin Treatment

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

For Durable Medical Equipment (DME) that requires Prior Authorization, refer to: Reference Library | MVP Health Care

CPT Codes:	Description:	
32664	Thoracoscopy, surgical; with thoracic sympathectomy	
64802	Sympathectomy, cervical	
64804	Sympathectomy, cervicothoracic	
64809	Sympathectomy, thoracolumbar	
64818	Sympathectomy, lumbar	
64823	Sympathectomy; superficial palmar arch	

Codes Subject to Retrospective Review

N/A

Experimental/Investigational/Cosmetic

N/A

Common Diagnosis Codes

ICD-10 Diagnosis Codes: L74.510, L74.511, L74.512, L74.513, L74.519, R61

Common Procedure Codes

N/A

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy.

Overview

Hyperhidrosis is a condition characterized by profuse and chronic sweating of the plantar, axillary, craniofacial, back, groin, legs, or palmar regions of the body. Sympathetic over-activity is the underlying basis for this disorder. Hyperhidrosis is considered a benign condition and conservative treatment may consist of topical and anticholingeric agents, antiperspirants and talcum powders.

Other treatments may consist of phenol blocks, tap water iontophoresis (drionic device), and injections of botulinum toxin (onabotulinumtoxinA [BOTOX®]) or (rimabotulinumtoxinB [Myobloc®]) for primary palmar and axillary hyperhidrosis and pharmacologic treatments. In tap water iontophoresis the palms of the hands and/or soles of the feet are immersed in a tray of tap water through which a weak electrical current is run. Sponges soaked in water can be used to treat the axillae. [15]

Surgical treatments may include surgery (sympathectomy) or excision of the axillary sweat glands. There are two approaches for performing sympathectomy, Endoscopic thoracic sympathectomy (ETS) or a more minimally invasive technique called video-assisted thoracoscopic sympathectomy (VTS).

Indications/Criteria

Tap water iontophoresis (Drionic devices) for home treatment are indicated for palmar, craniofacial, or focal axillary hyperhidrosis when all the criteria listed below are met. Requests must be received from a Dermatologist and medical information must demonstrate <u>all</u> the following:

- the severity of the disorder is disabling; and
- the customer is unable to perform activities of daily living; and

- focal, visible, severe sweating of at least six (6) months duration without apparent cause; and
- evidence the condition has caused damage to clothing due to the excessive sweating with focal axillary hyperhidrosis; and
- failure of topical therapy or use of topical therapy (e.g., use of aluminum chloride or other antiperspirants) resulted in skin irritation or itching; and
- there is failure, contraindication, or intolerance of oral pharmacotherapy.

Surgical treatments for primary palmar and axillary hyperhidrosis are covered when all the above medical necessity criteria have been met in addition failure with:

- focal, visible, severe sweating of at least six (6) months duration without apparent cause; and
- Botulinum toxin A onabotulinumtoxinA (BOTOX®) or rimabotulinumtoxinB (Myobloc®); or
- Aluminum Chloride: Drysol 20% Topical Solution, Hypercare 20% Topical Solution, Xerac AC Topical Solution; or
- Qbrexza 2.4% Topical Cloth; or
- o iontophoresis.

Refer to the MVP Botulinum Toxin Treatment medical policy for treatment of axillary and palmar hyperhidrosis.

DME co-payments may apply if a Drionic device is approved.

Exclusions

Not meeting criteria not listed under the Indications/Criteria section of this policy.

Craniofacial and plantar hyperhidrosis surgery utilizing sympathectomy, including endoscopic thoracic sympathectomy (ETS), video-assisted thoracoscopic sympathectomy (VTS) and lumbar sympathectomy are excluded from coverage because there is insufficient evidence in the published peer-reviewed literature to support their use.

References (Updated 2023)

- 1. Hornberger J, Grimes K, Naumann M, Glaser DA, NJ, Naver H, Ahn S, Stolman LP; Multi-Specialty Working Group on the Recognition, Diagnosis, and Treatment of Primary Focal Hyperhidrosis. Recognition, diagnosis, and treatment of primary focal hyperhidrosis. J Am Acad Dermatol. 2004 Aug;51(2):274-86.
- 2. National Government Services, Inc., Local Coverage Determinations (LCD) for Botulinum Toxins (L33646). Revision Effective Date 10/31/2019. Available: https://www.cms.gov/

- 3. Solish, et al. A comprehensive approach to the recognition, diagnosis, a severity-based treatment of focal hyperhidrosis: recommendations of the Canadian Hyperhidrosis Advisory Committee. Dermatology Surgery. 2007 33(8):908-23.
- 4. Haider, A., Solish, N. Focal hyperhidrosis: diagnosis and management. CMAJ. 2005 Jan 4:172(1):69-75.
- 5. HHFS Drug Information. Botulinum Toxin. 2013. Available at: http://www.ahfsdruginformation.com
- 6. Aydemir EH, Kalkan MT, Karakoç Y. Quantitative effect of anodal current in the treatment of primary hyperhidrosis by direct electrical current. Int J Dermatol. 2006 Jul;45(7):862-4.
- 7. Karakoc Y, Aydemir EH, Kalkan MT. Placebo-controlled evaluation of direct electrical current administration for palmoplantar hyperhidrosis. Int J Dermatol. 2004 Jul;43(7):503-5.
- 8. Na GY, Park BC, Lee WJ, Park DJ, Kim do W, Kim MN. Control of palmar hyperhidrosis with a new "dry-type" iontophoretic device. Dermatol Surg. 2007 Jan;33(1):57-61.
- 9. General Medical Company. Drionic. 2013. Available at: http://www.drionic.com/
- 10. R.A. Fischer Co. Galvanic Units. 2013. Available at: http://www.rafischer.com/
- 11. American Association of Neurological Surgery (AANS). Sympathectomy for hyperhidrosis. [position statement]. March 2007 Reaffirmed November 2009 Accessed April 14, 2021. Available at: <u>AANS Sympathectomy for Hyperhidrosis Position Statement by Curtis Dickman MD</u>
- 12. Cerfolio RJ, De Campos JR, Bryant AS, Connery CP, Miller DL, DeCamp MM, et al. The Society of Thoracic Surgeons expert consensus for the surgical treatment of hyperhidrosis. Ann Thorac Surg. 2011 May;91(5):1642-8.
- 13. HAYES Technology Assessment Tap Water Iontophoresis for the Treatment of Primary Hyperhidrosis. Hayes Inc. ©2021 TractManager April 27, 2018 Annual Review: June 15, 2020.
- 14. Nicholas R, Quddus A, Baker DM. Treatment of Primary Craniofacial Hyperhidrosis: A Systematic Review. Am J Clin Dermatol. 2015 Oct;16(5):361-70
- 15. Lima SO, de Santana VR, Valido DP, de Andrade RLB, Fontes LM, et al. Retroperitoneoscopic lumbar sympathectomy for plantar hyperhidrosis. J Vasc Surg. 2017 Dec;66(6):1806-1813
- 16. Lima SO, Santos RS, Moura AMM, de O Neto EG, de Andrade RLB, Valido AD, Dos Santos VF, Mendonça AKRH. A systematic review and meta-analysis to evaluate the efficacy of lumbar sympathectomy for plantar hyperhidrosis. Int J Dermatol. 2019 Aug;58(8):982-986.

- 17. Rieger R. Management of Plantar Hyperhidrosis with Endoscopic Lumbar Sympathectomy. Thorac Surg Clin. 2016 Nov;26(4):465-469.
- 18. Coelho M, Kondo W, Stunitz LC, Branco Filho AJ, Branco AW. Bilateral retroperitoneoscopic lumbar sympathectomy by unilateral access for plantar hyperhidrosis in women. J Laparoendosc Adv Surg Tech A. 2010 Feb;20(1):1-6.
- 19. Loureiro Mde P, de Campos JR, Kauffman P, Jatene FB, Weigmann S, Fontana A. Endoscopic lumbar sympathectomy for women: effect on compensatory sweat. Clinics (Sao Paulo). 2008 Apr;63(2):189-96.
- 20. International Hyperhidrosis Society (IHHS) clinical guidelines for primary axillary, facial, gustatory, palmar, plantar and generalized hyperhidrosis.
- 21. Jacob CI. Examining hyperhidrosis: an update on new treatments. Am J Manag Care. 2018 Dec;24(23 Suppl):S496-S501.

Customer Product	Medical Management Requirements*
New York Products	-
НМО	Prior Auth
PPO In Plan	Prior Auth
PPO OOP	Prior Auth
POS In Plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Prior Auth
MVP Child Health Plus	Prior Auth
MVP Harmonious Health Care Plan	Prior Auth
MVP Medicare Complete Wellness	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP Medicare WellSelect PPO	Prior Auth
MVP Medicare WellSelect Plus PPO	Prior Auth
MVP Medicare Patriot Plan PPO	Prior Auth
MVP DualAccess D-SNP HMO	Prior Auth
MVP DualAccess Complete D-SNP HMO	Prior Auth
MVP DualAccess Plus D-SNP HMO	Prior Auth
UVM Health Advantage Select PPO	Prior Auth
USA Care PPO	Potential for Retrospective Review
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	
POS In Plan	Prior Auth
POS OOP	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP VT HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD

[♦] Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Revision History:

08/01/2021 – Annual Review; added prior authorization to 32664 for endoscopic thoracic sympathectomy (ETS), limited covered surgeries to primary palmar and axillary hyperhidrosis, excluded surgical sympathectomy for treatment of craniofacial and plantar hyperhidrosis.

8/1/2023 – Annual review; no changes to indications or criteria. References updated.



Idiopathic Scoliosis Surgery and Growing Rods Technique

Type of Policy: Medical

Prior Approval Date: 06/04/2023

Approval Date: 03/28/2025

Effective Date: 06/01/2025

Related Polices: Electrical Stimulation Devices and

Therapies

Durable Medical Equipment

Scoliosis Bracing

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

CPT Codes: N/A

Codes Requiring Retrospective Review

CPT Codes:

22836 - Anterior thoracic vertebral body tethering, including thoracoscopy, when performed; up to 7 vertebral segments

22837 - Anterior thoracic vertebral body tethering, including thoracoscopy, when performed; 8 or more vertebral segments

22838 - Revision (eg, augmentation, division of tether), replacement, or removal of thoracic vertebral body tethering, including thoracoscopy, when performed

29999 - Unlisted procedure, arthroscopy

Experimental/Investigational

0656T - Vertebral body tethering, anterior; up to 7 vertebral segments

0657T - Vertebral body tethering, anterior; 8 or more vertebral segments

0790T - Revision (eg, augmentation, division of tether), replacement, or removal of thoracolumbar or lumbar vertebral body tethering, including thoracoscopy, when performed

Common Diagnosis Codes

ICD-10-CM Diagnosis Codes: G12-G12.9, M41-M41.9, M43.8X-M43.8X9, Q67.0, Q67.1, Q67.2, Q67.3, Q67.4, Q67.5, Q67.6, Q67.7, Q67.8, Q76.3

Common Procedure Codes

CPT Codes: 22558, 22612, 22614, 22630, 22632, 22800, 22802, 22804, 22808, 22810, 22812, 22819, 22845, 22846, 22847, 22848

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy.

Overview

Scoliosis is an abnormal lateral curvature of the spine. It is most often diagnosed in childhood or early adolescence. The spine's normal curves occur at the cervical, thoracic, and lumbar regions. Scoliosis can be classified by etiology: idiopathic, congenital, or neuromuscular. Idiopathic scoliosis is the diagnosis when all other causes are excluded and comprises about 80 percent of all cases. Adolescent idiopathic scoliosis (AIS) is the most common type of scoliosis and is usually diagnosed during puberty.

There are several signs that may indicate the possibility of scoliosis:

- shoulders are uneven one or both shoulder blades may stick out; head is not centered directly above the pelvis;
- one or both hips are raised or unusually high; rib cages are at different heights;
- waist is uneven;
- the appearance or texture of the skin overlying the spine changes (dimples, hairy patches, color abnormalities); or
- the entire body leans to one side

Treatment options are considered based on the maturity of the patient, degree and extent of the curvature, location of the deformity, and the possibility of curve progression. Observation, bracing and surgery are the available treatment options. There are numerous surgical treatments available depending on the severity and location of the scoliosis, including: spinal fusion (anterior and/or posterior), thoracoscopic surgery (Video-Assisted Thoracoscopic Surgery [VATS]), osteotomies (bone removal).

Indications/Criteria

Surgical Treatment (spinal fusion) for Idiopathic Scoliosis

Surgery (e.g., spinal fusion with instrumentation and bone grafting) for the treatment of idiopathic scoliosis medically necessary for any of the following conditions:

- An increasing curve (greater than 40 degrees) in a growing child who is skeletally immature; or Scoliosis related pain that is refractory to conservative treatments; or
- Severe deformity (curve greater than 50 degrees) with trunk asymmetry in children and adolescents; or
- Thoracic lordosis that cannot be treated conservatively.

Growing Rods Spinal Surgery

Traditional or magnetically (e.g. MAGEC® magnetic growth rod) controlled growing rod technique is considered medically necessary when all of the following the criteria are met:

- Skeletally immature individual with potential for additional spinal growth, who are < 10 years of age,
- Cobb angle of 30 degrees or more; and Thoracic spine height less than 22 cm; and
- There is a risk of thoracic insufficiency syndrome (TIS), defined as the inability of the thorax to support normal respirations for lung growth.

OR

• Used as a temporary distraction rod in individual with severe scoliosis (Cobb angle above 40 degrees) as a staged procedure prior to spinal fusion.

Frequency of Nonsurgical Adjustments for Magnetically Controlled Growing Rod

Frequency

A lengthening is performed in the office approximately every 3 months depending on the patient needs.

Exclusions

Due to lack of evidence in peer reviewed literature, vertebral body tethering for the treatment of progressive idiopathic scoliosis is considered investigational and, therefore not medically necessary.

Medicare

Based on review, there is no Medicare National Coverage Decision (NCD) or Medicare Local Coverage Decision (LCD) for scoliosis surgery.

References (Updated 2025)

- 1. Scoliosis Research Society (SRS). Adolescent Idiopathic Scoliosis Treatment.© 2013 Scoliosis Research Society. Available: https://www.srs.org/professionals/online-education-and-resources/conditions-and-treatments/adolescent-idiopathic-scoliosis
- American Association of Neurological Surgeons (AANS). Scoliosis. July 2007.
 Available: https://www.aans.org/Patients/Neurosurgical-Conditions-and-Treatments/Scoliosis
- 3. Cheung KM, Cheung JP, Samartzis D, et al. Magnetically controlled growing rods for severe spinal curvature in young children: A prospective case series. Lancet. 2012;379(9830):1967-1974.
- 4. Dannawi Z, Altaf F, Harshavardhana NS, et al. Early results of a remotely-operated magnetic growth rod in early-onset scoliosis. Bone Joint J. 2013;95-8(1):75-80.
- 5. Hickey BA, Towriss C, Baxter G, Yasso S, James S, Jones A, Howes J, Davies P, Ahuja S. Early experience of MAGEC magnetic growing rods in the treatment of early onset scoliosis. 2014;23 Suppl 1:S61-S65.
- 6. Jenks M, Craig J, Higgins J, et al. The MAGEC system for spinal lengthening in children with scoliosis: A NICE Medical Technology Guidance. Appl Health Econ Health Policy. 2014;12(6):587-599.
- 7. NHS England Clinical Commissioning Policy. Non-invasively lengthened spinal rods for scoliosis. April 2014. Available: http://www.england.nhs.uk/wp-content/uploads/2014/06/spinal-rods.pdf.
- 8. NuVasive. Magec® System. Available: https://www.nuvasive.com/procedures/spine/magec/.
- 9. U.S. Food and Drug Administration, Department of Health & Human Services. MAGEC® Spinal Bracing and Distraction System. 510 (k) approval number: K16'751. 09/02/2016. Available: U.S. Food and Drug Administration.
- 10. Figueiredo, Nicandro, et al. The use of magnetically controlled growing rod device for pediatric scoliosis. Neurosciences. 2016. Jan; 21(1) 17-25. Available: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5224406/.
- 11. Jenks, M., et al. The MAJEC System for Spinal Lengthening in Children with Scoliosis: A NICE Medical Technology Guidance. Applied health Economics and Health Policy. 2014; 12(6): 587-599. Available: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4232741/.
- 12. Nicandro Figueiredo, MD, PhD, Salman F. Kananeh, MD,et al. The use of magnetically controlled growing rod device for pediatric scoliosis. Neurosciences (Riyadh). 2016 Jan; 21(1): 17-25. Available: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5224406/.

- 13. J. P. Y Cheung, D. Samartzis, et al. Spine: Focus On. Management of early-onset scoliosis. Bone & Joint. 2013 The British Editorial Society of Bone and Joint Surgery.
- 14. Newton PO, Kluck DG, Saito W, Yaszay B, Bartley CE, Bastrom TP. Anterior Spinal Growth Tethering for Skeletally Immature Patients with Scoliosis: A Retrospective Look Two to Four Years Postoperatively. J Bone Joint Surg Am. 2018 Oct 3;100(19):1691-1697. doi: 10.2106/JBJS.18.00287. PMID: 30277999.
- 15. Hayes Health Technology Assessment. Magnetically Controlled Growing Rods For Treatment Of Early-Onset Scoliosis. HAYES, Inc.; © 2021 Hayes, a symplr company. November 27, 2018. Annual Review February 1, 2021 Archived December 27, 2021.
- 16. Hayes Health Evolving Evidence Review. Vertebral Body Tethering for Progressive Pediatric and Adolescent Idiopathic Scoliosis. HAYES, Inc.; © 2021 Hayes, a symplr company. March 30, 2021.
- 17. Wong HK, Ruiz JNM, Newton PO, Gabriel Liu KP. Non-fusion surgical correction of thoracic idiopathic scoliosis using a novel, braided vertebral body tethering device: minimum follow-up of 4 years. JB JS Open Access. 2019; 4(4):e0026.

Customer Product	Medical Management Requirements*
New York Products	
HMO	Retro Review
PPO in Plan	Retro Review
PPO OOP	Retro Review
POS in Plan	Retro Review
POS OOP	Retro Review
Essential Plan	Retro Review
MVP Medicaid Managed Care	Retro Review
MVP Child Health Plus	Retro Review
MVP Harmonious Health Care Plan	Retro Review
MVP Medicare Complete Wellness	Retro Review
MVP Medicare Preferred Gold HMO POS	Retro Review
MVP Medicare Secure HMO POS	Retro Review
MVP Medicare Secure Plus HMO POS	Retro Review
MVP Medicare WellSelect PPO	Retro Review
MVP Medicare WellSelect Plus PPO	Retro Review
MVP Medicare Patriot Plan PPO	Retro Review
MVP DualAccess D-SNP HMO	Retro Review
MVP DualAccess Complete D-SNP HMO	Retro Review
MVP DualAccess Plus D-SNP HMO	Retro Review
UVM Health Advantage Select PPO	Retro Review
USA Care PPO	Potential for Retrospective Review
Healthy NY	Retro Review
MVP Premier	Retro Review
MVP Premier Plus	Retro Review
MVP Premier Plus HDHP	Retro Review
MVP Secure	Retro Review
MVP EPO	Retro Review
MVP EPO HDHP	Retro Review
MVP EPO	Retro Review
MVP EPO HDHP	Retro Review
Student Health Plans	Retro Review
ASO	See SPD
Vermont Products	332 3. 2
POS in Plan	Retro Review
POS OOP	Retro Review
MVP Medicare Preferred Gold HMO POS	Retro Review
MVP Medicare Secure Plus HMO POS	Retro Review
UVM Health Advantage Select PPO	Retro Review
MVP VT HMO	Retro Review
MVP VT HDHP HMO	Retro Review
MVP VT Plus HMO	Retro Review
MVP VT Plus HDHP HMO	Retro Review
MVP Secure	Retro Review Retro Review
ASO	See SPD
AJU	J See SPD

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Revision History

08/01/2022 - Annual review; 0656T, 0657T for vertebral body tethering added to exclusions.

07/01/2023 – Prior authorization removed from 22558, 22612, 22614, 22630, 22632 because procedures managed previously by Magellan Healthcare are no longer medically managed or reviewed.

01/01/2024 - Added new codes 22836, 22837, 22838, 0790T to policy.

06/01/2025 – Annual review with no changes to the policy.



Imaging Procedures

Type of Policy: Imaging

Prior Approval Date: 08/05/2024

Approval Date: 12/02/2024

Effective Date: 04/01/2025

Related Polices:

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

N/A

Codes Requiring Retrospective Review for Experimental/Investigational Review:

Code:	Description:
76497	Unlisted computed tomography procedure (eg, diagnostic,
	interventional)
76498	Unlisted magnetic resonance procedure (eg, diagnostic,
	interventional)
76499	Unlisted diagnostic radiographic procedure
78609	Brain imaging, positron emission tomography (PET); perfusion
	evaluation
0609T	Magnetic resonance spectroscopy, determination and localization
	of discogenic pain
0610T	Magnetic resonance spectroscopy, determination and localization
	of discogenic pain
0611T	Magnetic resonance spectroscopy, determination and localization
	of discogenic pain
0612T	Magnetic resonance spectroscopy, determination and localization
	of discogenic pain

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0623T	Automated quantification and characterization of coronary
	atherosclerotic plaque to assess severity of coronary disease
0624T	Automated quantification and characterization of coronary
	atherosclerotic plaque to assess severity of coronary disease
0625T	Automated quantification and characterization of coronary
	atherosclerotic plaque to assess severity of coronary disease
0626T	Automated quantification and characterization of coronary
	atherosclerotic plaque to assess severity of coronary disease
0648T	Quantitative magnetic resonance for analysis of tissue
	composition (eg, fat, iron, water content)
0649T	Quantitative magnetic resonance for analysis of tissue
	composition (eg, fat, iron, water content),
0697T	Quantitative magnetic resonance for analysis of tissue
	composition (eg, fat, iron, water content)
0698T	Quantitative magnetic resonance for analysis of tissue
	composition (eg, fat, iron, water content)
0710T	Noninvasive arterial plaque analysis using software processing of
	data from non-coronary computerized tomography angiography
0711T	Noninvasive arterial plaque analysis using software processing of
	data from non-coronary computerized tomography angiography
0712T	Noninvasive arterial plaque analysis using software processing of
	data from non-coronary computerized tomography angiography
0713T	Noninvasive arterial plaque analysis using software processing of
	data from non-coronary computerized tomography angiography
G0219	PET imaging whole body; melanoma for noncovered indications
G0252	PET imaging, full and partial-ring PET scanners only, for initial
	diagnosis of breast cancer and/or surgical planning for breast
	cancer
S8080	Scintimammography (radioimmunoscintigraphy of the breast),
	unilateral, including supply of radiopharmaceutical
S8085	Fluorine-18 fluorodeoxyglucose (F-18 FDG) imaging using dual-
	head coincidence detection system (nondedicated PET scan)
S8092	Electron beam computed tomography (also known as ultrafast
	CT, cine CT)
C9788	Opto-acoustic imaging, breast (including axilla when performed),
	unilateral, with image documentation, analysis and report,
	obtained with ultrasound examination.

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Common Diagnosis Codes

ICD-10- CM Diagnosis Codes: I63.019, I63.119, I63.20, I63.219, I63.22, I63.139, I63.239, I63.30, I63.40, I63.50, I63.59

Common Procedure Codes

74263, 76390, 93356, S8042

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

The purpose of this policy is to address specific imaging procedures requiring retrospective review for specific products. Refer to Customer Product/Medical Management Requirements (last page).

Policy

Brain imaging, PET, perfusion evaluation (78609)

Brain imaging, PET, perfusion evaluation has not been proven to be effective and is, therefore, considered investigational.

Cerebral Magnetic Resonance Imaging (MRI) Perfusion (76498)

Cerebral magnetic resonance imaging (MRI) perfusion studies, including the obtaining of perfusion maps with determination of cerebral blood flow, cerebral blood volume, mean transit time (MTT) and time to peak (TTP) has not been proven in peer reviewed literature to provide superior outcomes to standard imaging procedures and is considered investigational.

Fluorine-18 fluorodeoxyglucose (F-18 FDG) imaging using dual-head coincidence detection system (non-dedicated PET scan) (S8085)

Fluorine-18 fluorodeoxyglucose (F-18 FDG) imaging using dual-head coincidence detection system (non-dedicated PET scan) has not been proven to be effective and is, therefore, considered investigational.

PET imaging whole body, melanoma for non-covered indications (G0219)

PET imaging whole body, melanoma for non-covered indications has not been proven to be effective and is, therefore, considered investigational.

<u>PET imaging, full & partial ring PET scanners only, for initial diagnosis of breast cancer</u> (initial staging of lymph nodes (G0252)

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PET imaging, full & partial ring PET scanners only, for initial diagnosis of breast cancer (initial staging of lymph nodes has not been proven to be effective, and therefore is considered investigational.

Scintimammography (S8080)

There is insufficient evidence in the peer-reviewed literature to support that Scintimammography is effective and is, therefore, considered investigational.

Myocardial Strain Imaging (MSI) (93356)

Myocardial strain imaging, which may be performed at the same time as Doppler echocardiography, measures myocardial contractility and is purported to detect myocardial ischemia. A technique called speckle-tracking is used to view the myocardium, particularly the left ventricle, at various angles during the echocardiographic procedure. Customers may be eligible under the Plan for tissue Doppler imaging as part of an overall echocardiographic examination. Tissue Doppler imaging with or without myocardial strain imaging is considered integral to the primary procedure and not separately reimbursable.

Opto-acoustic imaging, breast (C9788)

Opto-acoustic imaging combines laser pulses with ultrasound imaging for evaluation of breast abnormalities. There is not enough research to show that opto-acoustic imaging of the breast improves health outcomes. No clinical guidelines based on research recommend the use of opto-acoustic imaging of the breast. Therefore, opto-acoustic imaging of the breast is considered investigational for all indications.

Whole-Body Low-Dose CT

Whole-body low-dose CT is considered medically necessary for:

- Initial diagnostic workup for active multiple myeloma, smoldering myeloma, solitary plasmacytoma and monoclonal gammopathy of undetermined significance (MGUS).
- Whole-body CT scanning to screen for malignant diseases in individuals without symptoms is considered experimental and investigational.

Whole-Body MRI

Whole-Body MRI is considered medically necessary for:

- Initial diagnostic workup of Multiple Myeloma, to discern smoldering myeloma from multiple myeloma when whole-body low-dose CT or FDG PET/CT is negative.
- Follow-up/surveillance of Multiple Myeloma.
- Follow-up/surveillance of Smoldering Myeloma.

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- Initial diagnostic workup of Solitary Plasmacytoma.
- Whole-body MRI scanning to screen for other malignant diseases in individuals without symptoms is considered experimental and investigational.

Medicare Variations

Thermography

Thermography for any indication (including breast lesions which were excluded from Medicare coverage on July 20, 1984) is excluded from Medicare coverage because the available evidence does not support this test as a useful aid in the diagnosis or treatment of illness or injury. Therefore, it is not considered effective.

For full coverage of Indications and Limitations of Coverage refer to the following: 16.18. Centers for Medicare & Medicaid Services (CMS). Medicare Coverage Database. NCD for Thermography (220.11) Effective date: 12/21/1992. Available: www.cms.gov/.

<u>Angiography</u>

There is a Medicare National Coverage Determination (NCD) for Magnetic Resonance Angiography. For full coverage details refer to: Centers for Medicare & Medicaid Services (CMS). Medicare Coverage Database. National Coverage Determination (NCD) for Magnetic Resonance Angiography (220.3) Effective Date: 07/01/2003. Available: www.cms.gov/.

Calcium Scoring Test (CPT Code: 75571):

Computed tomography, heart, without contrast material, with quantitative evaluation of coronary calcium (Calcium Scoring Test) does not require prior authorization for Medicare plans.

References (Updated 2024)

- 1. Burgess RE, Kidwell CS. Use of MRI in the assessment of patients with stroke. Curr Neurol Neurosci Rep. 2011;11(1):28-34
- 2. Centers for Medicare & Medicaid Services (CMS). Medicare Claims Processing Manual. Chapter 13 radiology Services and Other Diagnostic Procedures. Rev. 4267. 03-27-2019. Available: www.cms.gov/manuals/downloads/clm104c13.pdf
- 3. Centers for Medicare & Medicaid Services (CMS). Medicare Coverage Database. NCD for Positron Emission Tomography (FDG) for Oncologic Conditions (220.6.17) June 11, 2013. Available: www.cms.gov/
- 4. Screening for Colorectal Cancer: Updated Evidence Report and Systematic Review for the US Preventive Services Task Force. *JAMA*, 2016; 315: 2576-2594.

Imaging Procedures Page 5 of 10

- 5. Qaseem A, Denberg TD, Hopkins RH, Humphrey LL, et al. Screening for colorectal cancer: A guidance statement from the American College of Physicians. Annals of Internal Medicine, 2012; 156:378-386.
- 6. Yee J, Kim DH, Rosen MP, Lalani T, et al. Expert Panel on Gastrointestinal Imaging. ACR Appropriateness Criteria® colorectal cancer screening. Reston (VA): American College of Radiology (ACR); 2013. 12 p.
- 7. Kim J, Leira EC, Callison RC, et al. Toward fully automated processing of dynamic susceptibility contrast perfusion MRI for acute ischemic cerebral stroke. Comput Methods Programs Biomed. 2010;98(2):204-213.
- 8. Kloska SP, Wintermark M, Engelhorn T, Fiebach JB. Acute stroke magnetic resonance imaging: Current status and future perspective. Neuroradiology. 2010;52(3):189-201.
- 9. Lee J, Inoue M, Mlynash M, et al. MR perfusion lesions after TIA or minor stroke are associated with new infarction at 7 days. Neurology. 2017;88(24):2254-2259.
- 10. Provenzale M, Shah K, Patel U, McCrory DC. Systematic Review of CT and MR Perfusion Imaging for Assessment of Acute Cerebrovascular Disease. American Journal of Neuroradiology, Sep 29, 2008.
- 11. Agency for Healthcare Research and Quality Technology Assessment, Magnetic Resonance Spectroscopy for Brain Tumors, June 2003.
- 12. Shah N, Sattar A, Benanti M, Hollander S, Cheuck L. Magnetic resonance spectroscopy as an imaging tool for cancer: A review of the literature. J Am Osteopath Assoc. 2006;106(1):23-27.
- 13. National Comprehensive Cancer Network ®. Clinical Practice Guidelines in Oncology™. Central Nervous System (CNS) Cancers Version 2.2020. Available: https://www.nccn.org/.
- 14. National Comprehensive Cancer Network ®. Clinical Practice Guidelines in Oncology™. Prostate Cancer Version 2.2020. Available: https://www.nccn.org/.
- 15. Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services. Effectiveness of non-invasive diagnostic tests for breast abnormalities. Comparative Effectiveness Review No. 2 February 2006.
- 16. Centers for Medicare & Medicaid Services (CMS). Medicare Coverage Database. NCD for Thermography (220.11) Effective date: 12/21/1992. Available: www.cms.gov/.
- 17. Mainiero MB, Lourenco A, Mahoney MC, Newell MS, Bailey L, Barke LD, et al. ACR Appropriateness Criteria Breast Cancer Screening. J Am Coll Radiol. 2016 Nov; 13(11S):R45-R49. Available: https://www.ncbi.nlm.nih.gov/pubmed/27814813.

Imaging Procedures Page 6 of 10

- 18. American Cancer Society (ACS). Breast Cancer Early Detection and Diagnosis. Last medical review. 10/03/2019. Available: http://www.cancer.org/cancer/breast-cancer/screening-tests-and-early-detection.html.
- 19. American College of Radiology (ACR). ACR appropriateness criteria ®. Low back pain. 2015. Available: https://acsearch.acr.org/list.
- 20. American College of Radiology (ACR). ACR appropriateness criteria ®. Myelopathy. 2015. Available: https://acsearch.acr.org/list.
- 21. National Comprehensive Cancer Network ®. Clinical Practice Guidelines in Oncology™. Breast cancer screening and diagnosis guidelines. Version 5.2020 Available: https://www.nccn.org/.
- 22. American Cancer Society (ACS). Breast Cancer. Tomosynthesis (3D Mammography). Last Medical review: 10/03/19. Last Revised: 03/05/20. Available: https://www.cancer.org/cancer/breast-cancer/screening-tests-and-early-detection/mammograms/mammogram-basics.html.
- 23. American College of Radiology (ACR). ACR Appropriateness Criteria: Breast Cancer Screening. Revised 2017. Available at: https://acsearch.acr.org/list.
- 24. Kupsch AR, Bajaj N, Weiland F, et al. Impact of DaTscan SPECT imaging on clinical management, diagnosis, confidence of diagnosis, quality of life, health resource use and safety in patients with clinically uncertain parkinsonian syndromes: a prospective 1-year follow-up of an open-label controlled study. J Neurol Neurosurg Psychiatry. 2012; 83(6):620-628.
- 25. Marshall VL, Reininger CB, Marquardt M et al. Parkinson's disease is overdiagnosed clinically at baseline in diagnostically uncertain cases: a 3-year European multicenter study with repeat [1231]FP-CIT SPECT. Mov Disord 2009; 24(4):500-8.
- 26. Vlaar AM, van Kroonenburgh MJ, Kessels AG et al. Meta-analysis of the literature on diagnostic accuracy of SPECT in parkinsonian syndromes. BMC Neurol 2007; 7:27.
- 27. Bairactaris C, Demakopoulos N, Tripsianis G et al. Impact of dopamine transporter single photon emission computed tomography imaging using I-123 ioflupane on diagnoses of patients with parkinsonian syndromes. J Clin Neurosci 2009; 16(2):246-52.
- 28. McKeith I, O'Brien J, Walker Z et al. Sensitivity and specificity of dopamine transporter imaging with 123I-FP-CIT SPECT in dementia with Lewy bodies: a phase III, multicentre study. Lancet Neurol 2007; 6(4):305-13.
- 29. Suchowersky O, Reich S, Perlmutter J et al. Practice Parameter: diagnosis and prognosis of new onset Parkinson disease (an evidence-based review): report of the Quality Standards Subcommittee of the American Academy of Neurology. Neurology 2006; 66(7):968-75. Available: http://www.neurology.org/content/66/7/968.full.pdf.

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30. There is a Medicare National Coverage Determination (NCD) for Centers for Medicare & Medicaid Services (CMS) for Thermography. For full coverage details refer to: Medicare Coverage Database. National Coverage Determination (NCD) for Thermography (220.11) Effective date: 12/21/1992. Available: https://www.cms.gov/.

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Customer Product	Medical Management Requirements*
New York Products	-
HMO	Retrospective Review
PPO in Plan	Retrospective Review
PPO OOP	Retrospective Review
POS in Plan	Retrospective Review
POS OOP	Retrospective Review
Essential Plan	Retrospective Review
MVP Medicaid Managed Care	Retrospective Review
MVP Child Health Plus	Retrospective Review
MVP Harmonious Health Care Plan	Retrospective Review
MVP Medicare Complete Wellness	Retrospective Review
MVP Medicare Preferred Gold HMO POS	Retrospective Review
MVP Medicare Secure HMO POS	Retrospective Review
MVP Medicare Secure Plus HMO POS	Retrospective Review
MVP Medicare WellSelect PPO	Retrospective Review
MVP Medicare Patriot Plan PPO	Retrospective Review
MVP DualAccess D-SNP HMO	Retrospective Review
MVP DualAccess Complete D-SNP HMO	Retrospective Review
MVP DualAccess Plus D-SNP HMO	Retrospective Review
UVM Health Advantage Select PPO	Retrospective Review
USA Care	Potential for Retrospective Review
Healthy NY	Retrospective Review
MVP Premier	Retrospective Review
MVP Premier Plus	Retrospective Review
MVP Premier Plus HDHP	Retrospective Review
MVP Secure	Retrospective Review
MVP EPO	Retrospective Review
MVP EPO HDHP	Retrospective Review
MVP PPO	Retrospective Review
MVP PPO HDHP	Retrospective Review
Student Health Plans	Retrospective Review
ASO	See SPD
Vermont Products	
POS in Plan	Retrospective Review
POS OOP	Retrospective Review
MVP Medicare Preferred Gold HMO POS	Retrospective Review
MVP Medicare Secure Plus HMO POS	Retrospective Review
MVP VT HMO	Retrospective Review
MVP VT HDHP HMO	Retrospective Review
MVP VT Plus HMO	Retrospective Review
MVP Secure	Retrospective Review
ASO	See SPD

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro ReviewRetrospective Review RequiredNot CoveredService is not a covered benefit.See SPDSee Specific Plan Design

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Revision History:

12/01/2021 – Magnetic resonance spectroscopy (76390), Magnetic resonance imaging (MRI), low-field (S8042) removed from investigational review into a covered benefit for all LOB. Computed tomographic (CT) colonography, screening (74263) removed from investigational review and will be covered for Commercial and Medicaid plans. Computed tomographic (CT) colonography, screening (74263) is not covered for Medicare plans as of 7/1/2021. Cerebral perfusion analysis using computed tomography (0042T) removed from investigational review for Medicare plans only. 78609, G0219, G0252, G0235, S8080, S8085, and S8092 removed from investigational review for Medicare plans and will deny at the claims level because they are not Medicare reimbursed codes.

10/01/22 – Added coverage for myocardial strain imaging (93356) to all plans. 0042T removed from experimental investigational review and now requires PA with eviCore.

02/01/2024 - Added C9788 Opto-acoustic imaging as an exclusion.

08/01/2024 – Added indications for whole-body low dose CT.

10/01/2024 -Added indications for whole-body MRI.

04/01/2025 – Added Calcium Score Test (CPT Code 75571) to Medicare plans.

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Immunizations Childhood, Adolescents, and Adults

Type of Policy: Medical

Prior Approval Date: 09/25/2023

Approval Date: 12/04/2023

Effective Date: 02/01/2024

Related Polices: N/A

Refer to the MVP website for the Medicare Part D formulary for vaccines that may be covered under the Part D benefit.

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

N/A

Codes Subject to Retrospective Review

N/A

Experimental/Investigational

90584 – Dengue vaccine, quadrivalent, live, 2 dose schedule, for subcutaneous use

Common Diagnosis Codes

N/A

Common Procedure Codes

CPT Codes: 90375, 90376, 90377, 90380, 90381, 90587, 90611, 90619, 90620, 90621, 90622, 90623, 90630, 90632, 90633, 90634, 90636, 90637, 90638, 90644, 90647, 90648, 90649, 90650, 90651, 90653, 90654, 90655, 90656, 90657, 90658, 90660, 90661, 90662, 90664, 90666, 90668, 90670, 90671, 90672, 90673, 90675, 90676, 90677, 90678, 90679, 90680, 90681, 90682, 90684, 90685, 90686, 90687, 90688, 90689, 90694, 90696, 90697,

Immunizations: Childhood, Adolescents, Adults Page 1 of 7

90698, 90700, 90702, 90707, 90710, 90713, 90714, 90715, 90716, 90723, 90732, 90733, 90734, 90736, 90739, 90740, 90743, 90744, 90746, 90747, 90748, 90750, 90756, 90759

Government authorized COVID-19 vaccine codes including: 91304, 91318, 91319, 91320, 91321, 91322

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy.

Overview

Immunization is the most effective way to control and eradicate infectious diseases. Focusing on prevention has contributed significantly to decreased morbidity and mortality of infants, adolescents and adults. Those who are not vaccinated are vulnerable to infectious diseases and pose a threat to themselves and to others.

Indications/Criteria

Childhood, adolescent and adult immunizations are considered when all of the following are met:

- Indications for childhood and adolescent immunizations follow recommendations of
 the American Academy of Pediatrics (AAP). The official recommendations of the
 United States Preventive Services Task Force (USPSTF) Guide to Clinical Preventive
 Services, the Advisory Committee on Immunization Practices (ACIP) and the United
 States Department of Health and Human Services Centers for Disease Control and
 Prevention (CDC) will be considered for childhood, adolescent and/or adult
 indications. MVP Health Care will cover immunizations recommended by the CDC
 when the recommendations of the ACIP are published on the CDC web site.
 Immunizations will be eligible for retrospective reimbursement back to the date of
 the ACIP meeting when the recommendation was approved; and
- immunizations must be administered according to FDA approved indications.
- In certain types of emergencies, the FDA can issue an emergency use authorization, or EUA, to provide more timely access to certain vaccines. Vaccines are considered medically necessary when the vaccine receives FDA EUA and is recommended by the CDC with the recommendation of the ACIP.

Permissive recommendations of the Advisory Committee on Immunization Practices (ACIP) are not considered medically necessary and, therefore, are not covered.

Additional vaccines may be licensed and recommended during the year.

Immunizations: Childhood, Adolescents, Adults

The schedule for routinely recommended vaccines is subject to change due to CDC recommendations during times of vaccine shortages.

Human postexposure treatment for rabies (CPT Codes 90375, 90376, 90377 (Immunoglobulin treatment) 90675, 90676 (rabies vaccine)) is covered for all lines of business. Providers should get pre-approval by the County Health Authority (CHA), however, it is not required.

Respiratory Syncytial Virus (RSV) Vaccines is indicated for:

- Adults 60 years of age and older may receive a single dose of Respiratory Syncytial Virus (RSV) vaccine (CPT Codes: 90678, 90679)
- Either vaccination, but not both will be covered.
- pregnant individuals at 32 through 36 weeks gestational age for the prevention of lower respiratory track disease (LRTD) caused by RSV in infants from birth through 6 months of age (CPT Code: 90678 only)

Exclusions

- Permissive recommendations of the Advisory Committee on Immunization Practices (ACIP) are not considered medically necessary and, therefore, are not covered.
- Immunizations for travel purposes, employment, or college entrance. Vaccinations or inoculations are excluded as immunizations unless they are directly related to the treatment of an injury or direct exposure to a disease or condition.
- Individuals with demonstrated allergy to any of the components of vaccines are exempt from immunization with the specific antigens or carrier when identified.
- Instances of unsubstantiated risk.
- Dengue vaccine, quadrivalent, live, 2 dose schedule, for subcutaneous use (CPT Code 90584) is not covered because it is pending FDA approval and not recommended by ACIP.

Medicare Part D Variation:

Some vaccines are covered under the Medicare Part D pharmacy benefit. Per CMS guidance, most Part D vaccines are covered at \$0 cost share for an applicable vaccine with the date on which the CDC director adopts the respective ACIP vaccine recommendation. Refer to the MVP website for the Medicare Part D formulary for vaccines that may be covered under the Part D benefit.

<u>Immunizations</u>-covered under Part B including but not limited to:

 Hepatitis B vaccine- when administered to patient who is at high or intermediate risk of contracting hepatitis B

Immunizations: Childhood, Adolescents, Adults

- High risk groups include: individuals with ESRD; individuals with hemophilia who received Factor VIII or IX concentrates; clients of institutions for individuals for the mentally handicapped; persons who live in the same household as a hepatitis B virus (HBV) carrier; homosexual men; illicit injectable drug abusers
- Intermediate risk groups include staff in institutions for the mentally handicapped and workers in health care professions who have frequent contact with blood or blood-derived body fluids during routine work
- Pneumococcal vaccines
- Tetanus-when administered directly related to the treatment of an injury
- Influenza vaccine

See Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health Services, Section 50.4.4.2. for details.

References (Review 2023)

- 1. Centers for Disease Control and Prevention (CDC). Immunization Schedules. Accessed March 1, 2021. Available at: http://www.cdc.gov/vaccines/schedules/hcp/index.html
- 2. Centers for Disease and Prevention (CDC) Adivory Committee on Immunization Practices (ADIP) Vaccine Recommendations and Guidelines Available: <u>ACIP Vaccine Recommendations | CDC</u>
- 3. Centers for Medicare and Medicaid (CMS) Medicare Benefit Policy Manual, Chapter 15 Covered Medical and Other Health Services, Section 50.4.4.2. Revision 202,Effective: 09/19/2014. Available: https://www.cms.gov/Regulations-and-guidance/Manuals/downloads/bp102c15.pdf
- State of New York Insurance Department. Circular Letter No. 13 (2006) Coverage for Preventive and Primary Care Services. Available: www.dfs.ny.gov/insurance/circltr/2006/cl06 13.htm
- U.S. Preventive Services Task Force. Recommendations for Primary Care Practice. Published Recommendations. Immunizations for adults. Accessed March 1, 2021. Available at: https://www.uspreventiveservicestaskforce.org/BrowseRec/ReferredTopic/232
- 6. U.S. Preventive Services Task Force. Recommendations for Primary Care Practice. Published Recommendations. Immunizations for children. Accessed March 1, 2021. Available at: https://www.uspreventiveservicestaskforce.org/BrowseRec/ReferredTopic/233
- 7. U. S. Food and Drug Administration. Letter of authorization: Emergency use Authorization (EUA) for use of Novavax COVID-19 Vaccine, Adjuvanted. July 13, 2022. Available at: https://www.fda.gov/media/159902/download

Immunizations: Childhood, Adolescents, Adults
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- 8. State of New York Public Health Law Chapter 655, post-exposure treatment for rabies, November 23, 2022 Available: <u>Law</u>
- 9. U.S. Food and Drug Administration. Amended emergency use authorizations (EUAs) April 18, 2023. Available: <u>Coronavirus (COVID-19) Update: FDA Authorizes Changes to Simplify Use of Bivalent mRNA COVID-19 Vaccines | FDA</u>

Customer Product	Medical Management Requirements*
New York Products	
HMO	Potential for Retrospective Review
PPO in Plan	Potential for Retrospective Review
PPO OOP	Potential for Retrospective Review
POS in Plan	Potential for Retrospective Review
POS OOP	Potential for Retrospective Review
Essential Plan	Potential for Retrospective Review
MVP Medicaid Managed Care	Potential for Retrospective Review
MVP Child Health Plus	Potential for Retrospective Review
MVP Harmonious Health Care Plan	Potential for Retrospective Review
MVP Medicare Complete Wellness	Potential for Retrospective Review
MVP Medicare Preferred Gold HMO POS	Potential for Retrospective Review
MVP Medicare Secure HMO POS	Potential for Retrospective Review
MVP Medicare Secure Plus HMO POS	Potential for Retrospective Review
MVP Medicare WellSelect PPO	Potential for Retrospective Review
MVP Medicare WellSelect Plus PPO	Potential for Retrospective Review
MVP Medicare Patriot Plan	Potential for Retrospective Review
MVP DualAccess D-SNP HMO	Potential for Retrospective Review
MVP DualAccess Complete D-SNP HMO	Potential for Retrospective Review
MVP DualAccess Plus D-SNP HMO	Potential for Retrospective Review
UVM Health Advantage Select PPO	Potential for Retrospective Review
USA Care PPO	Potential for Retrospective Review
Healthy NY	Potential for Retrospective Review
MVP Premier	Potential for Retrospective Review
MVP Premier Plus	Potential for Retrospective Review
MVP Premier Plus HDHP	Potential for Retrospective Review
MVP Secure	Potential for Retrospective Review
MVP EPO	Potential for Retrospective Review
MVP EPO HDHP	Potential for Retrospective Review
MVP PPO	Potential for Retrospective Review
MVP PPO HDHP	Potential for Retrospective Review
Student Health Plans	Potential for Retrospective Review
ASO	See SPD
Vermont Products	366 31 2
POS in Plan	Potential for Retrospective Review
POS OOP	Potential for Retrospective Review
MVP Medicare Preferred Gold HMO POS	Potential for Retrospective Review
MVP Medicare Secure Plus HMO POS	Potential for Retrospective Review
MVP VT HMO	Potential for Retrospective Review
MVP VT HDHP HMO	Potential for Retrospective Review
MVP VT Plus HMO	Potential for Retrospective Review
MVP VT Plus HDHP HMO	Potential for Retrospective Review
MVP Secure	Potential for Retrospective Review
ASO	See SPD

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Revision History:

12/06/2021 – Added codes for COVID-19 vaccines, criteria utilizing EUA and references updated.

08/01/2022 – annual review, links checked, added COVID19 vaccination codes and coverage indications for vaccine that receive FDA EUA.

01/20/2023 – Coverage updated to reflect New York State regulations regarding the coverage of post-exposure treatment for rabies.

5/12/2023 – The monovalent COVID-19 vaccines are no longer authorized for use by the FDA (91300, 91301, 91303, 91305, 91306, 91307, 91308, 91309, 91311) and removed from coverage.

9/22/23 - added CPT Codes 90678, 90679 to coverage as of 7/1/23.

9/25/2023 – added CPT Codes 90380, 90381 to coverage as of 9/1/2023. Added 91318, 91319, 91320, 91321, 91322 to coverage as of 9/11/2023.

Immunizations: Childhood, Adolescents, Adults



Implantable Cardioverter Defibrillators, Implantable Dual Chamber Automatic Defibrillators, Cardiac Resynchronization Devices

Type of Policy: Surgical

Prior Approval Date: 03/10/2023

Approval Date: 03/04/2024

Effective Date: 06/01/2024

Related Polices: Cardiac Output Monitoring by

Thoracic Electrical Bioimpedance

Biventricular Pacing – Cardiac Resynchronization Therapy

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

CPT Codes:

33270- Insertion or replacement of permanent subcutaneous implantable defibrillator system, with subcutaneous electrode, including defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters, when performed

33271 - Insertion of subcutaneous implantable defibrillator electrode

Codes Subject to Retrospective Review

N/A

Experimental/Investigational

N/A

Common Diagnosis Codes

ICD-10 Diagnosis Codes: I44.4, I44.5, I44.60, I44.69, I44.7, I45.0, I45.19, I44.30, I44.39, I45.4, I45.2, I46.2, I46.8, I46.9, I47.0, I47.2, I48.0, I48.2, I48.91, I49.01, I49.02, I50.20, I50.21, I50.23, I50.30, I50.31, I50.32, I50.33, I50.40, I50.41, I50.42, I50.43, I50.1, I50.9, Z86.79

Common Procedure Codes

CPT Codes: 33216, 33217, 33225, 33230, 33231, 33240, 33249, 33272, 33273, 93260, 93261, 93644, G0448

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy.

Overview

Implantable cardioverter defibrillator (ICD) or automated implantable cardioverter defibrillator (AICD) is an electronic device designed to detect and treat life-threatening tachyarrhythmia. The device consists of a pulse generator and electrodes for sensing dual chamber or single chamber and defibrillator. ICDs are indicated to prevent "sudden death" in patients who have experienced life-threatening ventricular arrhythmias such as sustained ventricular tachycardia (VT) and ventricular fibrillation (VF). Recently, there have been large, randomized studies that have established a significant reduction in mortality in those patients with CAD (Coronary Artery Disease) and/or prior myocardial infarction who have poor ventricular function as evidenced by an ejection fraction of 35% or less. Careful screening of candidates is necessary; the ideal candidate is one that is at high-risk of death from an arrhythmia but not death from other causes.

Biventricular pacing or Cardiac Resynchronization Therapy (CRT), using three leads (one in the right atrium and one in each ventricle), has been shown to improve hemodynamic status in patients with Congestive Heart Failure (CHF). It has been studied in patients with New York Heart Association (NYHA) Class III or IV that have intraventricular conduction disorders resulting in a discoordinated contraction pattern and a wide QRS interval on the electrocardiogram. It is estimated that 20-30% of patients with advanced heart failure may have a condition in which the ventricles are not beating in a synchronized fashion. This condition, ventricular dysynchrony, may worsen heart failure symptoms. Currently, there is no drug therapy available to correct ventricular dysynchrony. There are times when a combination CRT/ICD system is used when the customer has ventricular dysfunction that may also have indications for an ICD.

The subcutaneous implantable cardioverter defibrillator (S-ICD) has been proposed as an alternative to transvenous ICDs. This device differs from a transvenous ICD device because its leads are placed subcutaneously, rather than electrodes placed in or on the

heart. Evidence published to date evaluating the subcutaneous implantable cardioverter defibrillator (S-ICD) is limited.

Indications/Criteria

Documentation Requirements

- Medical necessity must be documented in the medical record and available upon request, including a functional classification of the customer's heart failure as well as diagnostic studies (EP Studies). Myocardial infarction should be documented by elevated cardiac enzymes or Q-waves on EKG and ejection fraction should be measured by angiography, radionuclide scanning or echocardiography.
- Classification of customer's heart failure must be according to New York Heart Association (NYHA) Classification - The Stages of Heart Failure:
 - 1. Class I No symptoms and no limitation in ordinary physical activity, e.g., shortness of breath when walking, climbing stairs etc.
 - 2. Class II Mild symptoms (mild shortness of breath and/or angina) and slight limitation during ordinary activity.
 - 3. Class III Marked limitation in activity due to symptoms, even during less-than-ordinary activity, e.g., walking short distances (20—100 m). Comfortable only at rest.
 - 4. Class IV Severe limitations. Experiences symptoms even while at rest. Mostly bedbound patients.
- For CRT, the treating physician must submit documentation that all medical therapies have been tried and exhausted.

Policy Criteria

Indications for Implantable Cardioverter Defibrillator (ICD)

Secondary Prevention

- Documented episode of cardiac arrest due to ventricular fibrillation (VF) not due to transient reversible cause (e.g., drug toxicity, electrolyte imbalance, ischemia).
- Documented sustained ventricular tachycardia (VT), either spontaneous or induced by an electrophysiology (EP) study, not associated with an acute myocardial infarction (MI) and not due to transient or reversible cause.
- Hypertrophic cardiomyopathy with prior documentation of cardiac arrest, ventricular fibrillation, or hemodynamically significant ventricular tachycardia (VT)

Primary Prevention

 Documented familial or inherited conditions with a high-risk of life-threatening VT, such as long QT syndrome or Brugada syndromes, hypertrophic cardiomyopathy,

Implantable Cardioverter Defibrillators, Implantable Dual Chamber Automatic Defibrillators, Cardiac Resynchronization Devices

- catecholaminergic polymorphic ventricular tachycardia and arrhythmogenic right ventricular dysplasia.
- documented prior myocardial infarction (MI), a measured left ventricular ejection fraction (LVEF) < 35% and inducible, sustained ventricular tachycardia (VT) or ventricular fibrillation (VF) at electrophysiology (EP) study. (The myocardial infarction (MI) must have occurred at least forty (40) days prior to defibrillator insertion. The electrophysiology (EP) study must be done more than four weeks after qualifying MI).
- customers with ischemic dilated cardiomyopathy (IDCM), documented prior myocardial infarction, New York Heart Association (NYHA) Class I, Class II and III heart failure, and measured left ventricular ejection fraction (LVEF) ≤ 35%;
- customers with non-ischemic dilated cardiomyopathy (NIDCM), NYHA Class II and III
 heart failure, measured LVEF ≤ 35%, and experienced continued symptoms after
 maximal medical treatment including ace inhibitors and beta blockers;
- customers who meet all current coverage requirements for a cardiac resynchronization therapy (CRT) device and have Class IV heart failure; or
- For each of the above-mentioned primary prevention conditions, the following additional criteria must be met:
 - o customers must be able to give informed consent; and
 - customers must not have:
 - cardiogenic shock or symptomatic hypotension while in a stable baseline rhythm;
 - had a coronary artery bypass graft (CABG) or percutaneous transluminal coronary angioplasty (PTCA) within the last three (3) months;
 - had an acute myocardial infarction (MI) within the past 40 days;
 - clinical symptoms or findings that would make them a candidate for coronary revascularization;
 - irreversible brain damage from pre-existing cerebral disease; or
 - any disease, other than cardiac disease (e.g., cancer, uremia, liver failure), associated with a likelihood of survival less than one year;
 - ejection fractions must be measured by angiography/ventriculography, radionuclide scanning, or echocardiography; MRI; or
 - myocardial infarctions must be documented and defined according to the consensus document of the Joint European Society of Cardiology/American College of Cardiology Committee for the Redefinition of Myocardial Infarction.

<u>Indication Dual Chamber Implantable Automatic Defibrillators (ICD)</u>

- Must meet the listed indications for ICD (noted above).
- Evidence of SA and AV nodal dysfunction, including, but not limited to, bradyarrhythmia, supraventricular tachycardia (i.e., atrial fibrillation, atrial flutter, atrioventricular nodal re-entry tachycardia), bundle branch block, or long PR interval.

Indication Subcutaneous Implantable Automatic Defibrillators (S-ICD)

- Must meet the listed indications for ICD (noted above), and
- Pacing for bradycardia, ventricular tachycardia termination, or as part of a cardiac resynchronization therapy is not anticipated or needed, and
- One of the following:
 - o Customer has inadequate vascular access, or
 - Customer is at a high risk of infection.

Cardiac resynchronization therapy (CRT) or biventricular pacing devices (CPT 33225)

Cardiac resynchronization therapy (CRT) is medically indicated for the following:

- customer has moderate to severe heart failure defined as NYHA Class III and IV; and
 - left ventricular ejection fraction of < 35%; and
 - o electrocardiogram QRS duration > 120 msec; and
 - customer remains symptomatic despite optimized medical therapy, includes use of an ACE inhibitor or angiotensin receptor blocker, beta-blocker, and diuretics for at least three months or more; or
- customer has moderate heart failure defined as NYHA Class II and left bundle branch block (LBBB); and
 - left ventricular ejection fraction of < 30%; and
 - o electrocardiogram QRS duration > 130 msec; and
 - customer remains symptomatic despite optimized medical therapy, includes use
 of an ACE inhibitor or angiotensin receptor blocker, beta-blocker, and diuretics
 for at least three months or more.

customer remains symptomatic despite optimized medical therapy, includes use of an ACE inhibitor or angiotensin receptor blocker, beta-blocker, and diuretics for at least three months or more. The use of biventricular pacemaker cardioverter is considered medically indicated when the customer meets criteria for biventricular pacing as well as one of the indications for ICD implantation. Interrogation device evaluation (in person and remote) is indicated for device evaluation, pacing and sensing thresholds, lead wire function, battery level, and recorded episodes of arrhythmia detection and device activation.

Exclusions

Implantable cardioverter-defibrillators are not medically indicated when:

- other disease processes are present that clearly limit the customer's life expectancy;
- customer has asymptomatic VT or symptomatic VT/VF associated with acute myocardial infarction within two days, controlled by appropriate drug therapy and amenable to a definitive therapy (e.g., ablative procedure);
- clinical symptoms or findings that would make the customer a candidate for revascularization;
- all customers being considered for implantation of ICD must not have irreversible brain damage, disease or dysfunction that would preclude the ability to give informed consent;
- cardiogenic shock or symptomatic hypotension while in a stable baseline rhythm;
- ICDs in the treatment of only chronic atrial fibrillation;
- implantable hemodynamic cardiovascular monitoring devices (e.g., Chronicle IHM System) are considered experimental/investigational. The evidence in the medical literature does not support that these devices improve health outcomes;

Medicare Variation

Implantable automatic defibrillators (including subcutaneous S-ICD) are covered according to the conditions set forth by the Centers for Medicare & Medicaid Services (CMS). Refer to the CMS link for the full details of CMS National Coverage Determination for Implantable Automatic Defibrillators (20.4). Available: https://www.cms.gov/

National Coverage Determination (NCD) for Routine Costs in Clinical Trials (310.1) available: https://www.cms.gov/

References (Updated 2024)

- Goldberger, Z., et al. Cost advantage of dual-chamber versus single-chamber cardioverter-defibrillator implantation. Journal of American College of Cardiology (2005), 46:850-857. [On-Line] Available: http://www.onlinejacc.org/content/46/5/850.
- 2. Kolb, C. et al. Long-term follow-up of patients supplied with single-chamber or dual-chamber cardioverter defibrillators. Pacing Clinical Electrophysiology (2006). 9:946-952.

- Centers for Medicare and Medicaid Services. Decision Memo for Implantable Defibrillators (CAG-00157R3). January 2005. Available: https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=148.
- Priori, Silvia G., Napolitano, Carlo, Memmi, Mirella, et al. Clinical and Molecular Characterization of Patients with Catecholaminergic Polymorphic Ventricular Tachycardia. Circulation (2002); 106:69-74. Available: https://www.ahajournals.org/.
- 5. Antzelevitch, C., Brugada, P., Brugada, R., et al. Brugada Syndrome: A Decade of Progress. Circulation Research (2002); 91:1114-1118. Available: https://www.ahajournals.org/.
- Centers for Medicare & Medicaid Services (CMS). Medicare Coverage Database. NCD for Implantable Automatic Defibrillators (100-3). Updated 3/26/2019. Available: https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=110&ncdver=4&bc=AAAAgAAACAAA&.
- 7. FDA Talk Paper, July 18, 2002. FDA Approves New Indication for Implantable Cardioverter Defibrillators. Available: www.fda.gov.
- 8. FDA Talk Paper, May 2, 2002. FDA Approves New Type of Defibrillator. Available: www.fda.gov.
- 9. Gregoratos, Gabriel et al., American College of Cardiology, American Heart Association 2002 Guideline Update for Implantation of Cardiac Pacemakers and Antiarrhythmia Devices, September 2002. Available: www.acc.org.
- 10. Hunt, Sharon et al, American College of Cardiology, American Heart Association Guidelines for the Evaluation and Management of Chronic Heart Failure in the Adult, November 2001. Available: www.acc.org.
- 11. Abraham, William T., Fisher, Westby G., Smith, Andrew L., et al, Cardiac Resynchronization in Chronic Heart Failure. The New England Journal of Medicine Volume 346: 1845-1853. June 2002.
- 12. Moss, Arthur J., Zareba, Wojciech, Hall, Jackson W., et al., Prophylactic Implantation of a Defibrillator in Patients with Myocardial Infarction and Reduced Ejection Fraction. The New England Journal of Medicine, Volume 346: 877-883. March 2002.
- 13. Cooper, Joshua M., Katcher, Michael S., Orlov, Michael V., Implantable Devices for the Treatment of Atrial Fibrillation. The New England Journal of Medicine Volume 346: 2062-2068. June 2002.
- 14. Young, James B., Abraham, William T., Smith, Andrew L. Combined Cardiac Resynchronization and Implantable Cardioversion Defibrillation in Advanced Chronic Heart Failure. Journal of the American Medical Association. Volume 289: 2685-2694. 2003.

- 15. Leon, Angel R., Cardiac Resynchronization Therapy Devices: Patient Management and Follow-up Strategies. Reviews in Cardiovascular Medicine. Volume 4, (Suppl. No 2): S38-S46. 2003.
- 16. Bourge, R C, et al. Randomized controlled trial of an implantable continuous hemodynamic monitor in patients with advanced heart failure: the COMPASS-HF study. Journal of the American College of Cardiology. 2008; 51; 1073-1079.
- 17. Epstein, A., et al. ACC/AHA/HRS 2008 Guidelines for device-based therapy of cardiac rhythm abnormalities. Journal of the American College of Cardiology 2008; 51: e1-62.
- 18. Kadish, A. et al. Patients with recently diagnosed non-ischemic cardiomyopathy benefit from implantable cardioverter-defibrillators. Journal of the American College of Cardiology. 2006. 47; 2477-2482.
- 19. Kadish, A. et al. Prophylactic defibrillator implantation in patients with non-ischemic dilated cardiomyopathy. New England Journal of Medicine 2004, 350: 2151-2158.
- 20. Connolly, S.J., et al. Meta-analysis of the implantable cardioverter defibrillator secondary prevention trials. European Heart Journal. 2000; 21: 2071-2078.
- 23. AVID Investigators. A comparison of antiarrhythmic-drug therapy with implantable defibrillators in patients resuscitated from near-fatal ventricular arrhythmias. The Antiarrhythmics versus implantable defibrillators (AVID) investigators. 1997; 337 (22): 1621-1623.
- 24. Gersh, BJ, et al. 2011 ACCF/AHA guideline for the diagnosis and treatment of hypertropic cardiomyopathy: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines developed in collaboration with the American Association for Thoracic Surgery, American Society of Echocardiography, American Society of Nuclear Cardiology, Heart Failure Society of America, Heart Rhythm Society, Society for Cardiovascular Angiography and Interventions, and Society of Thoracic Surgeons. Journal of the American College of Cardiology. 2011; 58; e212-e210.
- 25. 2009 American College of Cardiology Foundation/American Heart Association (ACCF/AHA). Focused Update: ACCF/AHA Guidelines for the Diagnosis and Management of Heart Failure in Adults. A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. (March 2009). Circulation. 019.192064v1.
- 26. Ganz, L. Implantable cardioverter-defibrillators: Patient follow-up. UpToDate. November 2006.
- 27. National Institute for Health and Clinical Excellence (NICE). Technology appraisal guidance TA314. Implantable cardioverter defibrillators and cardiac

- resynchronisation therapy for arrhythmias and heart failure. London, UK: NICE; June 2014 Jan. Available: https://www.nice.org.uk/guidance/ta314
- 28. Zipes DP, Camm AJ, Borgrefe M, Buxton AE, Chaitman B, Fromer M, et al. ACC/AHA 2006 guidelines for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death: a report of the American College of Cardiology/American Heart Association Task Force and the European Society of Cardiology Committee for Practice Guidelines (Writing Committee to Develop Guidelines for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death). J Am Coll Cardiol 2006; 48:247-346.
- 29. Bardy G, Lee KL, Mark DB, Poole JE, Packer DL, Boineau R for the Sudden Cardiac Death in Heart Failure Trial (SCD0HeFT) Investigators. Amiodarone or an implantable cardioverter-defibrillator for congestive heart failure. N Engl J Med. 2005 Jan 20; 352(3):225-37.
- 30. Russo AM, Stainback RF, Bailey SR, Epstein AE, Heidenreich PA, Jessup M, et al. ACCF/HRS/AHA/ASE/HFSA/SCAI/SCCT/SCMR 2013 appropriate use criteria for implantable cardioverter-defibrillators and cardiac resynchronization therapy: a report of the American College of Cardiology Foundation appropriate use criteria task force, Heart Rhythm Society, American Heart Association, American Society of Echocardiography, Heart Failure Society of America, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, and Society for Cardiovascular Magnetic Resonance. J Am Coll Cardiol. 2013 Mar 26; 61(12):1318-68.
- 31. Tracy CM, Epstein AE, Darbar D, Dimarco JP, Dunbar SB, Estes NA 3rd, et al. 2012 ACCF/AHA/HRS focused update of the 2008 guidelines for device-based therapy of cardiac rhythm abnormalities: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol. 2012 Oct 2; 60(14):1297-313.
- 32. Yankee CW, Jessup M, Bosket B, Missouri FA, Butler J, McBride PE, et al.; ACCF/AHA Task Force Members. 2013 ACCF/AHA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol. 2013 Jun 5. pii: S0735-1097(13)02114-1.
- 33. Stavrakis S, Lazzara R, Thadani U. The benefit of cardiac resynchronization therapy and QRS duration: a meta17 analysis. J Cardiovasc Electrophysiol. 2012; 23:163-8.
- 34. Sipahi I, Chou JC, Hyden M, Rowland DY, Simon DI, Fang JC. Effect of QRS morphology on clinical event reduction with cardiac resynchronization therapy: meta-analysis of randomized controlled trials. Am Heart J. 2012 Feb; 163(2):260-7.

- 35. Köbe J, Reinke F, Meyer C, Shin DI, Martens E, Kääb S, Implantation and follow-up of totally subcutaneous versus conventional implantable cardioverter-defibrillators: A multicenter case-control study. Heart Rhythm. 2012 Sep 29. pii: S1547-5271(12)01185-X. doi: 10.1016/j.hrthm.2012.09.126.
- 36. Olde Nordkamp LR, Dabiri Abkenari L, Boersma LV, Maass AH, de Groot JR, van Oostrom AJ, et al. The entirely subcutaneous implantable cardioverter-defibrillator: initial clinical experience in a large Dutch cohort. J Am Coll Cardiol 2012 Nov 6; 60(19):1933-9.
- 37. Bardy GH, Smith WM, Hood MA, et al. An entirely subcutaneous implantable cardioverter-defibrillator. *N Engl J Med*. 2010; 363(1):36-44. Available: http://www.nejm.org/doi/full/10.1056/NEJMoa0909545.
- 38. Pettit SJ, McLean A, Colquhoun I, Connelly D, McLeod K. Clinical experience of subcutaneous and transvenous implantable cardioverter defibrillators in children and teenagers. *Pacing Clin Electrophysiol*. 2013 Dec 36 (12): 1532-8.
- 39. Hayes Health Technology Assessement. Subcutaneous Implantable Cardioverter Defibrillator (S-ICD) for Prevention of Sudden Cardiac Death. HAYES, Inc.; © 2021 Hayes, a symplr company. May 7, 2020. Annual review: May 3, 2022.
- 40. Boston Scientific Corp. S-ICD® System 2013. Available: http://www.bostonscientific.com/s-icd/index.html.
- 41. Zareba W, Klein H, Cygankiewicz I, et al; MADIT-CRT Investigators. Effectiveness of cardiac resynchronization therapy by QRS morphology in the Multicenter Automatic Defibrillator Implantation Trial-Cardiac Resynchronization Therapy (MADIT-CRT). Circulation. 2011; 123(10):1061-1072.
- 42. Tang AS, Wells GA, Talajic M, et al; Resynchronization-Defibrillation for Ambulatory Heart Failure Trial Investigators. Cardiac-resynchronization therapy for mild-to-moderate heart failure. N Engl J Med. 2010; 363(25):2385-2395.
- 43. Linde C, Daubert C. Cardiac resynchronization therapy in patients with New York Heart Association class I and II heart failure: An approach to 2010. Circulation. 2010;122(10):1037-1043.
- 44. U.S. Food and Drug Administration. Center for Devices and Radiological Health (CDRH). Premarket Approval. Cognis CRT-D Models N118, N119, Livian CRT-D Models H220, H225, H227 and H229, Contak Renewal 3 RF HE CRT-D Models H210, H215, H217, H219 P010012/S230. September 16, 2010. Available: http://www.accessdata.fda.gov/cdrh docs/pdf/p010012s230a.pdf.
- 45. Maron, BJ, et al. Implantable cardioverter-defibrillators and prevention of sudden cardiac death in hypertrophic cardiomyopathy. JAMA. 2007 July 25; 298(4):405-12.

Customer Product	Medical Management Requirements*
New York Products	
HMO	Prior Auth
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MVP Medicare Complete Wellness	Prior Auth
MP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP Medicare WellSelect PPO	Prior Auth
MVP Medicare WellSelect Plus PPO	Prior Auth
MVP DualAccess D-SNP HMO	Prior Auth
MVP DualAccess Complete D-SNP HMO	Prior Auth
MVP DualAccess Plus D-SNP HMO	Prior Auth
UVM Health Advantage Select PPO	Prior Auth
USA Care	Potential for Retrospective Review
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	
POS in Plan	Prior Auth
POS OOP	Prior Auth
MP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP VT HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD
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[♦] Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Revision History:

12/1/2022 – Annual review; eliminated references to ejection fractures of $\leq 30\%$, eliminated Medicare criteria as criteria and indications for MVP are the same, updated references.

04/01/2023 – Prior authorization removed.

06/01/2023 – Added prior authorization and coverage criteria to permanent subcutaneous implantable defibrillator systems (CPT 33270, 33271)



Advanced Infertility Services and In Vitro Fertilization (IVF)

Type of Policy: Medical

Prior Approval Date: 03/04/2024

Approval Date: 07/01/2024

Effective Date: 10/01/2024

Related Polices: Infertility (Drug Therapy) Pharmacy Policy

Fertility Preservation Services Medical Policy

Basic Infertility Services Medical Policy Preimplantation Genetic Testing - PGT

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

58970, 58974, 89250, 89254, 89255, 89257, 89258, 89264, 89268, 89272, 89280, 89281, 89342, 89352, S4011, S4015, S4016, S4022, S4027, S4028, S4037, S4040

Codes Subject to Retrospective Review

54900, 54901, 58750, 58752, 89251, 89253, 89398

Experimental/Investigational

89251, 89253, 89398

Common Diagnosis Codes

ICD-10 Diagnosis Codes: E23.0, N46.01, N46.021, N46.022, N46.023, N46.024, N46.025, N46.029, N46.11, N46.121, N46.122, N46.123, N46.124, N46.125, N46.129, N46.8, N46.9, N81.3, N97.0, N97.1, N97.2, N97.8, N97.9, Z31.83, Z31.84

Common Procedure Codes

CPT Codes:, S4017, S4018, S4020, S4021, S4031,

Advanced Infertility Services

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Non-Covered Codes

CPT Codes: 58976, S4013, S4014, S4023, S4025, S4026, S4042

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy.

Authorization Requirements

MVP Health Care's authorization requirements comply with all relevant statutes and regulations, including but not limited to Part L of the Health and Mental Hygiene portion of the budget (A.2007-C/S.1507-C); New York State Insurance Laws §3216, §3221, §4303.

MVP Health Care's authorization requirements comply with all billing and coverage guidance issued by the NY State Department of Health.

For plans that have fertility preservation services coverage; see the MVP Health Care Fertility Preservation Services Medical Policy.

For plans that do not have in vitro fertilization coverage; see the MVP Health Care Basic Infertility Services Medical Policy.

For pharmacologic treatment of infertility please refer to MVP Infertility (Drug Therapy) Pharmacy Policy.

Some ASO products may have advanced infertility and IVF coverage. Please consult the customers individual plan description (SPD) regarding ASO group coverage for IVF. If an ASO group has coverage for IVF, then the coverage criteria described in this policy applies.

Overview

This policy addresses coverage of advanced infertility services including treatment with in vitro fertilization for those customers that have plan coverage and met the criteria for infertility. In order to determine eligibility, MVP Health Care uses guidelines established by the American College of Obstetricians and Gynecologists, the American Society of Reproductive Medicine and New York State Department of Financial Services.

Documentation Requirements

Diagnostic work-up demonstrating infertility per medical policy must be documented in the medical record. Documentation of infertility history and treatment plan must be submitted for requests for In vitro fertilization (IVF). Advanced Services must be performed by an OB-GYN specialist or a reproductive endocrinologist qualified to provide such services within the guidelines established by the American Society for Reproductive Medicine.

Coverage for infertility services must be prescribed as part of a treating physician's overall plan of care and must be consistent with the criteria set forth below. Coverage for infertility is for persons who reasonably expect fertility as a natural state.

Infertility is determined by:

- The inability of opposite-sex partners to establish a clinical pregnancy after twelve months of regular, unprotected intercourse; OR
- The inability of opposite-sex partners to establish a clinical pregnancy after six months of regular, unprotected intercourse for a female thirty-five years of age or older; OR
- The inability of an individual to establish a clinical pregnancy due to sexual orientation or gender identity.

Coverage for advanced services are for individuals who have been unable to conceive or sustain a successful pregnancy through reasonable effort with conservative medically viable infertility treatments or procedures covered by MVP policy, unless the individual's physician determines that those treatments are likely to be unsuccessful.

In vitro fertilization (IVF)

In vitro fertilization, IF covered by specific contract/benefit, is covered after meeting coverage criteria for infertility (above) and either of the following:

- unable to conceive after six (6) failed intrauterine insemination (IUI) or artificial insemination (AI) cycles in a twelve (12) month period for a person less than thirty-five years of age; OR
- unable to conceive after three (3) failed intrauterine insemination (IUI) or artificial insemination (AI) cycles in a six (6) months period for a person thirty-five years of age or older.
- In vitro fertilization IF covered by specific contract/benefit, is limited to a lifetime maximum of 3 cycles.
 - ➤ An IVF cycle is defined as either:
 - All treatment that starts when preparatory medications are administered for ovarian stimulation for oocyte retrieval with the intent of undergoing IVF using a fresh embryo transfer; or
 - Medications are administered for endometrial preparation with the intent of undergoing IVF using a frozen embryo transfer.

If donor sperm is used, related fees such as cost of sperm or preparation of the sperm will not be covered (except sperm washing) and are the responsibility of the customer.

Specialized sperm retrieval techniques are part of the IVF benefit. Techniques such as microsurgical epididymal sperm aspiration (MESA) percutaneous epididymal sperm aspiration (PESA), testicular sperm aspiration (TESA); or percutaneous biopsy of the testis (PercBiopsy) are covered.

Cryopreservation, storage and thawing of embryos (CPT Code: 89342) is considered medically necessary while the individual is currently under covered active infertility treatment (IVF).

Exclusions and Benefit Limitations:

- Any drug or services rendered in connection with any non-covered infertility procedure, including IVF (when not covered under customer contract or NYS mandate), Gamete Intrafallopian Transfer (GIFT), Zygote Intrafallopian Transfer (ZIFT) program, cycle or treatment are not covered.
- In vitro fertilization (IVF) is contract dependent. Some ASO products may have IVF coverage. Please consult the customer's individual plan description (SPD) regarding ASO group coverage for IVF. If an ASO group has coverage for IVF, then the coverage criteria described in this policy applies.
- Gamete Intrafallopian Transfer (GIFT) (58976, S4013) is not covered and excluded from all commercial plan contracts. Some ASO products may have GIFT coverage.
 Please consult the customer's individual plan description (SPD) regarding ASO group coverage for GIFT.
- Zygote Intrafallopian Transfer (ZIFT) (58976, S4014) is not covered and excluded from all commercial plan contracts. Some ASO products may have ZIFT coverage.
 Please consult the customer's individual plan description (SPD) regarding ASO group coverage for ZIFT.
- Gender selection is not covered.
- There is no coverage for surgery to reverse a previous voluntary sterilization procedure. (54900, 54901, 58750, 58752)
- Evaluation or treatment of infertility for customers who have undergone a previous voluntary sterilization procedure, or a reversal of a previous voluntary sterilization is not covered.
- Donor fees including preparation or purchase of sperm and ovum (egg or embryo) are not covered (\$4023, \$4025, \$4026).
- Travel expenses

- External pump for the administration of infertility drugs other than GnRH will be considered only on a case-by-case-basis.
- Cloning services and procedures are not covered.
- Infertility treatments and/or FDA-approved drugs not indicated by the NYS mandate.
- Any services related to infertility for an individual who is not a customer of MVP; or
- Surrogacy and associated infertility services performed in conjunction with surrogacy are not covered; or
- Ovulation predictor kits

Investigational Exclusions:

- Medical or surgical services or procedures for infertility that are deemed
 experimental or investigational are not covered in accordance with the guidelines
 and standards of the American College of Obstetricians and Gynecologists (ACOG)
 and the American Society of Reproductive Medicine (ASRM) which state: "A
 procedure for the treatment of infertility is considered experimental until there is
 adequate scientific evidence of safety and efficacy from appropriately designed,
 peer-reviewed, published studies by different investigator groups."
- Assisted embryo hatching (89253). The use of assisted hatching has been proposed as a method to facilitate implantation and pregnancy rates. It may be performed in conjunction with IVF and ZIFT to enhance the probability of achieving pregnancy. Evidence in the published, peer-reviewed scientific literature has yielded few randomized clinical studies, inconsistent success rates, and no specific patient selection criteria.
- Co-culture of oocyte(s)/embryos (89251). Co-culturing of embryos is the culturing of embryos on a layer of cells that in theory, removes toxic substances produced by the embryo. However, co-culturing of embryos using feeder cells (e.g., granulosa, endometrial, tubal) in order to improve implantation success has not been demonstrated in the published, peer-reviewed scientific literature to improve implantation or pregnancy rates.
- Mock embryo transfer (58999) has not been demonstrated in the published, peerreviewed scientific literature to improve implantation or pregnancy rates.

MVP Medicaid Managed Care Exclusion

- In vitro fertilization (IVF) is not a covered benefit for MVP Medicaid Managed Care Plans:
- Any drug or services rendered in connection with any non-covered infertility procedure, including frozen embryo transfer (FET), IVF, GIFT, ZIFT program, cycle or treatment are not covered;

- Infertility treatments and/or FDA-approved drugs not indicated by the NYS mandate;
- Customer's age for treatment is less than 21 years or greater than 44 years

MVP Child Health Plus Variation

No basic or advanced infertility services for MVP Child Health Plus.

References (Updated 2024)

- State of New York Insurance Law § 7657, Amendment 11723, effective 2003 Jan.
 Part L of the Health and Mental Hygiene portion of the budget (A.2007-C/S.1507-C);
 New York State Insurance Laws §3216, §3221, §4303.
- 2. American Society for Reproductive Medicine (ASRM). Definitions of infertility and recurrent pregnancy loss: a committee opinion. Fertil Steril. 2008; 90(Suppl 3):S60. Revised Fertil Steril® January 2013; 99:63. Available: https://www.asrm.org/globalassets/asrm/asrm-content/news-and-publications/practice-guidelines/for-non-customers/definitions of infertility and recurrent pregnancy loss.pdf.
- 3. The Practice Committee of the American Society for Reproductive Medicine. Effectiveness and treatment for unexplained infertility. Fertil Steril 2006; 86:S111-4. Available: https://www.fertstert.org/article/S0015-0282(06)03249-3/fulltext.
- 4. Speroff L, Fritz MA. Female infertility. In: Clinical Gynecologic Endocrinology and Infertility. Seventh ed. Philadelphia: Lippincott Williams & Wilkins; 2005. p. 1013-1067.
- 5. American Society for Reproductive Medicine (ASRM). Practice Committee of the American Society for Reproductive Medicine. Optimal Evaluation of the Infertile Female. Fertil Steril. June 2000, revised November 2006, 2012d, revised 2015; 103:e44-50. ©2015 American Society for Reproductive Medicine. Available: https://www.fertstert.org/article/S0015-0282(04)01050-7/fulltext.
- American Society for Reproductive Medicine (ASRM). Female age-related fertility decline. Committee Opinion No. 589. Fertil Steril®. 2014; 101:633-4. Available: https://journals.lww.com/greenjournal/Fulltext/2014/03000/Committee Opinion No_589 Female Age Related.43.aspx.
- 7. American Society for Reproductive Medicine (ASRM). Use of clomiphene citrate in infertile women: a committee opinion. Fertil Steril. August 2013e 100(2) 341-348. Available: https://www.fertstert.org/article/S0015-0282(13)00643-2/abstract.
- 8. American Society for Reproductive Medicine (ASRM). Endometriosis and infertility: a committee opinion. Fertil Steril. 2012; 98:591-598. Available: https://www.fertstert.org/article/S0015-0282(12)00585-7/fulltext.

- American Society for Reproductive Medicine (ASRM). Diagnostic Evaluation of the Infertile Male: a committee opinion. Fertil Steril 2012e:98:294-301. Revised Fertil Steril® 2015;103:e18-e25. Available: https://www.fertstert.org/article/S0015-0282(12)00587-0/fulltext.
- 10. American Society for Reproductive Medicine (ASRM). A Practice Committee Technical Bulletin. Sperm retrieval for obstructive azoospermia. Fertil Steril. 2008e Nov; 90(5 Suppl):S213-8. Available: https://www.fertstert.org/article/S0015-0282(08)03512-7/fulltext.
- 11. American Society for Reproductive Medicine (ASRM). A Practice Committee Report. The Role of Assisted Hatching in in vitro fertilization: a guideline. Fertil Steril 2014; 102-348-51. © 2014 American Society for Reproductive Medicine.
- 12. American Urological Association, Inc. (AUA) The Optimal Evaluation of the Infertile Male. AUA Best Practice Statement. Published April 2001. Revised 2010 (a). Reviewed and Validity Confirmed 2011. Available: https://www.auanet.org/guidelines/male-infertility-optimal-evaluation-best-practice-statement.
- 13. Guzick D.S., Carson S.A., Coutifaris C., Overstreet J.W., Factor-Litvak P., Steinkampf M.P., et al. Efficacy of super ovulation and intrauterine insemination in the treatment of infertility. National Cooperative Reproductive Medicine Network [see comments]. N Engl J Med 1999; 340:177-83.
- 14. Hershlag, A., et al. Acrobeads test as a predictor of fertilization In Vitro. American Journal of Reproductive Immunology. 1997; 37(4): 291-299.
- 15. Kervancioglu ME, Saridogan E, Atasu T, Camlibel T, Demircan A, Sarikamis B, Djahanbakhch O.Human Fallopian tube epithelial cell co-culture increases fertilization rates in male factor infertility but not in tubal or unexplained infertility. Hum Reprod. 1997 Jun;12(6):1253-8.
- 16. National Institute for Clinical Excellence. Fertility: assessment and treatment. Nice Guidance [CG156. February 2013. Available: http://www.nice.org.uk/guidance/cg156.
- 17. Rubio C, Simon C, Mercader A, Garcia-Velasco J, Remohi J, Pellicer A. Clinical experience employing co-culture of human embryos with autologous human endometrial epithelial cells. Hum Reprod. 2000 Dec;15 Suppl 6:31-8.
- 18. Wiemer KE, Cohen J, Tucker MJ, Godke RA. The application of co-culture in assisted reproduction: 10 years of experience with human embryos. Hum Reprod. 1998 Dec;13 Suppl 4:226-38.
- 19. American College of Obstetricians and Gynecologists (ACOG). Preimplantation genetic testing. ACOG Committee Opinion No. 799. Washington, DC: ACOG; March 2020.

- 20. Trans Care BC. Provincial Health Services Authority. Gender Inclusive Language. Available: Gender Inclusive Language Clinical.pdf (phsa.ca).
- 21. New York State Department of Financial Services Insurance Circular Letter No. 3 (2021) Health Insurance Coverage of Infertility Treatments Regardless of Sexual Orientation or Gender Identity. Available: https://www.dfs.ny.gov/industry_guidance/circular_letters/cl2021_03.
- 22. Borkar A, Shah A, Gudi A, Homburg R. Outcome of mock embryo transfer before the first IVF cycle: A randomized control trial. Int J Reprod Biomed. 2020 Nov 22;18(11):951-960. doi: 10.18502/ijrm.v13i11.7962. PMID: 33349803; PMCID: PMC7749976.
- 23. Miller KL, Frattarelli JL. The pre-cycle blind mock embryo transfer is an inaccurate predictor of anticipated embryo transfer depth. J Assist Reprod Genet. 2007 Feb-Mar;24(2-3):77-82. doi: 10.1007/s10815-006-9098-1. Epub 2007 Jan 11. PMID: 17216563; PMCID: PMC3454990.

Customer Product	Medical Management Requirements*
New York Products	
НМО	Prior Auth
PPO in Plan	Prior Auth
PPO OOP	Prior Auth
POS in Plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Not Covered
MVP Medicaid Managed Care	Not Covered
MVP Child Health Plus	Not Covered
MVP Medicare Complete Wellness	Not Covered
MP Medicare Preferred Gold HMO POS	Not Covered
MVP Medicare Secure HMO POS	Not Covered
MVP Medicare Secure Plus HMO POS	Not Covered
MVP Medicare WellSelect PPO	Not Covered
MVP Medicare WellSelect Plus PPO	Not Covered
MVP Medicare Patriot Plan PPO	Not Covered
MVP DualAccess D-SNP HMO	Not Covered
MVP DualAccess Complete D-SNP HMO	Not Covered
MVP DualAccess Plus D-SNP HMO	Not Covered
UVM Health Advantage Select PPO	Not Covered
USA Care	Not Covered
Healthy NY	Not Covered
MVP Premier	Not Covered
MVP Premier Plus	Not Covered
MVP Premier Plus HDHP	Not Covered
MVP Secure	Not Covered
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Not Covered
ASO	See SPD
Vermont Products	
POS in Plan	Not Covered
POS OOP	Not Covered
MVP Medicare Preferred Gold HMO POS	Not Covered
MVP Medicare Secure Plus PPO	Not Covered
MVP VT HMO	Not Covered
MVP VT HDHP HMO	Not Covered
MVP VT Plus HMO	Not Covered
MVP VT Plus HDHP HMO	Not Covered
MVP Secure	Not Covered
ASO	See SPD
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[♦] Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Auth
Prior Authorization Required
Potential for Retrospective Review
No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Retrospective Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Revision History:

6/14/2021 – criteria for infertility updated according to NYS DFS Insurance Circular Letter No. 3, added coverage for preimplantation genetic testing (89290, 89291). Policy title changed to Advance Infertility Services and IVF Medical Policy.

10/01/2022 – Annual review; Removed Medicaid Managed Care Variation because coverage for this line of business is only for basic infertility that is addressed in the Basic Infertility Services Medical Policy.

04/01/2023 - Added exclusion for Mock Embryo Transfer.

06/01/2024 – Added coverage criteria that Cryopreservation, storage and thawing of embryos (89342) is considered medically necessary while the individual is currently under covered active infertility treatment (IVF).

10/01/2024 – Removed CPT Codes 89290 and 89291 from policy. Please see the new Preimplantation Genetic Testing Medical Policy for these CPT codes.



Basic Infertility Services Medical Policy

Type of Policy: Medical

Prior Approval Date: 08/01/2022

Approval Date: 08/05/2024

Effective Date: 10/01/2024

Related Polices: Infertility Drug Therapy (Medicaid/HARP) Drug

Therapy Policy

Advanced Infertility Services and In vitro

fertilization (IVF) Medical Policy

Fertility Preservation Services Medical Policy

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

55870 – Electroejaculation (Prior Authorization for MVP Medicaid Managed Care Plans Only)

Codes Subject to Retrospective Review

54900 – Epididymovasostomy, anastomosis of epididymis to vas deferens; unilateral

54901- Epididymovasostomy, anastomosis of epididymis to vas deferens; bilateral

58750 - Tubotubal anastomosis

58752 - Tubouterine implantation

Experimental/Investigational

N/A

Common Diagnosis Codes

ICD-10 Diagnosis Codes: E23.0, N46.01, N46.021, N46.022, N46.023, N46.024, N46.025, N46.029, N46.11, N46.121, N46.122, N46.123, N46.124, N46.125, N46.129, N46.8, N46.9, N81.3, N97.0, N97.1, N97.2, N97.8, N97.9

Common Procedure Codes

CPT Codes: 49320, 54500, 54505, 55400, 55530, 55540, 55870, 58100, 58321, 58322, 58323, 58340, 58345, 58660, 58661, 58662, 58672, 58673, 58760, 74740, 76856, 76857, 76870, 76872, 80424, 80426, 81015, 82024, 82088, 82157, 82160, 82528, 82533, 82626, 82670, 82671, 82672, 82677, 82679, 82757, 83001, 83002, 83003, 83498, 84144, 84146, 84402, 84403, 89260, 89261, 89300, 89310, 89320, 89321, 89322, 89325, 89329, 89330, 89331, S4035

Non-Covered Codes

CPT Codes: S4042 – Management of ovulation induction (interpretation of diagnostic tests and studies, nonface-to-face medical management of the patient), per cycle

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy.

Overview

This medical policy addresses diagnostic testing to establish the diagnosis of infertility and basic infertility treatments. Basic infertility treatments can be medical treatments or surgical procedures.

Advanced infertility services are available for plans that have the New York State mandated in vitro fertilization (IVF) coverage or specific ASO groups that cover IVF. For coverage of in vitro fertilization and related advanced infertility services, see the MVP Health Care Advanced Infertility Services Medical Policy.

For plans that have the New York State mandated fertility preservation services coverage, see the MVP Health Care Fertility Preservation Services Medical Policy.

For pharmacologic treatment of infertility please refer to MVP Infertility (Drug Therapy) Pharmacy Policy.

Documentation Requirements

Diagnostic work-up demonstrating infertility per medical policy must be documented in the medical record. Documentation of infertility history and treatment plan must be submitted for artificial insemination (usually intrauterine insemination) or for the use of injectable follicle stimulating hormone (FSH)-containing preparations.

Indications/Criteria

In order to determine eligibility, MVP Health Care uses guidelines established by the American College of Obstetricians and Gynecologists, the American Society of Reproductive Medicine, and New York State Department of Financial Services.

Infertility is determined by:

- The inability of opposite-sex partners to establish a clinical pregnancy after twelve months of regular, unprotected intercourse.
- The inability of opposite-sex partners to establish a clinical pregnancy after six months of regular, unprotected intercourse for a person with internal reproductive organs thirty-five years of age or older.
- The inability of an individual to establish a clinical pregnancy due to sexual orientation or gender identity.

Basic Infertility Services

The following basic infertility services are eligible for coverage when the above criteria are met:

- Initial history and physical exam of the covered partner.
- Education regarding infertility. Assessment for ovulatory dysfunction based on history (e.g., amenorrhea or oligomenorrhea) or testing (e.g., basal body temp recording, timed serum progesterone determinations, urinary luteinizing hormone (LH) surge monitoring, and/or endometrial biopsy.
- Laboratory evaluations and blood tests, as clinically indicated for the causes of infertility, such as hyperprolactinemia, thyroid disease, polycystic ovary syndrome, diminished ovarian reserve, (e.g., in cases of amenorrhea, grossly irregular cycles, luteal phase ≤10 days, or follicular phase ≤10 days).
- Cervical cultures as clinically indicated (e.g., history of prior cervical/pelvic infection or exam suggestive of active infection).
- Post coital test.
- Hysterosalpingogram (HSG) optional in patients at low-risk for tubal disease, recommended for all others and in patients who have not conceived after three (3) clomiphene cycles. This is required for patients at high-risk for tubal disease (e.g., history of PID, tubal pregnancy).
- Sono-Hysterogram as clinically indicated (usually if abnormal bleeding pattern suggestive of uterine cavity abnormality, ultrasound evidence for intracavitary filling defect, or non-diagnostic HSG).
- Pelvic ultrasound study as clinically indicated (e.g., history and physical exam suggestive of endometriosis, myomas, congenital malformations, or PCOS).
- Ovulation induction and monitoring.

- Semen analysis
- Vasography, testicular biopsy or testicular fine-needle aspiration for evaluation of conditions such as obstructive or non-obstructive azoospermia.
- endocrine evaluation including follicle-stimulating hormone (FSH) and total testosterone. Abnormal total testosterone results may require measurement of repeat total testosterone, free testosterone, luteinizing hormone (LH), Prolactin, and thyroid-stimulating hormone (TSH).
- Post-ejaculatory urinalysis should be performed with an ejaculate volume < 1.0 mL, except in those with hypogonadism or CBAVD, to exclude retrograde ejaculation.
- Scrotal or transrectal ultrasound as clinically indicated.
- Intrauterine Insemination (IUI) or Artificial Insemination (AI).
 - A total of nine (9) cycles of artificial insemination (Al) or nine (9) intrauterine inseminations (IUI) per pregnancy.
 - Sperm washing is a covered benefit when done in conjunction with artificial insemination.
 - o If donor sperm is used, related fees such as cost of sperm or preparation of the sperm will not be covered (except sperm washing).
 - Although the minimal number of sperm required to produce a pregnancy is not well established, a semen analysis within a year before a prior authorization request must indicate the presence of at least 1,000,000 motile sperm (before processing), since it is very unlikely that pregnancy will otherwise occur.
 - o Ectopic pregnancy is included in the number of covered cycles.

Surgical procedures

- Operative laparoscopy or other surgical procedures (such as a laparotomy) for pelvic diseases such as adhesions or endometriosis is covered.
- Laparoscopy and/or hysteroscopy as clinically indicated (e.g., abnormal HSG findings, ultrasound findings suggestive of endometriosis, history strongly suggestive of abnormal pelvic anatomy [e.g., history of pelvic infection or pelvic surgery likely to result in tubal disease]).
- Varicocele surgery or other surgical procedure to correct infertility in persons with external reproductive organs, except when the infertility diagnosis is due to a previous voluntary sterilization procedure.

Infertility Medications

 For coverage of Clomiphene citrate, injectable FSH containing preparations, GnRH antagonists, GnRH agonists, and human chorionic gonadotropin please refer to MVP Infertility (Drug Therapy) Pharmacy Policy.

Exclusions

- Any drug or services rendered in connection with any non-covered infertility procedure, including in vitro fertilizations (IVF), gamete intrafallopian transfer (GIFT), zygote intrafallopian transfer (ZIFT) procedures, cycle or treatment are not covered.
- Gender selection is not covered.
- There is no coverage for surgery to reverse a previous voluntary sterilization procedure (54900, 54901, 58750, 58752).
- Evaluation or treatment of infertility for customers who have undergone a previous voluntary sterilization procedure, or a reversal of a previous voluntary sterilization is not covered.
- Donor fees including preparation or purchase of sperm and ovum (egg or embryo) are not covered (\$4023, \$4025, \$4026).
- Travel expenses
- Sperm banking is not covered.
- Cloning is not covered.
- Infertility treatments and/or FDA-approved drugs not indicated by the NYS mandate.
- Specialized sperm retrieval techniques such as microsurgical epididymal sperm aspiration (MESA) percutaneous epididymal sperm aspiration (PESA), testicular sperm aspiration (TESA); or percutaneous biopsy of the testis (PercBiopsy) are not covered.
- Any services related to infertility for an individual who is not a customer of MVP.
- Surrogacy and associated infertility services performed in conjunction with surrogacy are not covered.
- Ovulation predictor kits

Investigational Exclusions:

Medical or surgical services or procedures for infertility that are deemed experimental or investigational are not covered in accordance with the guidelines and standards of the American College of Obstetricians and Gynecologists (ACOG) and the American Society of Reproductive Medicine (ASRM) which state: "A procedure for the treatment of infertility is considered experimental until there is adequate scientific evidence of safety and efficacy from appropriately designed, peer-reviewed, published studies by different investigator groups."

MVP Medicaid Managed Care Variation

MVP Medicaid Managed Care plans cover ovulation enhancing drugs and the services related to prescribing and monitoring the use of such drugs. The ovulation enhancing drug benefit is limited to coverage for 3 cycles of treatment per lifetime.

See the MVP Infertility Drug therapy (Medicaid/HARP) policy for pharmacologic coverage. The infertility medical benefit includes the office visits, x-rays of the uterus and fallopian tubes, pelvic ultrasounds and blood testing for infertility.

MVP Medicaid Managed Care customers are eligible for infertility services if they meet the following criteria:

- 21-34 years old and are unable to get pregnant after 12 months of regular, unprotected sex.
- 35-44 years old and are unable to get pregnant after 6 months of regular, unprotected sex.
- The inability of an individual to establish a clinical pregnancy due to sexual orientation or gender identity

To implement Chapter 645 of the Laws of 2005, which seeks to ensure that the Medicaid program will not provide coverage for erectile dysfunction (ED) drugs, procedures, or supplies to convicted sex offenders, prior approval is required for electroejaculation (CPT Code 55870) with MVP Health Care. Prior approval requests for recipient's ineligible for ED services per Chapter 645 of the Laws of 2005 will be denied.

MVP Medicaid Managed Care Exclusion

- Any drug or services rendered in connection with any non-covered infertility procedure, including frozen embryo transfer (FET), IVF, GIFT, ZIFT program, cycle or treatment are not covered;
- Infertility treatments and/or FDA-approved drugs not indicated by the NYS mandate;
- Customer's age for treatment is less than 21 years or greater than 44 years

MVP Child Health Plus Variation

No basic or advanced infertility services for MVP Child Health Plus.

Vermont (except Federal Employee Health Benefits (FEHB) HMO customers) and ASO Groups Variation

Basic and advanced infertility services coverage varies across Vermont plans. Refer to the plans certificate of coverage, riders or benefit plan document for coverage details. If coverage is available; the medical necessity criteria in this policy would apply.

Advanced infertility services are not covered out-of-network for any Vermont plan.

Advanced infertility for ASO groups is indicated by the specific plan design (SPD).

References (Updated 2024)

- 1. State of New York Insurance Law § 3216 (13), § 3221 (6) and § 4303 (1990, 2002, 2011). New York Insurance Law §§ 3221(k)(6)(New York Insurance Law §§ 3221(k)(6)(C) Laws of New York (state.ny.us)
- 2. New York Insurance Law §§ 4303(s)(3) Laws of New York (state.ny.us)
- 3. American Society for Reproductive Medicine (ASRM). Definitions of infertility and recurrent pregnancy loss: a committee opinion. Fertil Steril. 2008; 90(Suppl 3):S60. Revised Fertil Steril® January 2013; 99:63. Available: <u>Definitions of infertility and recurrent pregnancy loss: a committee opinion Fertility and Sterility (fertstert.org)</u>.
- 4. The Practice Committee of the American Society for Reproductive Medicine. Effectiveness and treatment for unexplained infertility. Fertil Steril 2006; 86:S111-4. Available: Effectiveness and treatment for unexplained infertility Fertility and Sterility (fertstert.org)
- 5. Speroff L, Fritz MA. Female infertility. In: Clinical Gynecologic Endocrinology and Infertility. Seventh ed. Philadelphia: Lippincott Williams & Wilkins; 2005. p. 1013-1067.
- 6. American Society for Reproductive Medicine (ASRM). Practice Committee of the American Society for Reproductive Medicine. Diagnostic evaluation of the infertile female. Fertil Steril 2015;103:e44–50. 2015 by American Society for Reproductive Medicine Available: <u>Diagnostic evaluation of the infertile female: a committee opinion Fertility and Sterility (fertstert.org)</u>.
- 7. American Society for Reproductive Medicine (ASRM). Female age-related fertility decline. Committee Opinion No. 589. Fertil Steril®. 2014; 101:633-4. Available: Female age-related fertility decline Fertility and Sterility (fertstert.org).
- 8. American Society for Reproductive Medicine (ASRM). Use of clomiphene citrate in infertile women: a committee opinion. Fertil Steril. August 2013e 100(2) 341-348... Available: <u>Use of clomiphene citrate in infertile women: a committee opinion Fertility and Sterility (fertstert.org)</u>.
- 9. American Society for Reproductive Medicine (ASRM). Endometriosis and infertility: a committee opinion. Fertil Steril. 2012; 98:591-598. Available: Endometriosis and infertility: a committee opinion Fertility and Sterility (fertstert.org).
- 10. American Society for Reproductive Medicine (ASRM) Diagnostic evaluation of the infertile male: a committee opinion. Available: <u>Diagnosis and treatment of infertility in men: AUA/ASRM guideline part I (2020) | American Society for Reproductive Medicine | ASRM.</u>
- 11. American Society for Reproductive Medicine (ASRM). A Practice Committee Technical Bulletin. Sperm retrieval for obstructive azoospermia. Fertil Steril. 2008e Nov; 90(5

- Suppl):S213-8. Available: <u>Sperm retrieval for obstructive azoospermia Fertility and Sterility (fertstert.org)</u>.
- 12. American Urological Association, Inc. (AUA) Diagnosis and Treatment of Infertility in Men: AUA/ASRM Guideline. (2020). Available: <u>Diagnosis and Treatment of Infertility in Men: AUA/ASRM Guideline (2020)</u> <u>American Urological Association (auanet.org)</u>.
- 13. Guzick D.S., Carson S.A., Coutifaris C., Overstreet J.W., Factor-Litvak P., Steinkampf M.P., et al. Efficacy of super ovulation and intrauterine insemination in the treatment of infertility. National Cooperative Reproductive Medicine Network [see comments]. N Engl J Med 1999; 340:177-83.
- 14. Hershlag, A., et al. Acrobeads test as a predictor of fertilization In Vitro. American Journal of Reproductive Immunology. 1997; 37(4): 291-299.
- 15. National Institute for Clinical Excellence. Fertility: assessment and treatment. f Nice Guidance [CG156. February 2013. Available: Overview | Fertility problems: assessment and treatment | Guidance | NICE.
- 16. Trans Care BC. Provincial Health Services Authority. Gender Inclusive Language. Available: Gender Inclusive Language Clinical.pdf (phsa.ca).

Customer Product	Medical Management Requirements*
New York Products	-
НМО	Potential for Retrospective Review
PPO in Plan	Potential for Retrospective Review
PPO OOP	Potential for Retrospective Review
POS in Plan	Potential for Retrospective Review
POS OOP	Potential for Retrospective Review
Essential Plan	Potential for Retrospective Review
MVP Medicaid Managed Care	Potential for Retrospective Review
MVP Child Health Plus	Not Covered
MVP Harmonious Health Care Plan	Potential for Retrospective Review
MVP Medicare Complete Wellness	Not Covered
MVP Medicare Preferred Gold HMO POS	Not Covered
MVP Medicare Secure HMO POS	Not Covered
MVP Medicare Secure Plus HMO POS	Not Covered
MVP Medicare WellSelect PPO	Not Covered
MVP Medicare WellSelect Plus PPO	Not Covered
MVP Medicare Patriot Plan PPO	Not Covered
MVP DualAccess D-SNP HMO	Not Covered
MVP DualAccess Complete D-SNP HMO	Not Covered
MVP DualAccess Plus D-SNP HMO	Not Covered
UVM Health Advantage Select PPO	Not Covered
USA Care PPO	Potential for Retrospective Review
Healthy NY	Potential for Retrospective Review
MVP Premier	Potential for Retrospective Review
MVP Premier Plus	Potential for Retrospective Review
MVP Premier Plus HDHP	Potential for Retrospective Review
MVP Secure	Potential for Retrospective Review
MVP EPO	Potential for Retrospective Review
MVP EPO HDHP	Potential for Retrospective Review
Student Health Plans	Potential for Retrospective Review
ASO	See SPD
Vermont Products	
POS in Plan	Potential for Retrospective Review
POS OOP	Potential for Retrospective Review
MVP Medicare Preferred Gold HMO POS	Not Covered
MVP Medicare Secure Plus HMO POS	Not Covered
MVP VT HMO	Potential for Retrospective Review
MVP VT HDHP HMO	Potential for Retrospective Review
MVP VT Plus HMO	Potential for Retrospective Review
MVP VT Plus HDHP HMO	Potential for Retrospective Review
MVP Secure	Potential for Retrospective Review
ASO	See SPD

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro ReviewRetrospective Review RequiredNot CoveredService is not a covered benefit.See SPDSee Specific Plan Design

Revision History:

06/14/2021 – Policy title changed to Basic Infertility Services, updated medical policy to address diagnostic testing to establish the diagnosis of infertility and basic infertility treatments. Basic infertility treatments can be medical treatments or surgical procedures. Moved all references to advanced infertility services and IVF into the Advanced Infertility Services and IVF Medical Policy. Updated coverage criteria for the diagnosis of infertility.

11/01/2021- Added prior authorization to electroejaculation (CPT code 55870) for Medicaid Managed Care plans only.

10/01/2022 – Annual Review; updated Medicaid Managed Care Variation to make clear that coverage is only for ovulation enhancing drugs as part of the basic infertility benefit.

10/01/2024 – Annual Review; no changes to the indications or criteria, references checked and updated.



Inhaled Nitric Oxide (INOmax)

Type of Policy: Medical

Prior Approval Date: 03/07/2022

Approval Date: 04/01/2024

Effective Date: 06/01/2024

Related Polices: N/A

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

CPT Codes: N/A

HCPCS Codes: N/A

Codes Requiring Retrospective Review

CPT Codes: 93463 - Pharmacologic agent administration (eg, inhaled nitric oxide, intravenous infusion of nitroprusside, dobutamine, milrinone, or other agent) including assessing hemodynamic measurements before, during, after and repeat pharmacologic agent administration, when performed (List separately in addition to code for primary procedure)

Experimental/Investigational

N/A

Common Diagnosis Codes

ICD-10 CM Diagnosis Codes: I27.0, I27.2, P07.20 – P07.39, P22.0, P28.5, P29.3, P36.0 - P36.9, P84, P91.60 - P91.63, Q33.1, Q33.2, Q33.3, Q33.4 Q33.5, Q33.6, Q33.8, Q33.9

Common Diagnosis Codes associated with this policy have been provided for informational purposes only. The list of codes may not be all-inclusive and may be updated to reflect any applicable revisions to the ICD-10 code set and/or medical necessity guidelines applied in this policy.

Common Procedure Codes

Inhaled Nitric Oxide (INOMax)

N/A

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

Inhaled nitric oxide (iNO) is a pulmonary vasodilator, proposed for the treatment of hypoxic respiratory failure associated with persistent pulmonary hypertension. It is most often utilized in conjunction with ventilatory support in term or near-term (greater than 34 weeks gestation) neonates to improve oxygenation and decrease the need for extracorporeal membrane oxygenation (ECMO). When inhaled, pulmonary vasodilation occurs and an increase in the partial pressure of arterial oxygen results. Dilation of pulmonary vessels in well ventilated lung areas redistributes blood flow away from lung areas where ventilation/perfusion ratios are poor.

Medical Record Documentation

Medical necessity must be documented in the medical record and available upon request.

Indications/Criteria

Hypoxic Respiratory Failure in Neonates

- Inhaled nitric oxide (INO) therapy is indicated as a component of the treatment of hypoxic respiratory failure associated with clinical or echocardiographic evidence of pulmonary hypertension in term and near neonates (>34 weeks gestation) when all of the following criteria are met:
 - o Neonates do not have congenital diaphragmatic hernia; and
 - When conventional therapies such as administration of high concentrations of oxygen, hyperventilation, high-frequency ventilation, the induction of alkalosis, neuromuscular blockade, and sedation have failed or are expected to fail.
- The recommended dose of INOmax® is 20ppm, maintained for up to 14 days or until the underlying oxygen desaturation has resolved.
 - Dose greater than 20 ppm is not recommended.

<u>Postoperative Management of Pulmonary Hypertension following repair of Congenital</u> Heart Disease

 Inhaled nitric oxide (INO) therapy is considered medically necessary for postoperative management of pulmonary hypertensive crisis in infants and children with congenital heart disease.

Assessing Pulmonary Vaso-reactivity in Persons with Pulmonary Hypertension.

 The diagnostic use of INO is medically necessary as a method of assessing pulmonary vaso-reactivity in persons with pulmonary hypertension.

INO therapy is considered medically necessary for no longer than 14 days if the oxygen desaturation has been resolved. **Exclusions**

- Not meeting criteria under Indications/Criteria of this policy.
- Neonates known to be dependent on right-to-left shunting of blood
- Acute bronchiolitis; or
- Acute hypoxemic respiratory failure in children (other than those who meet the medical necessity criteria above) and in adults; or
- Acute hypoxemic respiratory failure in adults; or
- Acute pulmonary embolism, or
- Acute respiratory distress syndrome or acute lung injury; or
- Bronchopulmonary dysplasia, prevention in preterm infants without hypoxic respiratory failure; or
- Lung transplantation, prevention of ischemia-reperfusion injury/acute rejection following lung transplantation; *or*
- Malaria, adjunctive treatment; or
- Sickle cell disease, treatment of vaso-occlusive crises or acute chest syndrome (sickle cell vasculopathy); or
- Treatment of persons with congenital diaphragmatic hernia; or
- Treatment of post-cardiac arrest syndrome; or
- Treatment of pulmonary hypertension associated with pulmonary fibrosis; or
- Treatment of right heart failure after hemorrhagic shock and trauma pneumonectomy; or
- Treatment of traumatic brain injury.

Medicare

Based on review there is no Medicare Local Coverage Determination (LCD) or Medicare National Coverage Determination (NCD) for inhaled nitric oxide (iNO).

References (Updated 2024)

- Barrington KJ, Finer N, Pennaforte T, Altit G. Nitric oxide for respiratory failure in infants born at or near term. Cochrane Database Syst Rev. 2017 Jan 5;1(1):CD000399. doi: 10.1002/14651858.CD000399.pub3. PMID: 28056166; PMCID: PMC6464941.
- 2. Finer NN, Barrington KJ. Nitric oxide for respiratory failure in infants born at or near term. Cochrane Database Syst Rev. 2006;(4):CD000399.
- 3. Barrington KJ, Finer N. Inhaled nitric oxide for respiratory failure in preterm infants. Cochrane Database Syst Rev. 2010;(12):CD000509.
- 4. DiBlasi, RM, myers, TR, et al. Evidence-based clinical practice guideline: inhaled nitric oxide for neonates with acute hypoxic respiratory failure. Respir Care. 2010 Dec;55(12):1717-45. Available: https://www.ncbi.nlm.nih.gov/pubmed/21122181
- 5. Brunner N, de Jesus Perez VA, Richter A, et al. Perioperative pharmacological management of pulmonary hypertensive crisis during congenital heart surgery. Pulm Circ. 2014;4(1):10-24. Available: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4070760/
- 6. Abman SH, Hansmann G, Archer SL, et al; American Heart Association Council on Cardiopulmonary, Critical Care, Perioperative and Resuscitation; Council on Clinical Cardiology; Council on Cardiovascular Disease in the Young; Council on Cardiovascular Radiology and Intervention; Council on Cardiovascular Surgery and Anesthesia; and the American Thoracic Society. Pediatric pulmonary hypertension: Guidelines from the American Heart Association and American Thoracic Society. Circulation. 2015;132(21):2037-2099. Available: http://circ.ahajournals.org/content/circulationaha/132/21/2037.full.pdf
- 7. González de Dios J, Ochoa Sangrador C; Grupo de Revisión del Proyecto aBREVIADo (BRonquiolitis-Estudio de Variabilidad, Idoneidad y Adecuación). Consensus conference on acute bronchiolitis (IV): Treatment of acute bronchiolitis. Review of scientific evidence. An Pediatr (Barc). 2010;72(4):285.e1-285.e42.
- 8. Afshari A, Brok J, Møller AM, Wetterslev J. Inhaled nitric oxide for acute respiratory distress syndrome (ARDS) and acute lung injury in children and adults. Cochrane Database Syst Rev. 2010;(7):CD002787.
- 9. Bergmark B, Bergmark R, Beaudrap PD, et al. Inhaled nitric oxide and cerebral malaria: Basis of a strategy for buying time for pharmacotherapy. Pediatr Infect Dis J. 2012;31(12):e250-e254.
- 10. Hawkes M, Opoka RO, Namasopo S, et al. Inhaled nitric oxide for the adjunctive therapy of severe malaria: Protocol for a randomized controlled trial. Trials. 2011;12:176.

- 11. Al Hajeri A, Serjeant GR, Fedorowicz Z. Inhaled nitric oxide for acute chest syndrome in people with sickle cell disease. Cochrane Database Syst Rev. 2008;(1):CD006957.
- 12. Cole FS, Alleyne C, Barks JD, et al. NIH Consensus Development Conference statement: Inhaled nitric-oxide therapy for premature infants. Pediatrics. 2011;127 (2):363-369.
- 13. Kumar P; Committee on Fetus and Newborn; American Academy of Pediatrics. Use of inhaled nitric oxide in preterm infants. Pediatrics. 2014;133(1):164-170.
- 14. Donohue PK, Gilmore MM, Cristofalo E, et al. Inhaled nitric oxide in preterm infants: A systematic review. Pediatrics. 2011;127(2):e414-e422.
- 15. Taylor RW, Zimmerman JL, Dellinger RP, et al. Low-dose inhaled nitric oxide in patients with acute lung injury: A randomized controlled trial. JAMA. 2004;291(13):1603-1609.
- 16. Pediatric Acute Lung Injury Consensus Conference Group Pediatric acute respiratory distress syndrome: Consensus recommendations from the Pediatric Acute Lung Injury Consensus Conference. Pediatr Crit Care Med. 2015;16(5):428-439.
- 17. Mercier JC, Hummler H, Durrmeyer X, et al; EUNO Study Group. Inhaled nitric oxide for prevention of bronchopulmonary dysplasia in premature babies (EUNO): A randomised controlled trial. Lancet. 2010;376(9738):346-354.
- 18. Food and Drug Administration (FDA) [website]. Center for Drug Evaluation and Research (CDER). INOmax™ (nitricoxide) for inhalation Label Information. 1999a.
- 19. Bizzarro M, Gross I. Inhaled nitric oxide for the postoperative management of pulmonary hypertension in infants and children with congenital heart disease. Cochrane Database Syst Rev. 2005;(4):CD005055. (Last updated July 2015)
- 20. Ichinose F, Roberts JD Jr, Zapol WM. Inhaled nitric oxide: A selective pulmonary vasodilator: Current uses and therapeutic potential. Circulation. 2004;109(25):3106-3111.
- 21. American Academy of Pediatrics (AAP). Committee on Fetus and Newborn. Use of inhaled nitric oxide. Pediatrics.2000;106(2 Pt 1):344-345. Reaffirmed April 2010. Available: http://pediatrics.aappublications.org/content/106/2/344
- 22. Sokol J, Jacobs SE, Bohn D. Inhaled nitric oxide for acute hypoxic respiratory failure in children and adults: A meta-analysis. Anesth Analg. 2003;97:989-998. Available: https://www.ncbi.nlm.nih.gov/pubmed/12535438
- 23. Kato GJ, Gladwin MT. Evolution of novel small-molecule therapeutics targeting sickle cell vasculopathy. JAMA. 2008;300(22):2638-2646. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2756016/

- 24. Gorenflo M, Gu H, Xu Z. Peri-operative pulmonary hypertension in paediatric patients: Current strategies in children with congenital heart disease. Cardiology. 2010;116(1):10-17. Available: https://www.ncbi.nlm.nih.gov/pubmed/20424447
- 25. Kawakami H, Ichinose F. Inhaled nitric oxide in pediatric cardiac surgery. Int Anesthesiol Clin. 2004 Fall;42(4):93-100.
- 26. Hermon MM, Burda G, Golej J, Boigner H, Stoll E, Kitzmüller E, Wollenek G, Pollak A, Trittenwein G. Methemoglobin formation in children with congenital heart disease treated with inhaled nitric oxide after cardiac surgery. Intensive Care Med. 2003 Mar;29(3):447-52. Available: https://www.ncbi.nlm.nih.gov/pubmed/12536266
- 27. Krasuski RA, Devendra GP, Hart SA, Wang A, Harrison JK, Bashore TM. Response to inhaled nitric oxide predicts survival in patients with pulmonary hypertension. J Card Fail. 2011 Apr;17(4):265-71. Available: https://www.ncbi.nlm.nih.gov/pubmed/21440863
- 28. Finer NN, Evans N. Inhaled nitric oxide for the preterm infant: evidence versus practice. Pediatrics. 2015 Apr;135(4):754-6. Available: http://pediatrics.aappublications.org/content/135/4/754.long
- 29. Bloch KD, Ichinose F, Roberts JD Jr, Zapol WM. Inhaled NO as a therapeutic agent. Cardiovasc Res. 2007 Jul 15;75(2):339-48. Epub 2007 May 4. Available: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1986790/
- 30. Barrington KJ, Finer N, Pennaforte T. Inhaled nitric oxide for respiratory failure in preterm infants. Cochrane Database Syst Rev. 2017;1:CD000509. Available: https://www.ncbi.nlm.nih.gov/pubmed/28056166
- 31. Hill NS, Preston IR, Roberts KE. Inhaled Therapies for Pulmonary Hypertension. Respir Care. 2015 Jun;60(6):794-802. Available: https://www.ncbi.nlm.nih.gov/pubmed/26070575
- 32. Barr, F.E., MD, Macrae, D., MB. Inhaled Nitric Oxide and Related Therapies. Pediatr Crit Care Med. 2010 Mar; 11(2 Suppl): S30–S36. Available: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2844851/
- 33. Klinger, James R., MD. Inhaled nitric oxide in adults: Biology and indications for use. UpToDate®. Last Update: 08/08/2017. https://www.uptodate.com/contents/inhaled-nitric-oxide-in-adults-biology-and-indications-for-use#H6
- 34. Keszler, Martin. Guidelines for Rational and Cost-Effective Use of iNO Therapy in Term and Preterm Infants. Journal of Clinical Neonatology. 2012. Apr Jun; 1(2): 59-63. Available. http://www.jcnonweb.com/article.asp?issn=2249-4847;year=2012;volume=1;issue=2;spage=59;epage=63;aulast=Keszler

- 35. Atz AM, Adatia I, Lock JE, Wessel DL. Combined effects of nitric oxide and oxygen during acute pulmonary vasodilator testing. J Am Coll Cardiol. 1999; 33(3):813-819. Available:
 - https://www.academia.edu/14220088/Combined Effects of Nitric Oxide and Oxyge n During Acute Pulmonary Vasodilator Testing.
- 36. Balzer DT, Kort HW, Day RW, et al. Inhaled nitric oxide as a preoperative test (INOP Test I): the INOP Test Study Group. Circulation. 2002; 106(12 Suppl 1):76-81. Available: http://circ.ahajournals.org/content/106/12_suppl_1/l-76.long
- 37. Barst RJ, Agnoletti G, Fraisse A, et al.; NO Diagnostic Study Group. Vasodilator testing with nitric oxide and/or oxygen in pediatric pulmonary hypertension. Pediatr Cardiol. 2010; 31(5):598-606. Available: https://www.ncbi.nlm.nih.gov/pubmed/20405117
- 38. Krasuski RA, Devendra GP, Hart SA, et al. Response to inhaled nitric oxide predicts survival in patients with pulmonary hypertension. J Card Fail. 2011; 17(4):265-271. Available: https://dukespace.lib.duke.edu/dspace/handle/10161/11030
- 39. Loukanov T, Bucsenez D, Springer W, et al. Comparison of inhaled nitric oxide with aerosolized iloprost for treatment of pulmonary hypertension in children after cardiopulmonary bypass surgery. Clin Res Cardiol. 2011;100(7):595-602.
- 40. Bhat T, Neuman A, Tantary M, et al. Inhaled nitric oxide in acute pulmonary embolism: A systematic review. Rev Cardiovasc Med. 2015;16(1):1-8.
- 41. Mercier JC, Hummler H, Durrmeyer X, et al; EUNO Study Group. Inhaled nitric oxide for prevention of bronchopulmonary dysplasia in premature babies (EUNO): A randomised controlled trial. Lancet. 2010;376(9738):346-354.
- 42. Arul N, Konduri GG. Inhaled nitric oxide for preterm neonates. Clin Perinatol. 2009;36(1):43-61.
- 43. American Association for Respiratory Care (AARC). Evidence-based clinical practice guideline: inhaled nitric oxide for neonates with acute hypoxic respiratory failure. 2010.
- 44. Hayes Inc. Health Technology Assessment. Inhaled Nitric Oxide For The Treatment Of Respiratory Failure In Preterm Newborns. HAYES, Inc.; © 2021 Hayes, a symplr company. November 6, 2018. Annual Review March 17, 2021 and January 24, 2023.

Customer Product	Medical Management Requirements*
New York Products	
HMO	Retrospective Review
PPO in Plan	Retrospective Review
PPO OOP	Retrospective Review
POS in Plan	Retrospective Review
POS OOP	Retrospective Review
Essential Plan	Retrospective Review
MVP Medicaid Managed Care	Retrospective Review
MVP Child Health Plus	Retrospective Review
MVP Medicare Complete Wellness	Retrospective Review
MVP Medicare Preferred Gold HMO POS	Retrospective Review
MVP Medicare Secure HMO POS	Retrospective Review
MVP Medicare Secure Plus HMO POS	Retrospective Review
MVP Medicare WellSelect PPO	Retrospective Review
MVP Medicare WellSelect Plus PPO	Retrospective Review
MVP Medicare Patriot Plan PPO	Retrospective Review
MVP DualAccess D-SNP HMO	Retrospective Review
MVP DualAccess Complete D-SNP HMO	Retrospective Review
MVP DualAccess Plus D-SNP HMO	Retrospective Review
UVM Health Advantage Select PPO	Retrospective Review
USA Care	Retrospective Review
Healthy NY	Retrospective Review
MVP Premier	Retrospective Review
MVP Premier Plus	Retrospective Review
MVP Premier Plus HDHP	Retrospective Review
MVP Secure	Retrospective Review
MVP EPO	Retrospective Review
MVP EPO HDHP	Retrospective Review
MVP PPO	Retrospective Review
MVP PPO HDHP	Retrospective Review
Student Health Plans	Retrospective Review
ASO	See SPD
Vermont Products	
POS in Plan	Retrospective Review
POS OOP	Retrospective Review
MVP Medicare Preferred Gold HMO POS	Retrospective Review
MVP Medicare Secure Plus HMO POS	Retrospective Review
MVP VT HMO	Retrospective Review
MVP VT HDHP HMO	Retrospective Review
MVP VT Plus HMO	Retrospective Review
MVP VT Plus HDHP HMO	Retrospective Review
MVP Secure	Retrospective Review
ASO	See SPD

[♦] Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review.

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Revision History:

06/01/2022 – Annual Review with no changes to the indications or criteria. References and websites updated.

06/01/2024 – Annual Review; Added INO therapy is considered medically necessary for no longer than 14 days if the oxygen desaturation has been resolved and additional exclusions for cardiac arrest syndrome, pulmonary fibrosis, heart failure and brain injury.



Insulin Infusion Pump (External Continuous Subcutaneous)

Type of Policy: DME

Prior Approval Date: 04/03/2023

Approval Date: 05/06/2024

Effective Date: 08/01/2024

Related Polices: Durable Medical

Equipment

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

For Durable Medical Equipment (DME) that requires Prior Authorization, refer to: Reference Library - MVP Health Care

E0784, E0787, S1034, S1035, S1036, S1037

Codes Subject to Retrospective Review

N/A

Experimental/Investigational

N/A

Common Diagnosis Codes

ICD-10- CM Diagnosis Codes: E10.311, E10.319, E10.321, E10.329, E10.331, E10.339, E10.341, E10.349, E10.351, E10.359, E10.36, E10.39, E10.40, E10.41, E10.42, E10.43, E10.44, E10.49, E10.51, E10.52, E10.59, E10.610, E10.618, E10.620, E10.622, E10.628, E10.630, E10.638, E10.649, E10.65, E10.69, E10.65, E10.8, E10.9, E11.65, E11.00, E10.69, E11.641, E13.11, E13.641, E10.11, E11.01, E11.21, E11.22, E11.29, E13.21, E13.22, E13.29, E10.21, E10.22, E10.29, E11.311, E11.319, E11.321, E11.329, E11.331, E11.339, E11.341, E11.351,

E11.359, E11.36, E11.39, E11.40, E11.41, E11.42, E11.43, E11.44, E11.49, E11.51, E11.52, E11.59, E11.65, E11.69, E11.610, E11.618, E11.620, E11.622, E11.630, E11.628, E11638, E11.649, E11.8, E11.9, E13.311, E13.319, E13.321, E13.329, E13.331, E13.339, E13.341, E13.349, E13.351, E13.359, E13.36, E13.39, E13.40, E13.41, E13.42, E13.43, E13.44, E13.49, E13.51, E13.52, E13.59, E13.610, E13.618, E13.620, E13.621, E3.622, E13.628, E13.630, E13.638, E13.649, E13.65, E13.69, E13.8, E13.9

Common Procedure Codes

A4230, A4231, and A4232

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy.

Overview

External insulin pumps are programmable infusion devices designed to facilitate insulin delivery via the continuous subcutaneous or peritoneal route. The external insulin pump may be appropriate for customers who require multiple daily insulin injections (MDI) to maintain glycemic control. External insulin pumps may be either disposable or have disposable components. Examples of FDA cleared external insulin pumps are: ACCU-CHEK, t:slim X2 OmniPod and MiniMed. These devices work with a separate glucometer through manual or remote functions. An insulin pump is considered Durable Medical Equipment.

Indications/Criteria

Documentation Requirements

Medical record documentation requirements prior to approval:

- medical necessity must be documented in the medical record and available upon request;
- documentation of blood glucose, glycosylated hemoglobin, cognitive ability and motivation must be provided prior to consideration for approval; and
- documentation of customer's compliance regarding prescribed insulin therapy (i.e., at least three (3) injections/day for a period of six (6) months).

Policy Criteria

A diabetic customer with type 1 or type 2 diabetes mellitus will be considered for an insulin pump when **all** the following criteria are met:

- ordered by an endocrinologist or a medical practitioner who has experience managing patients on continuous subcutaneous insulin infusion therapy; and
- the age of the customer is consistent with U.S. Food and Drug Administration (FDA) indications for the specific insulin pump; and
- the customer/caregiver has been compliant with a diabetes management program;
 and
- the customer requires multiple daily injections of insulin (at least three per day); with frequent self-adjustments of insulin dose for at least six (6) months prior to initiation of the insulin pump. Consideration will be given to day-to-day variations in work/school schedule, mealtimes and/or activity level, which may confound the degree of regimentation required for self-management of glycemia with multiple insulin injections; and
- the customer has a documented frequency of glucose self-testing an average of at least four (4) times per day during the two (2) months prior to initiation of the insulin pump or documented use of a continuous glucose monitor (CGM) during the two (2) months prior to initiation of the insulin pump; and
- it is an expectation and a requirement the customer/caregiver has completed a comprehensive diabetes program and demonstrates the ability to use the pump; and
- the customer, despite evidence of optimized diabetic treatment, meets one or more of the following criteria while on the multiple injection regimen:
 - HgbA1C greater than 7% (documented by two HgbA1Cs three (3) months apart);
 or
 - o recurring hypoglycemia less than 60mg/dL; or
 - o hypoglycemic unawareness resulting in emergency department treatment; or
 - wide fluctuations in blood glucose before mealtime frequently exceeding 140 mg/dL; or
 - o dawn phenomenon with fasting blood sugars frequently exceeding 200mg/dL; or
 - o pregnant and insulin injections \geq 3 times per day and fail to meet target goals (fasting glucose 70 to 90 mg/dL and one hour post prandial 100-130 mg/dL).

The customer has been on an external insulin infusion pump prior to enrollment with MVP Health Care and has documented frequency of glucose self-testing an average of at least 4 times per day during the month prior to MVP Health Care enrollment.

Insulin infusion pumps, in combination with continuous glucose monitors (CGM), must also meet criteria outlined in the MVP Continuous Glucose Monitoring medical policy.

Replacement of External Insulin Pump or System Component

An existing external insulin pump or system component is covered for a customer that is successfully managing their type 1 or type 2 diabetes mellitus when the following criteria are met:

- documentation that the pump/component is malfunctioning, no longer under warranty and cannot be repaired
- documentation from a health care provider managing the customer's diabetes within the last six months that includes a recommendation supporting continued use of a replacement device

When an infusion pump is covered, the necessary supplies (HCPCS codes: A4230, A4231, A4232) are also covered.

Exclusions

- Not meeting criteria under Indications/Criteria in this policy.
- External insulin infusion pump for a customer non-compliant with diabetes management is considered not medically necessary.
- External insulin infusion pump for customers failing to comply with all components of conventional insulin therapy is considered not medically necessary.
- Lack of medical documentation to support continued use of the external insulin infusion pump following delivery or termination of pregnancy in customers with gestational diabetes.
- Implantable pumps (E0782, E0783) are considered not medically necessary.
- Replacement of the insulin infusion pump due to slight damage to the pump without causing the pump to malfunction or replacement desired due to advanced technology is considered not medically necessary.
- Additional software or hardware required for downloading data to a device such as a personal computer, smart phone, or tablet to aid in self-management of diabetes mellitus.
- Failure to rotate the insulin pump injection site, as recommended by the manufacturer, which leads to increased skin sensitivity, or lessened insulin efficacy/absorption is not an indication of pump malfunction requiring replacement.
- Artificial pancreas device systems have no proven advantages of over separate insulin pumps and continuous glucose monitors in the general population, therefore there is no separate coverage for the artificial pancreas device systems. (S1034, S1035, S1036, S1307)
- The following items are considered convenience items and are not medically necessary:

- Hypoglycemic wristband alarms (e.g., Sleep Sentry, GlucoWatch, Diabetes Sentry)
- o insulin infuser (e.g., i-port®, Mio™ Infusion Set, inset® Infusion Set)

MVP Medicare Products:

The Local Coverage Determination (LCD): External Infusion Pumps by Noridian Healthcare Solutions, LLC Local Coverage Determination (LCD): External Infusion Pumps (L33794). Available: Medicare Coverage Database Search (cms.gov)

Disposable drug delivery systems, including elastomeric infusion pumps (A4305, A4306, A9274) are non-covered devices because they do not meet the Medicare definition of durable medical equipment. Drugs and supplies used with disposable drug delivery systems are also non-covered items.

MVP Medicaid Managed Care (MMC) Variation:

An external ambulatory insulin infusion pump will be covered for the diagnosis of diabetes mellitus when ordered by an endocrinologist or a medical practitioner who has experience managing patients on continuous subcutaneous insulin infusion therapy if the following criteria are demonstrated and documented in the clinical and DMEPOS provider's records:

- 1. The customer has been on a program of multiple daily injections of insulin (i.e., at least 3 injections per day) with frequent self-adjustments of insulin dose for at least 6 months prior to initiation of the insulin pump and has failed to achieve acceptable control of blood sugars that are not explained by poor motivation or compliance AND
 - has one or more of the following criteria while receiving multiple daily injections:
 - a) HbA1c > 7%
 - b) History of recurring hypoglycemia
 - c) Wide fluctuations in blood glucose before mealtime (>140mg/dl)
 - d) Dawn phenomenon in a fasting state (>200mg/dl) (e) History of severe glycemic excursions AND
 - has completed a comprehensive diabetes education program.
- 2. The customer has a diagnosis of gestational diabetes.

References (Updated 2024)

 InterQual® Clinical Decision Support Criteria. McKesson Health Solutions LLC, Copyright © 2022 McKesson Corporation.

- 2. DiMeglio et al. ISPAD Clinical Practice Consensus Guidelines 2018: Glycemic control targets and glucose monitoring for children, adolescents, and young adults with diabetes. Pediatr Diabetes 2018. 19 Suppl 27:105-14.
- 3. Noridian Healthcare Solutions. DME Jurisdiction D. External Infusion Pumps (L33794). Revision Effective Date 01/01/2023. Available: MCD Search (cms.gov)
- 4. Centers for Medicare & Medicaid Services (CMS). Medicare Coverage Database. NCD for Infusion Pumps (280.14). Feb. 18, 2005. Available: MCD Search (cms.gov)
- 5. American Association of Clinical Endocrinologists (AACE). Statement by the American Association of Clinical Endocrinologists Consensus Panel on insulin pump management. Sept./Oct. 2010. Available: AACE Issues Recommendations on CGM and Insulin Pump Use Diabetes Self-Management (diabetesselfmanagement.com)
- 6. American Association of Clinical Endocrinology. American Association of Clinical Endocrinology Clinical Practice Guideline: The Use of Advanced Technology in the Management of Persons With Diabetes Mellitus; 2021.
- 7. American Diabetes Association (ADA) Standards of Medical Care in Diabetes 2019. Pharmacological Approaches to Glycemic Treatment. Diabetes Care 2019 Jan; 42(Supplement 1): S90-S102. Available: https://care.diabetesjournals.org/content/42/Supplement_1/S90
- 8. American Diabetes Association. Standards of Medical Care in Diabetes. Diabetes Care 2022. 45(Supplement_1):S1-S264.
- 9. Silverstein, J., et al. Care of Children and Adolescents with Type 1 Diabetes. A statement of the American Diabetes Association. Diabetes Care. 2005; 28:186-212.
- 10. Cummins, E, et al. Clinical effectiveness and cost-effectiveness of continuous subcutaneous insulin infusion for diabetes: systematic review and economic evaluation. Health Technology Assessment 2010;14(11)
- 11. Fatourechi, M., et al., Hypoglycemia with intensive insulin therapy: A systematic review and meta-analyses of randomized trials of continuous subcutaneous insulin versus multiple daily injections. Journal of Clinical Endocrinology Metabolism. 2009; 94(3):729-740.
- 12. National Institute for Health and Clinical Excellence. Continuous subcutaneous insulin treatment of diabetes mellitus. Review of technology appraisal guidance 57. 2008.
- 13. National Institute of Diabetes and Digestive and Kidney Diseases. Continuous Glucose Monitoring. National Diabetes Information Clearinghouse (NDIC); 2017.
- 14. Armstrong, Dana and King, Allen. Basal Insulin: Continuous Glucose Monitoring Reveals Less Overnight Hypoglycemia with Continuous Subcutaneous Insulin Infusion than with Glargine. Diabetes 2002 June; 51(2): PA92.

- 15. Lenhard MJ, Reeves GD: Continuous subcutaneous insulin infusion: a comprehensive review of insulin pump therapy. Arch Intern Med 2001. *161:2293*–2300.
- 16. Pickup, John, Mattock, Martin and Kerry, Sally, Glycaemic Control with CSII compared with Intensive Insulin Injections in Patients with Type 1 Diabetes: Meta-analysis of randomized controlled trials. British Medical Journal 2002 March; 324: 705-710.
- 17. Chapter 378 of New York State Insurance Law (1993). Insurance Coverage of Diabetes Related Goods and Services in New York State.
- 18. Calhoune, P., et al. Performance comparison of the Medtronic sof-sensor and enlite glucose sensors in inpatient studies of individuals with type 1 diabetes. Diabetes Technology & Therapeutics. Sep 2013; 15(9):758-61.
- 19. Keenan, D B., et al. Accuracy of the Enlite 6-day glucose sensor with guardian and Veo calibration algorithms. Technology & Therapeutics. Mar 2012; 14(3): 225-31.
- 20. Keenan, DB, et al. Continuous glucose monitoring considerations for the development of a closed-loop artificial pancreas system. J Diabetes Sci Technology. 2011 Nov 1;5(6):1327-36.
- 21. Phillip M, Battelino T, Atlas E et al. Nocturnal glucose control with an artificial pancreas at a diabetes camp. N Engl J Med 2013; 368(9):824-33.
- 22. Nimri R, Danne T, Kordonouri O et al. The "Glucositter" overnight automated closed loop system for type 1 diabetes: a randomized crossover trial. Pediatr Diabetes 2013; 14(3):159-67.
- 23. Nimri R, Muller I, Atlas E et al. Night glucose control with MD-Logic artificial pancreas in home setting: a single blind, randomized crossover trial-interim analysis. Pediatr Diabetes 2013.
- 24. Grunberger G, Abelseth J, Bailey T, et al. Consensus statement by the American Association of Clinical Endocrinologists/American College of Endocrinology Insulin Pump Management Task Force. Endocr Pract. 2014; 20(5):463-489.
- 25. U. S. Food and Drug Administration. FDA approves first continuous glucose monitoring system with a fully implantable glucose sensor and compatible mobile app for adults with diabetes. Silver Spring, MD: Food and Drug Administration; 2018. Available from:
 - https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm611454.htm

Customer Product	Medical Management Requirements*
New York Products	
HMO	Prior Auth
PPO in Plan	Prior Auth
PPO OOP	Prior Auth
POS in Plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Prior Auth
MVP Child Health Plus	Prior Auth
MVP Harmonious Health Care Plan	Prior Auth
MVP Medicare Complete Wellness	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP Medicare WellSelect PPO	Prior Auth
MVP Medicare WellSelect Plus PPO	Prior Auth
MVP Medicare Patriot Plan PPO	Prior Auth
MVP DualAccess D-SNP HMO	Prior Auth
MVP DualAccess Complete D-SNP HMO	Prior Auth
MVP DualAccess Plus D-SNP HMO	Prior Auth
UVM Health Advantage Select PPO	Prior Auth
USA Care	Prior Auth
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	366 6. 5
POS in Plan	Prior Auth
POS OOP	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP VT HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD

[♦] Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

*Medical Management Requirements

Prior Auth

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

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MVP Health Care Medical Policy Revision History:

07/01/2021 - added Medicaid Managed Care (MMC) variation because NYS Medicaid allows external insulin pumps to be ordered by an endocrinologist as well as a medical practitioner who has experience managing patients on an insulin pump and removed blood glucose testing as a perquisite for coverage.

06/01/2023 – Endocrinologist is no longer required to order an insulin pump. Added clarification that when an infusion pump is covered, the necessary supplies are also covered (without prior authorization).

08/01/2024 – Annual review; added criteria that age of coverage based on FDA indications.



Interspinous Process Decompression Systems (IPD)

Type of Policy: Surgical

Prior Approval Date: 05/02/2022

Approval Date: 06/01/2024

Effective Date: 08/01/2024

Related Polices: N/A

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

Codes Requiring Retrospective Review

CPT Codes:

22867 - Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; single level

22868 - Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; second level (List separately in addition to code for primary procedure)

22869 - Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; single level

22870 - Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; second level (List separately in addition to code for primary procedure)

HCPCS Codes:

C1821 - Interspinous process distraction device (implantable)

Experimental/Investigational

CPT Codes: 22867, 22868, 22869, 22870

HCPCS Codes: C1821

Common Diagnosis Codes

ICD-10-CM Diagnosis Codes: G96.9*, M48.06, M48.061, M48.062

*The ICD-10-CM code G96.9 (Disorder of central nervous system, unspecified) may be used for neurogenic intermittent claudication.

Common Diagnosis Codes associated with this policy have been provided for informational purposes only. The list of codes may not be all-inclusive and may be updated to reflect any applicable revisions to the ICD-10 code set and/or medical necessity guidelines applied in this policy.

Common Procedure Codes

CPT Codes: N/A

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

Interspinous process decompression (IPD) is a minimally invasive surgical procedure used to treat lumbar spinal stenosis when conservative treatment measures have failed to relieve symptoms. IPD involves surgically implanting a spacer between one or two affected spinous processes of the lumbar spine. After implantation the device is opened or expanded to distract (open) the neural foramen and decompress the nerves.

Interlaminar spacers are implanted midline between adjacent lamina and spinous processes to provide dynamic stabilization following decompressive surgery. IPD is purported to block stenosis-related lumbar extension and, thus, relieve associated pain and allow resumption of normal posture.

The following are the current FDA approved minimally invasive devices that decompress (reduce) the pressure on the spinal nerve root:

• The Coflex® Interlaminar Stabilization Device is an implantable titanium interspinous process device (IPD) that reduces the amount of lumbar spinal extension possible while preserving range of motion in flexion, axial rotation, and lateral bending. The device is implanted after decompression of stenosis at the affected level(s).

• The Superion® InterSpinous Spacer is intended to "stand-alone" (does not requiring surgical decompression). It is delivered percutaneously as a single piece through a cannula after dilators have opened the interspinous space. The Superion Spacer is made of titanium alloy.

Indications/Criteria

Due to the lack of long-term outcome data in the literature indicating safety and effectiveness, interlaminar and interspinous process decompression systems are considered investigational for all indications.

Medicare

Based on review there is no active Medicare National Coverage Determination (NCD) or Local Coverage Determinations (LCD).

References (Updated 2024)

- 1. National Institute for Health and Clinical Excellence (NICE). IPG365 Interspinous distraction procedures for lumbar spinal stenosis causing neurogenic claudication Issued: November 2010. Available: https://www.nice.org.uk/quidance/ipg365
- 2. Kim DH, Tantorski M, Shaw J, et al. Occult Spinous Process Fractures Associated with Interspinous Process Spacers. Spine (Phila Pa 1976). 2011; 36(16):E1080-1085.
- 3. Miller LE, Block JE. Interspinous spacer implant in patients with lumbar spinal stenosis: preliminary results of a multicenter, randomized, controlled trial. Pain Res Treat 2012; 2012:823509.
- CMS Manual System, New Technology Add-On Payment, Pub 100-4 Medicare Claims Processing, Transmittal 1067. Available: www.cms.hhs.gov/Transmittals/downloads/R1067CP.pdf
- 5. National Government Services, Local Coverage Determination (LCD) for Category III CPT® Codes (L33392). Retired 07/01/2020. Available: MCD Search (cms.gov).
- 6. North American Spine Society (NASS). Evidence-Based Clinical Guidelines for Multidisciplinary Spine Care. Diagnosis and treatment of degenerative lumbar spinal stenosis. http://www.spine.org. Published 2007. Updated 2011. Accessed June 22, 2021.
- 7. North American Spine Society (NASS). Evidence-Based Clinical Guidelines for Multidisciplinary Spine Care. Diagnosis and treatment of degenerative lumbar spondylolisthesis. http://www.spine.org. Published 2008. Updated 2014.
- 8. Hayes Health Technology Assessment. Coflex Interlaminar Stabilization Device (Surgalign Spine Technologies Inc.) for Treatment of Lumbar Spinal Stenosis. HAYES, Inc.. October 13, 2021. Annual Review: November 29, 2023.

- 9. Hayes Health Evidence Review. Superion Interspinous Spacer System (Vertiflex) for Treatment of Neurogenic Claudication Caused by Spinal Stenosis. HAYES, Inc.; © 2021 Hayes, a symplr company. September 17, 2021.
- 10. Hong, P, Liu, Y, Li, H. Comparison of the efficacy and safety between interspinous process distraction device and open decompression surgery in treating lumbar spinal stenosis: a meta-analysis. Journal of investigative surgery: the official journal of the Academy of Surgical Research. 2015 Feb;28(1):40-9.

Customer Product	Medical Management Requirements*
New York Products	-
HMO	Retrospective Review
PPO in Plan	Retrospective Review
PPO OOP	Retrospective Review
POS In Plan	Retrospective Review
POS OOP	Retrospective Review
Essential Plan	Retrospective Review
MVP Medicaid Managed Care	Retrospective Review
MVP Child Health Plus	Retrospective Review
MVP Harmonious Health Care Plan	Retrospective Review
MVP Medicare Complete Wellness	Retrospective Review
MVP Medicare Preferred Gold HMO POS	Retrospective Review
MVP Medicare Secure HMO POS	Retrospective Review
MVP Medicare Secure Plus HMO POS	Retrospective Review
MVP Medicare WellSelect PPO	Retrospective Review
MVP Medicare WellSelect Plus PPO	Retrospective Review
MVP Medicare Patriot Plan PPO	Retrospective Review
MVP DualAccess D-SNP HMO	Retrospective Review
MVP DualAccess Complete D-SNP HMO	Retrospective Review
MVP DualAccess Plus D-SNP HMO	Retrospective Review
UVM Health Advantage Select PPO	Retrospective Review
USA Care	Potential for Retrospective Review
Healthy NY	Retrospective Review
MVP Premier	Retrospective Review
MVP Premier Plus	Retrospective Review
MVP Premier Plus HDHP	Retrospective Review
MVP Secure	Retrospective Review
MVP EPO	Retrospective Review
MVP EPO HDHP	Retrospective Review
MVP PPO	Retrospective Review
MVP PPO HDHP	Retrospective Review
Student Health Plans	Retrospective Review
ASO	See SPD
Vermont Products	
POS In Plan	Retrospective Review
POS OOP	Retrospective Review
MVP Medicare Preferred Gold HMO POS	Retrospective Review
MVP Medicare Secure Plus HMO POS	Retrospective Review
MVP VT HMO	Retrospective Review
MVP VT HDHP HMO	Retrospective Review
MVP VT Plus HMO	Retrospective Review
MVP VT Plus HDHP HMO	Retrospective Review
MVP Secure	Retrospective Review
ASO	See SPD

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Revision History:

08/01/2022 – Annual review; added that only FDA approved devices are eligible for coverage, eliminated the Medicare variation.

08/01/2024 – Annual review; no changes to criteria.



Intraoperative Neurophysiologic Monitoring During Spinal Surgery

Type of Policy: Surgical

Prior Approval Date: 10/03/2022

Approval Date: 06/04/2023

Effective Date: 06/01/2023

Related Polices: N/A

Codes Requiring Prior Authorization

N/A

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

Codes Requiring Retrospective Review

CPT Codes: N/A

Experimental/Investigational

CPT Codes: N/A

Common Diagnosis Codes

ICD-10- CM Diagnosis Codes: C72.0, C72.1, C79.31, D33.4, D43.2, D43.4, G11.4, G25.3, G37.3, G37.3, G95.0, G95.9, M47.12, M47.14, M47.16, M47.814, M47.817, M48.02, M48.04, M48.06, S12.000A, S12.001A, S12.100A, S12.101A, S12.200A, S12.201A, S12.300A, S12.301A, S12.400A, S12.401A, S12.500A, S12.501A, S12.600A, S12.601A, S12.000B, S12.001B, S12.100B, S12.101B, S12.200B, S12.201B, S12.300B, S12.301B, S12.400B, S12.401B, S12.500B, S12.501B, S12.600B, S12.601B, S14.101A, S14.102A, S14.103A, S14.104A, S14.105A, S14.106A, S14.107A, S14.111A, S14.112A, S14.113A, S14.114A, S14.115A, S14.116A, S S14.117A, 14.121A, S14.122A, S14.123A, S14.124A,

\$14.125A, \$14.126A, \$14.127A, \$14.131A, \$14.132A, \$14.133A, \$14.134A, \$14.135A, \$14.136A, \$14.137A, \$14.151A, \$14.152A, \$14.153A, \$14.154A, \$14.155A, \$14.156A, \$14.157A, \$22.019A, \$22.029A, \$22.039A, \$22.049A, \$22.059A, \$22.069A, \$22.079A, \$22.089A, \$22.069B, \$22.079B, \$22.089B, \$24.101A, \$24.102A, \$24.103A, \$24.104A, \$24.111A, \$24.112A, \$24.113A, \$24.114A \$24.131A, \$24.132A, \$24.133A, \$24.134A, \$24.151A, \$24.152A, \$24.153A, \$24.154A, \$32.009A, \$32.019A, \$32.029A, \$32.039A, \$32.059A, \$34.101A, \$34.102A, \$34.103A, \$34.104A, \$34.105A, \$34.109A, \$34.111A, \$34.112A, \$34.113A, \$34.114A, \$34.115A, \$34.119A, \$34.121A, \$34.122A, \$34.123A, \$34.124A, \$34.125A, \$34.125

Common Procedure Codes

95925, 95926, 95927, 95938 - somatosensory evoked potentials

95939 - Central motor evoked potential study

95870 – Needle electromyography (EMG)

95940 - Continuous intraoperative neurophysiology monitoring in the operating room, one on one monitoring requiring personal attendance, each 15 minutes

95941 – Continuous intraoperative neurophysiology monitoring, from outside the operating room (remote or nearby) or for monitoring of more than one case while in the operating room, per hour

G0453 - Continuous intraoperative neurophysiology monitoring, from outside the operating room (remote or nearby), per patient, (attention directed exclusively to one patient) each 15 minutes.

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

This policy addresses only evoked potentials (EPs) used in surgical intraoperative neurophysiologic monitoring during spinal procedures.

Evoked potentials (EPs) are a type of neurophysiological monitoring technique used during spinal procedures to assess the integrity of the nervous system. EPs are generated by delivering a stimulus to a specific sensory pathway and measuring the electrical response in the central nervous system.

During spinal procedures, three types of EPs are commonly monitored:

1. Somatosensory Evoked Potentials (SSEPs) – SSEPs are generated by stimulating a peripheral nerve and measuring the response in the sensory cortex of the brain. In

- spinal procedures, SSEPs are used to monitor the integrity of the dorsal column pathway, which carries sensory information from the limbs and trunk to the brain
- 2. Motor Evoked Potentials (MEPs) MEPs are generated by stimulating the motor cortex of the brain and measuring the response in the muscles. In spinal procedures MEPs are used to monitor the integrity of the corticospinal tract, which carries motor signals from the brain to the muscles.
- 3. Electromyography (EMG) EMG Is used to measure the electrical activity of muscles. During spinal procedures, EMG is used to monitor the function of the muscles innervated by the nerves being manipulated during surgery.

By monitoring these EPS, the surgical team can detect any changes in the function of the nervous system during the procedure, allowing for prompt intervention to prevent permanent damage.

Medical Record Documentation Requirements

Medical record must document the spinal surgical intervention to be performed by the spinal surgeon and documentation of the intraoperative neuromonitoring signals to be performed and interpreted by a certified neurologist is required to support medical necessity for neuromonitoring during the spinal surgical intervention. Also, documentation of a pre-operative assessment of the patient's neurological condition defining the diagnosis and showing the presence of neurological function potentially at risk by the surgery is necessary to support medical necessity.

Indication/Criteria

Intraoperative neurophysiological monitoring is considered medically necessary when all the following are met:

- A. Monitoring is requested by the operating surgeon; and
- B. Monitoring must be performed in the operating room by a trained, dedicated technician and must be supervised by a physician who is not a member of the surgical team and actively interprets the intra-operative evoked potentials during surgery, who is either physically in attendance in the operating room or present by means of a real-time remote mechanism, and provides direct, continuous communication to the surgeon during the procedure; and
- C. The technician is expected to have credentials from the American Board of Neurophysiologic Monitoring or the American Board of Registration of Electrodiagnostic Technologists (ABRET); and
- D. The technician must be in continuous attendance in the operating room, is recording and monitoring a single surgical case; and
- E. A monitoring licensed physician trained in clinical neurophysiology (e.g., neurologist, physiatrist) must supervise the technologist; and

- F. Intra-operative neurophysiologic monitoring is considered medically necessary when testing is used to monitor neural integrity during spinal, neurologic, cranial, or vascular procedures that may compromise neurologic function; and
- G. The following tests may be medically necessary when the neural pathway measured by the test is likely to be affected by the spinal surgical procedure:
 - 1. Somatosensory-evoked potentials (SSEP); or
 - 2. Electromyogram (EMG); or
 - 3. Motor evoked potentials (MEP);

Exclusions

- Not meeting criteria under Indications/Criteria of this policy.
- Intraoperative monitoring is not medically necessary in situations where historical data and current practices reveal no potential for damage to neural integrity during spinal surgery.
- Intra-operative neurophysiologic monitoring is considered not medically necessary when used for predicting post-operative outcomes.
- Intraoperative neurophysiological monitoring used during spinal surgeries in the absence of myelopathy or other complicating conditions that would create significant potential risk of damage to the nerve root, plexus or spinal cord.

References (Reviewed 2023)

- American Academy of Neurology (AAN). Principles of coding for intraoperative neurophysiologic monitoring (IOM) and testing model medical policy. 2008. Updated August 2016. Available: https://www.aan.com/siteassets/home-page/tools-and-resources/practicing-neurologist--administrators/billing-and-coding/model-coverage-policies/16iommodelpolicy_tr.pdf
- 2. Fehlings MG, Brodke DS, Norvell DC, Dettori JR. The evidence for intraoperative neurophysiological monitoring in spine surgery: Does it make a difference? Spine. 2010;35(9 Suppl):S37-S46.
- 3. Gunnarsson T, Krassioukov AV, Sarjeant R, Fehlings MG. Real-time continuous intraoperative electromyographic and somatosensory evoked potential recordings in spinal surgery: Correlation of clinical and electrophysiologic findings in a prospective, consecutive series of 213 cases. Spine. 2004;29(6):677-684.
- 4. Jimenez JC, Sani S, Braverman B, et al. Palsies of the fifth cervical nerve root after cervical decompression: Prevention using continuous intraoperative
- 5. Krassioukov AV, Sarjeant R, Arkia H, Fehlings MG. Multimodality intraoperative monitoring during complex lumbosacral procedures: Indications, techniques, and

- long-term follow-up review of 61 consecutive cases. J Neurosurg Spine. 2004;1(3):243-253.
- 6. Nuwer, MR., et al. Evidence-based guideline update: Intraoperative spinal monitoring with somatosensory and transcranial electrical motor evoked potentials: Report of the therapeutics and technology assessment subcommittee of the American Academy of Neurology and the American Clinical Neurophysiology Society. Neurology®. February 2012. 78: 585-589
- 7. Paradiso G, Lee GY, Sarjeant R, et al. Multimodality intraoperative neurophysiologic monitoring findings during surgery for adult tethered cord syndrome: Analysis of a series of 44 patients with long-term follow-up. Spine. 2006;31(18):2095-2102.
- 8. Reidy DP, Houlden D, Nolan PC, et al. Evaluation of electromyographic monitoring during insertion of thoracic pedicle screws. J Bone Joint Surg Br. 2001;83(7):1009-1014.
- 9. Slimp JC. Electrophysiologic intraoperative monitoring for spine procedures. Phys Med Rehabil Clin N Am. 2004;15(1):85-105.
- Thirumala PD, Muralidharan A, Loke YK, et al. Value of intraoperative neurophysiological monitoring to reduce neurological complications in patients undergoing anterior cervical spine procedures for cervical spondylotic myelopathy. J Clin Neurosci. 2016;25:27-35.

Customer Product	Medical Management Requirements*
New York Products	-
НМО	Potential for Retrospective Review
PPO in Plan	Potential for Retrospective Review
PPO OOP	Potential for Retrospective Review
POS in Plan	Potential for Retrospective Review
POS OOP	Potential for Retrospective Review
Essential Plan	Potential for Retrospective Review
MVP Medicaid Managed Care	Potential for Retrospective Review
MVP Child Health Plus	Potential for Retrospective Review
MVP Harmonious Health Care Plan	Potential for Retrospective Review
MVP Medicare Complete Wellness	Potential for Retrospective Review
MVP Medicare Preferred Gold HMO POS	Potential for Retrospective Review
MVP Medicare Secure HMO POS	Potential for Retrospective Review
MVP Medicare Secure Plus HMO POS	Potential for Retrospective Review
MVP Medicare WellSelect PPO	Potential for Retrospective Review
MVP Medicare WellSelect Plus PPO	Potential for Retrospective Review
MVP Medicare Patriot Plan PPO	Potential for Retrospective Review
MVP DualAccess D-SNP HMO	Potential for Retrospective Review
MVP DualAccess Complete D-SNP HMO	Potential for Retrospective Review
MVP DualAccess Plus D-SNP HMO	Potential for Retrospective Review
UVM Health Advantage Select PPO	Potential for Retrospective Review
USA Care PPO	Potential for Retrospective Review
Healthy NY	Potential for Retrospective Review
MVP Premier	Potential for Retrospective Review
MVP Premier Plus	Potential for Retrospective Review
MVP Premier Plus HDHP	Potential for Retrospective Review
MVP Secure	Potential for Retrospective Review
MVP EPO	Potential for Retrospective Review
MVP EPO HDHP	Potential for Retrospective Review
MVP PPO	Potential for Retrospective Review
MVP PPO HDHP	Potential for Retrospective Review
Student Health Plans	Potential for Retrospective Review
ASO	See SPD
Vermont Products	
POS In Plan	Potential for Retrospective Review
POS OOP	Potential for Retrospective Review
MVP Medicare Preferred Gold HMO POS	Potential for Retrospective Review
MVP Medicare Secure Plus HMO POS	Potential for Retrospective Review
MVP VT HMO	Potential for Retrospective Review
MVP VT HDHP HMO	Potential for Retrospective Review
MVP VT Plus HMO	Potential for Retrospective Review
MVP VT Plus HDHP HMO	Potential for Retrospective Review
MVP Secure	Potential for Retrospective Review
ASO	See SPD

[♦] Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Review History:

12/01/22 – Annual Review; added technician and physician requirements, exclusions and updated references.

08/01/2023 – Removed prior authorization from policy and codes 95925, 95926, 95927, 95940, 95941, G0453. Overview rewritten, removed specific indications, added tests that are covered when criteria is met in policy, removed "routine" from the exclusions.



Investigational Procedures, Devices, Medical Treatments and Tests

Type of Policy: Medical

Prior Approval Date: 11/04/2024

Approval Date: 03/28/2025

Effective Date: 06/01/2025

Related Policies: MVP Experimental or Investigational Procedures, Behavioral

Health Services, Drugs and Treatment, Off-Label use of FDA

Approved Drugs and Clinical Trial Policy

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

CPT Codes: None

For Durable Medical Equipment (DME) that requires Prior Authorization, refer to: Reference Library - MVP Health Care

Codes Subject to Retrospective Review

CPT Code: 0232T, 0594T, 0596T, 0597T, 0598T, 0599T, 0600T, 0601T, 20983, 29999, 31574, , 47383, 49659, 49999, 53451, 53452, 53453, 53454, 62287, 64454, 64624, 64640, 64999, 68841, 84112, 84999, 88299, 91112, 91113, 91117, 91020, 91022, 91299, 92548,

HCPCS Code: C9762, C9763, C9750, M0076, S2348, S9090, 0200T, 0201T, 0441T, 0509T, 0546T, C9761

PLU Code: 0029U, 0070U, 0071U, 0072U, 0073U, 0074U, 0075U, 0076U, 0097U

Experimental/Investigational

CPT Code: 0232T, 0594T, 0598T, 0599T, 0600T, 0601T, 20983, 29999, 33289, 47383, 49659, 49999, 53451, 53452, 53453, 53454, 62287, 64454, 64624, 64640, 64999, 68841,

84112, 84999, 88299, 91112, 91113, 91117, 91020, 91022, 91299, 92548, 93264, 97037, 99500

HCPCS Code: C9762, C9763, E0830, M0076, S2348, S9001, S9090, C9473, 0232T, 0441T, 0509T, 0546T, C9750, C9761

PLU Code: 0029U, 0070U, 0071U, 0072U, 0073U, 0074U, 0075U, 0076U, 0097U

Common Diagnosis Codes

N/A

Common Procedure Codes

N/A

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy.

Overview

This policy addresses procedures, devices, medical treatments, and tests not covered because they have not been proven to provide long-term safe and effective outcomes indicated by a preponderance of scientific evidence and, therefore, are considered investigational.

The listing provided should not be considered all-inclusive.

The process for evaluation of services not included in this policy to determine if they are investigational can be found in the MVP Experimental or Investigational Procedures, Behavioral Health Services, Drugs and Treatment, Off-Label use of FDA Approved Drugs, and Clinical Trial Policy

Policy

Athletic pubalgia (49659, 49999)

Due to the lack of evidence from the published peer-reviewed literature, the effectiveness of athletic pubalgia surgery has not been established, therefore, all athletic pubalgia surgery is considered investigational.

Tumor In Vitro Chemosensitivity and Chemoresistance Assays

ChemoFx® (88299)

There is insufficient evidence in the peer-reviewed literature that ChemoFx results in proven beneficial outcomes and is, therefore, considered investigational.

Fluorescent Cytoprint Assay (88299)

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There is insufficient evidence in the peer-reviewed literature that Fluorescent Cytoprint Assay results in proven beneficial outcomes and is, therefore, considered investigational.

Human Tumor Stem Cell Drug Sensitivity Assays (88299)

There is insufficient evidence in the peer-reviewed literature that human tumor stem cell drug sensitivity assays result in proven beneficial outcomes and are, therefore, considered investigational.

<u>Immunotherapy for Recurrent Spontaneous Abortion</u>

Due to lack of evidence in the peer reviewed literature, immunotherapy for recurrent spontaneous abortion is considered investigational and, therefore, not medically necessary.

<u>Mechanized Spinal Distraction Therapy</u> (64999, 97799) (E0830 requires prior authorization)

Due to the lack of evidence from peer-reviewed literature, mechanized spinal distraction is considered investigational.

Microsurgical Treatments of Lymphedema

Microsurgical treatments to include but are not limited to microsurgical lymphaticovenous anastomosis, lymphatic-capsular-venous anastomosis, lymphovenous bypass are considered to be investigational for the treatment of customers with chronic obstructive lymphedema because the long-term effectiveness of these procedures has not been established by the peer-reviewed medical literature.

<u>Patient-operated Spinal Unloading Devices</u> (64999, 97799, S9090) (E0830 requires prior authorization)

Due to the lack of evidence from peer-reviewed literature demonstrating improved patient outcomes, patient operated spinal unloading devices are considered investigational.

Genicular nerve blocks/Genicular Nerve Rhizotomy/Peripheral Nerve Ablation (64624, 64454)

Due to lack of evidence in the peer reviewed literature, genicular nerve blocks, genicular nerve rhizotomy and genicular peripheral nerve ablation for any indication including, but not limited to, the treatment of osteoarthritic knee pain is considered investigational and, therefore, not medically necessary.

Genicular nerve blocks are considered medically necessary for peri-operative analgesia and/or surgical anesthesia for postoperative pain management.

Cryoneurolysis, also referred to as cryoanalgesia, such as the lovera System, is investigational for any indication including, but not limited to, knee osteoarthritis or before/during/after total knee replacement surgery. (CPT Code 64640, 0441T)

Implantable peripheral nerve stimulation (PNS) and peripheral nerve stimulation (PNFS) are considered experimental, investigational for any indication but not limited to the treatment of acute or chronic pain conditions.

Medicare Variation

Genicular Nerve Rhizotomy/Peripheral Nerve Ablation and Genicular Nerve Block are a covered benefit for Medicare plans according to the Medicare Local Coverage Determination (LCD) for Peripheral Nerve Blocks (L36850).

Cryoneurolysis is a covered benefit for Medicare plans according to the Medicare Local Coverage Determination (LCD) Nerve Blockade for Treatment of Chronic Pain and Neuropathy (L35456) by Noridian Healthcare Solutions.

Platelet-rich plasma injections (0232T, G0460)

There is insufficient evidence in the peer-reviewed literature that platelet-rich plasma injections for any indication, including ligament injuries, tendon injuries, or wound healing, results in proven beneficial outcomes and are, therefore, considered investigational.

Medicare Variation

Centers for Medicare & Medicaid Services (CMS) will cover autologous platelet-rich plasma for the treatment of chronic non-healing diabetic wounds for a duration of 20 weeks, when prepared by devices whose Food and Drug Administration-cleared indications include the management of exuding cutaneous wounds, such as diabetic ulcers.

Platelet rich plasma injections and/or applications are considered not medically reasonable and necessary for any use outside of the National Coverage Determination (NCD) 270.3 Blood-Derived Products for Chronic Non-Healing Wounds.

This Medicare criteria is based on the full Local Coverage Determination (LCD): Blood-Derived Products for Chronic Non-Healing Wounds (270.3) Effective Date: 04/13/2021 Available: MCD Search (cms.gov)PAMG-1 (84112)

Rupture of Membranes (ROM) Testing in Pregnancy

Rupture of Membranes (ROM) Testing in Pregnancy (AmniSure ROM Test [PAMG-1], ROM Plus® Fetal Membrane Rupture test [PP12, AFP], and Actim® PROM [GFBP-1] test for Detection of Fetal Membrane Rupture (CPT 84112):

There is insufficient evidence in the peer-reviewed literature to support that AmniSure ROM Test [PAMG-1, ROM Plus Fetal Membrane Rupture test [PP12, AFP], and Actim

Investigational Procedures, Devices, Medical Treatments, and Tests

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PROM [GFBP-1] for the detection of fetal membrane rupture improves outcomes and therefore, is considered investigational.

Medicaid Managed Care Variation:

PAMG-1 or Rupture of Membranes (ROM) Testing is a covered service for Medicaid Managed Care customers.

Prolotherapy (M0076)

Due to the lack of peer reviewed scientific literature demonstrating effectiveness of prolotherapy for the treatment of joint and ligament instability, prolotherapy is considered investigational for any indication including joint and ligament instability.

Shoulder Resurfacing for Treatment of Arthritis and Degenerative Joint Disease

There is no reliable evidence for the use of humeral resurfacing in the existing literature and, therefore, it is considered investigational.

Thermal Intradiscal procedures (62287, S2348)

There is insufficient evidence in peer reviewed literature that thermal intradiscal procedures result in proven beneficial outcomes and, therefore, are considered not medically necessary.

Although not intended to be an all-inclusive list, Thermal Intradiscal Procedures (TIPs) are commonly identified as intradiscal electrothermal therapy (IDET), intradiscal thermal annuloplasty (IDTA), percutaneous intradiscal radiofrequency thermocoagulation (PIRFT), radiofrequency annuloplasty (RA), intradiscal biacuplasty (IDB), percutaneous (or plasma) disc decompression (PDD) or coblation, or targeted disc decompression (TDD). At times, TIPs are identified or labeled based on the name of the catheter/probe that is used (e.g., SpineCath, discTRODE, SpineWand, Accutherm, or TransDiscal electrodes).

This determination is based on the Medicare National Coverage Determination (NCD) for Thermal Intradiscal Procedures (TIPs) (150.11) for coverage conditions available at: https://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx

Gastrointestinal transit and pressure measurement with wireless capsule (CPT code 91112)

Due to insufficient evidence in the medical literature, wireless capsule for the evaluation of suspected gastric motility disorders (SmartPill GI Monitoring System) is considered investigational and, therefore, not medically necessary for all indications.

Medicare variation

A Wireless Gastrointestinal Motility Monitoring System using a wireless capsule is considered medically necessary when:

It is used to evaluate and/or treat Customers with suspected gastroparesis

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- It is used to evaluate colonic transit in patients with chronic idiopathic constipation lasting over 6 months.
- Basic clinical investigations, including endoscopy, have failed to elucidate a diagnosis.

For full details refer to the Medicare Local Coverage Determination (LCD): Wireless Gastrointestinal Motility Monitoring Systems (L33455).

Gastrointestinal tract imaging (e.g., wireless capsule endoscopy) of the colon (CPT code 91113)

Gastrointestinal tract imaging, intraluminal (e.g., wireless capsule endoscopy), of the colon is considered investigational and not medically necessary for evaluation of all conditions including but not limited to colorectal cancer screening, detecting colorectal polyps or in evaluating the colon.

Medicare Variation

Diagnostic and/or surveillance (performed for signs/symptoms of disease) colon capsule colonoscopy (CCE) is medically necessary for the detection of colon polyps.

For full details refer to the Medicare Local Coverage Determination (LCD): National Government Services (NGS, Inc.) LCD for Colon Capsule Endoscopy (CCE) (L38571).

<u>Bioimpedance Devices and Bioimpedance Spectroscopy for Detection of Lymphedema</u> (e.g., ImpediMed LDex™) (93702)

Bioimpedance devices for detection of lymphedema are not covered and considered investigational for the diagnosis or management of lymphedema. There is insufficient evidence in the peer reviewed medical literature to support the efficacy of bioimpedance devices for detection of lymphedema.

The AngelMed® Guardian System

The AngelMed® Guardian System (Angel Medical Systems, Inc., Shrewsbury, NJ) is an intracardiac ST-segment electrogram device currently being manufactured as an intracardiac ischemic monitoring system (C9750). The Guardian detects acute ischemic events by analyzing ST-segment shifts which are typically identified by electrocardiography (ECG) in the emergency room setting after the onset of symptoms, such as chest pain, shortness of breath, nausea, diaphoresis (sweating), etc. Intracardiac ischemia monitoring is considered investigational and not medically necessary for all indications including, but not limited to, detection of acute myocardial ischemic events.

Home Uterine Monitoring (99500, S9001)

Home uterine monitoring is used to continuously monitor pregnancy at home for the detection of early-stage uterine contractions suggestive of pre-mature labor. Home

uterine activity monitoring is considered investigational as the peer-reviewed medical literature has not proven the procedure to improve health outcomes over standard high-risk obstetric care and therefore is not covered.

Computerized Dynamic Posturography (CDP) (92548)

Computerized Dynamic Posturography (CDP) is a technique used for evaluation and treatment of balance disorders. Computerized Dynamic Posturography (CDP) is considered investigational because it is unproven for evaluating and treating any condition including but not limited to balance disorders due to insufficient evidence of efficacy.

Medicare Variation

Computerized Dynamic Posturography (CDP) is covered for Medicare Customers when performed only by licensed audiologists with a physician's order; by a licensed physician, preferably with certification by the American Board of Medical Specialties in Otolaryngology, Neurology or Otology/Neurology; or other providers licensed to practice medicine under the personal supervision of an appropriate physician as described in the Code of Federal Register (CFR).

This Medicare criteria is based on the Local Coverage Article (LCA): Billing and Coding: Vestibular Function Testing (A56497) Effective Date: 01/01/2021 Available: MCD Search (cms.gov)

<u>Electroretinography (ERG)</u> (0509T) Electroretinography (ERG) for glaucoma (either diagnosis or management) is considered experimental and investigational as the available published clinical evidence does not support clinical value. Therefore, the use of ERG, (all forms: ERG, fERG, mfERG, PERG, etc.) for glaucoma is not medically necessary.

Medicare Variation

Electroretinography (ERG) (0509T) is covered for Medicare plans according to Medicare criteria. This Medicare criteria is based on the Local Coverage Article (LCA): Billing and Coding: Visual Electrophysiology Testing (A57060) Effective Date: 10/01/2023 Available: MCD Search

Radiofrequency Spectroscopy for intraoperative margin assessment (0546T)

There is insufficient evidence in peer reviewed literature that radiofrequency spectroscopy results in proven beneficial outcomes or has had an effect on subsequent clinical management and, therefore, is considered investigational.

Drug-Eluting Devices

Drug-eluting devices have been developed using such medications as Dextenza (dexamethasone ophthalmic insert) 0.4mg Ocular Therapeutic™ (Therapeutix Inc.

Investigational Procedures, Devices, Medical Treatments, and Tests

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Bedford, MA) which are inserted into the canaliculus to improve pain following ocular surgery. These drug-eluting punctual plugs made of resorbable material are inserted into the lacrimal punctum (tear duct) and purportedly emit sustained release medications for a 30-60-day period until degrading and exiting via the nasolacrimal system. Drug-eluting ocular devices (68841) implanted into the lacrimal canaliculus are experimental and investigational for the treatment of post-surgical ocular pain for all indications because its effectiveness has not been established.

Medicare Variation:

Medicare considers the use of the Dextenza® dexamethasone insert reasonable and necessary for the treatment of ocular inflammation and pain following ophthalmic surgery.

<u>Iliopsoas tendon release (Tenotomy)</u>

lliopsoas tendon release (tenotomy) is a surgical procedure proposed to relieve tension through arthroscopic lengthening of the iliopsoas tendon to address contracture or snapping hip syndrome and is considered to be investigational.

Vocal Cord Paralysis Treatment

Injections of bulking agents [e.g., Prolaryn Gel or Prolaryn Plus (31574, C1878) is medically necessary for customers with unilateral vocal cord paralysis. One treatment (either left or right) is allowed to be performed per calendar year. Injections of bulking agents into vocal cords determined to have bilateral or permanent paralysis is experimental and investigational because their effectiveness has only been established for unilateral paralysis.

Gastrointestinal Pathogen Nucleic Acid Detection Panels (0097U)

Infectious pathogen detection using nucleic acid panels that are detecting more than 12 gastrointestinal infections (e.g., FilmArray by BioFire PLU Code: 0097U) is considered investigational and experimental when being done in the outpatient setting. The clinical utility of panel testing for greater than 12 gastrointestinal infectious pathogens in the outpatient setting has not been established in the published, peer-reviewed medical literature.

Medicare variation:

Medicare customers who are immune competent are covered up to 5 bacterial agents (87505). When there is clinical concern for Clostridium difficile colitis, Medicare customers may be covered up to 11 targets if Clostridium difficile is one of the organisms tested for (87506). Testing for 12 or more organisms (87507, 0097U) will only be covered in critically ill or immunosuppressed patients (e.g., receiving cancer treatment, organ transplant recipient).

Pharmacogenetic testing for CYP2D6 gene variants for opioid treatment (0029U, 0070U, 0071U, 0072U, 0073U, 0074U, 0075U, 0076U)

Opioid-related genetic testing is considered experimental/investigational.

Percutaneous Ultrasonic Ablation of Soft Tissue

Percutaneous ultrasonic ablation of soft tissue utilizing Tenex treatment procedure is considered investigational for the treatment of any condition.

Trochleoplasty in patellofemoral instability

Trochleoplasty used for any indications, including patellofemoral instability or recurrent patellar instability is considered investigational, experimental or unproven because there is a lack of evidence from peer-reviewed literature demonstrating improved patient outcomes and no support in professional medical clinical practice guidelines and position statements.

Non-Contact Real-Time Fluorescent Wound Imaging (NCRFI) (0598T, 0599T)

Non-Contact Real-Time Fluorescent Wound Imaging (NCRFI) is a medical imaging technique that is used to visualize and monitor wounds in real time using fluorescent light. Non-Contact Real-Time Fluorescent Wound Imaging is considered investigational, experimental, or unproven because there is a lack of evidence from peer-reviewed literature demonstrating improved patient outcomes and no support in professional medical clinical practice guidelines and position statements.

Percutaneous peripheral nerve stimulation (PNS) (CPT - 64555)

Percutaneous peripheral nerve stimulation is considered experimental, investigational or unproven for any indication, including but not limited to the treatment of acute or chronic pain conditions.

Medicare Variation:

Medicare plans have coverage for percutaneous peripheral nerve stimulation.

For full Medicare coverage details about peripheral nerve stimulation please refer to the following NCD for Medicare Customers: National Coverage Determination (NCD) Electrical Nerve Stimulators (160.7) Effective Date: 08/07/1995. Available: https://www.cms.gov/medicare-coverage-database

Low Level Laser Therapy (LLLT) (CPT Code: 97037)

Low Level Laser Therapy (LLLT), (CPT Code: 97037) also known as cold laser, photobiomodulation therapy, or high-power laser therapy for any indication is considered experimental and investigational because there is inadequate evidence of the effectiveness of these treatments in nationally recognized peer-reviewed medical literature.

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High Resolution Esophageal Pressure Topography

High Resolution Esophageal Pressure Topography (EndoFlip; CPT code: 91299) for any indication is considered experimental and investigational because there is a lack of evidence from peer-reviewed literature demonstrating improved patient outcomes and no support in professional medical clinical practice guidelines and position statements.

Cryosurgical Tumor Ablation

Cryosurgical tumor ablation is considered investigational as a treatment method for any other tumor other than renal and non-small cell lung cancer (NSCLC), including but not limited to, primary/metastatic liver malignancies, breast tumors (benign and malignant), and pancreatic cancer (CPT Codes: 20983, 47383).

Adjustable Balloon Continence Devices

Transperineal Implantation of Permanent Adjustable Balloon Continence Devices are experimental and investigational because there is insufficient evidence to support the use of adjustable continence therapy devices (e.g., including but not limited to ProACT Therapy System, ACT) that have been proposed as minimally invasive urological devices designed to treat persons with stress urinary incontinence (SUI). (CPT Code: 53451, 53452, 53453, 53454)

Gastrointestinal Manometry (Motility Testing) (CPT Codes 91117, 91020, 91022)

Gastrointestinal manometry is a diagnostic test that records intraluminal pressure or contraction activity in the gastrointestinal tract. There is insufficient evidence regarding the effectiveness of gastrointestinal manometry or motility testing. Patient selection criteria and the role of manometry in the management of motility abnormalities (e.g., refractory constipation) must be better defined in well-designed studies. (This does not apply to esophageal motility testing)

<u>CVAC Aspiration System (Calyxo CVAC System) All-in-One Kidney Stone Treatment C9761)</u>

CVAC Aspiration System is considered to be investigational for the removal of urinary stones as there is a lack of published peer reviewed literature that supports the use of the CVAC Aspiration System as compared with established procedures.

References (Updated 2025)

Athletic pubalgia

1. Minnich JM, Hanks JB, Muschaweck U, et al. Sports hernia: diagnosis and treatment highlighting a minimal repair surgical technique. Am J Sports Med. 2011; 39(6):1341-9.

- 2. American Academy of Orthopaedic Surgeons (AAOS). Sports hernia (athletic pubalgia). Last reviewed 2010. Available: http://orthoinfo.aaos.org/topic.cfm?topic=A00573
- 3. Garvey JF, W Read J, Turner A. Sportsman hernia: what can we do? Hernia.2010; 14(1):17-25.
- 4. Morales-Conde S, Socas M, Barranco A. Sportsmen hernia: what do we know? Hernia. 2010; 14(1):5-15.
- 5. Campanelli G. Pubic inguinal pain syndrome: the so-called sports hernia. Hernia. 2010; 14(1):1-4.
- 6. Muschaweck U, Berger L. Minimal repair technique of sportsmen's groin: an innovative open-suture repair to treat chronic inguinal pain. Hernia. 2010; 14(1):27-33.
- 7. Paajanen, H., et al. Laparoscopic surgery for chronic groin pain in athletes is more effective than non-operative treatment: a randomized clinical trial with magnetic source imaging of 60 patients with sportsman's hernia (athletic pubalgia). Surgery. 2011 Jul; 150(1):99-107.
- 8. Litwin DE, Sneider EB, McEnaney PM, Busconi BD. Athletic pubalgia (sports hernia). Clin Sports Med. 2011; 30(2):417-34.
- 9. Larson CM, Pierce BR, Giveans MR. Treatment of athletes with symptomatic intraarticular hip pathology and athletic pubalgia/sports hernia: A case series. Arthroscopy. 2011; 27(6):768-775.
- 10. Hayes Health Technology Assessment: Laparoscopic And Open Surgical Repairs For Treatment Of Athletic Groin Pain. HAYES, Inc.April 21, 2016. (Annual review May 14, 2020)

Tumor In Vitro Chemosensitivity and Chemoresistance Assays

- 11. American Society of Clinical Oncology. American Society of Clinical Oncology Practice Guideline Update on the Use of Chemotherapy Sensitivity and Resistance Assays. Journal of Clinical Oncology 2011. 29: 1-4. Available: http://jco.ascopubs.org/cgi/doi/10.1200/JCO.2011.36.0354.
- 12. National Comprehensive Cancer Network. NCCN® Practice Guidelines in Oncology-v1.2024. Epithelial Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer.
- 13. Hayes Health Molecular Test Assessment: ChemoFx® (Helomics). HAYES, Inc.; December 2, 2020. Annual Review December 11, 2023.

14.

15. HAYES Health Technology Assessment: In Vitro Chemosensitivity Assays In Cancer Treatment. HAYES, Inc. February 28, 2003. (Annual review March 13, 2008)

Investigational Procedures, Devices, Medical Treatments, and Tests

Page 11 of 23

16. Centers for Medicare & Medicaid Services (CMS). Medicare Coverage Database. NCD for Human Tumor Stem Cell Drug Sensitivity Assays (190.7) Jul 1, 1996. Available: www.cms.gov/

Immunotherapy for Recurrent Spontaneous Abortion

- 17. American Society for Reproductive Medicine. The Practice Committee of the American Society for Reproductive Medicine. Evaluation and treatment of recurrent pregnancy loss: a committee opinion. Fertility and Sterility. November 2012. Volume 98. No. 5. 1103-1105.
- 18. Porter, T. F., et al. Immunotherapy for recurrent miscarriage. Cochrane Database of Systematic Reviews 2006, Issue 2. Art. No. CD000112.
- 19. Immunology and Allergy Clinics of North America Volume 22, Number 3, August 2002, An Update on the Role of Immunotherapy in Reproductive Failure, Mary D. Stephenson, MD, MSc, Mary H.H. Ensom, PharmD.
- 20. Chen J, Liu B, Zhang Y, Ao L, Li Z, Qu B, Li X, Yang J. Effect of immunotherapy on patients with unexplained recurrent spontaneous abortion. Ann Palliat Med 2020;9(5):2545-2550. doi: 10.21037/apm-19-440b

Mechanized Spinal Distraction Therapy

21. Hayes Health Technology Assessment. Mechanized Spinal Distraction Therapy For Low Back Pain. HAYES, Inc. January 13, 2003. (Annual review January 03,2008)

Patient-operated Spinal Unloading Devices

- 22. Hayes Health Technology Assessment. Spinal Unloading Devices For Low Back Pain. HAYES, Inc.; © 2021 Hayes, a symplr company. September 14, 2001. (Annual review August 9, 2006) Archived January 1, 2007.
- 23. Janneke J. P. Schimmel Æ M. de Kleuver Æ, P. P. Horsting Æ M. Spruit Æ W. C. H. Jacobs Æ, J. van Limbeek. No effect of traction in patients with low back pain: a single centre, single blind, randomized controlled trial of Intervertebral Differential Dynamics Therapy. European Spine Journal. 12 May 2009. 18:1843-1850.
- 24. CMS. NCD for Vertebral Axial Decompression (Vax-D) (160.16)

<u>Genicular Nerve Rhizotomy/Peripheral Nerve Ablation for the Treatment of Osteoarthritic Knee Pain</u>

- 25. Centers for Medicare & Medicaid Services (CMS). Medicare Local Coverage Determinations. Local Coverage Determination (LCD): Peripheral Nerve Blocks (L36850) Revision Effective Date 11/21/2019.
- 26. Hayes Health Technology Assessment. Radiofrequency Nerve Ablation for the Management of Osteoarthritis of the Knee. HAYES, Inc.;. December 22, 2020.

- 27. Ikeuchi M, Ushida T, Izumi M, et al. Percutaneous radiofrequency treatment for refractory anteromedial pain of osteoarthritic knees, Pain Med. Apr 2011; 12(4):546-551
- 28. Hayes Evolving Evidence Review The Iovera (Pacira Biosciences Inc.) System for Knee Osteoarthritis. Hayes Inc. December 20, 2022. Annual Review December 21, 2023.
- 29. Hayes Health Technology Assessment Genicular Nerve Block for Treatment of Knee Osteoarthritis. HAYES Inc. December 7, 2023.
- 30. Hayes Health Technology Assessment Radiofrequency Nerve Ablation for the Management of Osteoarthritis of the Knee. Hayes Inc. December 22, 2020. Annual Review December 28,2023.

Percutaneous Ultrasonic Ablation of Soft Tissue

- 31. Hayes Evolving Evidence Review. Tenex (Tenex Health TX) Percutaneous Ultrasonic Tenotomy System to Treat Achilles Tendinopathy. Hayes Inc. October 26, 2021. Annual Review November 14, 2023
- 32. Finnoff JT, Hall MM, Adams E, et al. American Medical Society for Sports Medicine position statement: interventional musculoskeletal ultrasound in sports medicine. Clin J Sport Med. 2015; 25(1):6-22.

Platelet rich plasma injections

- 33. Centers for Medicare & Medicaid Services Local Coverage Determination (LCD): Blood-Derived Products for Chronic Non-Healing Wounds (270.3) Effective Date: 04/13/2021 Available: MCD Search (cms.gov)
- 34. Chen X, Jones IA, Togashi R, Park C, Vangsness CT Jr. Use of Platelet-Rich Plasma for the Improvement of Pain and Function in Rotator Cuff Tears: A Systematic Review and Meta-analysis With Bias Assessment. Am J Sports Med. 2020 Jul;48(8):2028-2041. doi: 10.1177/0363546519881423. Epub 2019 Nov 19. PMID: 31743037; PMCID: PMC7234896.
- 35. Cohn CS, Lockhart E, McCullough JJ. The use of autologous platelet-rich plasma in the orthopedic setting. Transfusion. 2015 Jul;55(7):1812-20. doi: 10.1111/trf.13005. Epub 2015 Feb 3. PMID: 25646697.
- 36. Di Martino A, Di Matteo B, Papio T, Tentoni F, Selleri F, Cenacchi A, Kon E, Filardo G. Platelet-Rich Plasma Versus Hyaluronic Acid Injections for the Treatment of Knee Osteoarthritis: Results at 5 Years of a Double-Blind, Randomized Controlled Trial. Am J Sports Med. 2019 Feb;47(2):347-354. doi: 10.1177/0363546518814532. Epub 2018 Dec 13. PMID: 30545242.

- 37. de Vos RJ, Windt J, Weir A. Strong evidence against platelet-rich plasma injections for chronic lateral epicondylar tendinopathy: a systematic review. Br J Sports Med. 2014 Jun;48(12):952-6. doi: 10.1136/bjsports-2013-093281. Epub 2014 Feb 21. PMID: 24563387.
- 38. Del Fabbro M, Bucchi C, Lolato A, Corbella S, Testori T, Taschieri S. Healing of Postextraction Sockets Preserved With Autologous Platelet Concentrates. A Systematic Review and Meta-Analysis. J Oral Maxillofac Surg. 2017 Aug;75(8):1601-1615. doi: 10.1016/j.joms.2017.02.009. Epub 2017 Feb 20. PMID: 28288724.
- 39. Balbo R, Avonto I, Marenchino D, Maddalena L, Menardi G, Peano G. Platelet gel for the treatment of traumatic loss of finger substance. Blood Transfus. 2010 Oct; 8(4):255-9.
- 40. Luaces-Rey R, Arenaz-Búa J, Lopez-Cedrún-Cembranos JL, Herrero-Patiño S, Sironvalle-Soliva S, Iglesias-Candal E, Pombo-Castro M. Is PRP useful in alveolar cleft reconstruction? Platelet-rich plasma in secondary alveoloplasty. Med Oral Patol Oral Cir Bucal. 2010 Jul 1; 15(4):e619-23.
- 41. Al-Hamed FS, Hijazi A, Gao Q, Badran Z, Tamimi F. Platelet Concentrate Treatments for Temporomandibular Disorders: A Systematic Review and Meta-analysis. JDR Clin Trans Res. 2021 Apr;6(2):174-183. doi: 10.1177/2380084420927326. Epub 2020 May 28. PMID: 32464073.
- 42. Ali M, Benjamin B, Jain N, Malviya A. Does Platelet-rich Plasma Augmentation Following Hip Arthroscopy Improve Outcomes: A Systematic Review. Hip Pelvis. 2020;32(2):70-77. doi:10.5371/hp.2020.32.2.70
- 43. American Academy of Orthopedic Surgeons (AAOS). Management of glenohumeral joint osteoarthritis evidence-based clinical practice guideline. Mar 23, 2020. Available: https://www.aaos.org/globalassets/quality-and-practice-resources/glenohumeral/gjo-cpg.pdf
- 44. Chahla J, Cinque ME, Piuzzi NS, Mannava S, Geeslin AG, Murray IR, Dornan GJ, Muschler GF, LaPrade RF. A Call for Standardization in Platelet-Rich Plasma Preparation Protocols and Composition Reporting: A Systematic Review of the Clinical Orthopaedic Literature. J Bone Joint Surg Am. 2017 Oct 18;99(20):1769-1779. doi: 10.2106/JBJS.16.01374. PMID: 29040132.
- 45. Hayes Clinical Research Response: Platelet Rich Plasma for Spinal Fusion. HAYES, Inc.; © 2021 Hayes, a symplr company. August 4, 2021.
- 46. Hayes Health Technology Assessment: Platelet Rich Plasma for Hip Osteoarthritis. HAYES, Inc. June 14, 2019. Annual Review June 22, 2022.

- 47. Hayes Health Technology Assessment: Platelet Rich Plasma for Wound Treatment in Venous Leg Ulcers. HAYES, Inc.; October 26,2021. Annual Review December 1, 2023.
- 48. Hayes Health Technology Assessemtn: Platelet Rich Plasma for Wound Treatment in Diabetic Foot Ulcers. HAYES, Inc. January 26, 2024.
- 49. Hayes Comparative Effectiveness Review: Platelet-Rich Plasma For Tendinopathies Or Ligament Injuries Of The Knee. HAYES, Inc.; © 2021 Hayes, a symplr company. December 29, 2017. Annual Review January 26, 2022.
- 50. Hayes Comparative Effectiveness Review: Platelet-Rich Plasma For Knee Osteoarthritis: A Review Of Reviews. HAYES, Inc. November 9, 2017. Annual Review January 11, 2022.
- 51. Hayes Comparative Effectiveness Review: Platelet-Rich Plasma For Treatment Of Lateral Epicondylitis: A Review Of Reviews. HAYES, Inc. December 8, 2017. Annual Review January 11, 2022.
- 52. Hayes Comparative Effectiveness Review: Platelet-Rich Plasma for Rotator Cuff Repairs, Tendinopathies, and Related Conditions: A Review of Reviews. HAYES, Inc. May 31, 2018. Annual Review June 30, 2022.
- 53. Hayes Comparative Effectiveness Review: Platelet-Rich Plasma for Treatment of Conditions of the Achilles Tendon and Plantar Fascia. HAYES, IncMarch 14, 2019. Annual Review February 11, 2022.

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- 54. American College of Obstetricians and Gynecologists (ACOG). Committee on Practice Bulletins-Obstetrics. Practice Bulletin No. 217: Prelabor Rupture of Membranes. Obstet Gynecol. 2020 Mar;135(3):e80-e97.
- 55. Hayes Health Molecular Test Assessment. AmniSure ROM Test for Detection of Fetal Membrane Rupture. HAYES, Inc. March 20, 2018. Annual review June 13, 2022.

Prolotherapy

- 56. CMS. Medicare Coverage Database. NCDs. NCD for prolotherapy, joint sclerotherapy, and ligamentous injections with sclerosing agents (150.7).
- 57. Martin DP, M.D. Prolotherapy: An effective treatment for low back pain? Mayo Clinic. Aug 2, 2011. Available: https://www.mayoclinic.org/
- 58. Hayes Health Technology Assessment. Prolotherapy For Treatment Of Joint And Ligamentous Conditions. HAYES, Inc.; Annual review July 23, 2012.

Shoulder Resurfacing for Treatment of Arthritis and Degenerative Joint Disease

- 59. Hayes Health Technology Assessment. Shoulder Resurfacing For Treatment Of Arthritis And Degenerative Joint Disease. HAYES, Inc. July 29, 2010. Annual review July 30, 2012
- 60. Raiss P, Kasten P, Baumann F, et al. Treatment of osteonecrosis of the humeral head with cementless surface replacement arthroplasty. J Bone Joint Surg Am. 2009;91(2):340-349.
- 61. Raiss P, Pape G, Becker S, et al. Cementless humeral surface replacement arthroplasty in patients less than 55 years of age. Orthopade. 2010;39(2):201-208.
- 62. Elhassan B, Ozbaydar M, Diller D, et al. Soft-tissue resurfacing of the glenoid in the treatment of glenohumeral arthritis in active patients less than fifty years old. J Bone Joint Surg Am. 2009;91(2):419-424.
- 63. de Beer JF, Bhatia DN, van Rooyen KS, Du Toit DF. Arthroscopic debridement and biological resurfacing of the glenoid in glenohumeral arthritis. Knee Surg Sports Traumatol Arthrosc. 2010;18(12):1767-1773.
- 64. Elser F, Braun S, Dewing CB, Millett PJ. Glenohumeral joint preservation: Current options for managing articular cartilage lesions in young, active patients. Arthroscopy. 2010;26(5):685-696.
- 65. Gobezie R, Lenarz CJ, Wanner JP, Streit JJ. All-arthroscopic biologic total shoulder resurfacing. Arthroscopy. 2011;27(11):1588-1593.
- 66. Longo UG, Berton A, Alexander S, et al. Biological resurfacing for early osteoarthritis of the shoulder. Sports Med Arthrosc. 2011;19(4):380-394.
- 67. Lee BK, Vaishnav S, Rick Hatch GF 3rd, Itamura JM. Biologic resurfacing of the glenoid with meniscal allograft: Long-term results with minimum 2-year follow-up. J Shoulder Elbow Surg. 2013;22(2):253-260.
- 68. Merolla G, Bianchi P, Lollino N, et al. Clinical and radiographic mid-term outcomes after shoulder resurfacing in patients aged 50 years old or younger. Musculoskelet Surg. 2013;97 Suppl 1:23-29.

Thermal Intradiscal procedures

- 69. CMS. Medicare Coverage Database. NCD for Thermal Intradiscal Procedures (TIPS) (150.11). Effective date Sept 29, 2008. Available: https://www.cms.gov/
- 70. Barendse GA, van Den Berg SG, Kessels AH, et al. Randomized controlled trial of percutaneous intradiscal radiofrequency thermocoagulation for chronic discogenic back pain: lack of effect from a 90-second 70° C lesion. Spine. 2001; 26(3):287-292.
- 71. Chou, R, Hoyt Huffman, L. Non-pharmacologic therapies for acute and chronic low back pain: A review of the evidence for an American pain society/American college of physicians clinical practice guideline. Ann Intern Med. 2007; 147:492-504.

72. Freeman BJ, Mehdian R. Intradiscal electrothermal therapy, percutaneous discectomy, and nucleoplasty: What is the current evidence? Curr Pain Headache Rep. 2008; 12(1):14-21.

Wireless capsule for evaluation of suspected gastric motility disorders

- 73. Hayes Technology Assessment Smartpill® GI Monitoring System (SmartPill Corp.) for Diagnosis of gastroparesis and Monitoring of Intestinal Motility. HAYES, Inc.; © 2021 Hayes, a symplr company Jul 22, 2010. Annual review July 11, 2012.
- 74. HAYES Medical Technology Assessment. Wireless pH Monitoring. HAYES, Inc.; © 2021 Hayes, a symplr company May 19, 2008. (Annual review June 27, 2012). Archived June 19, 2013.
- 75. Hayes Health Technology Assessment. Wireless Capsule Systems For Diagnosis of Gastroparesis. HAYES, Inc.November 27, 2023
- 76. Hayes Health Technology Assessment Wireless Capsule Systems for Diagnosis of Small and Large Bowel Motility Disorders. Hayes Inc. September 26, 2023.

<u>Bioimpedance Devices and Bioimpedance Spectroscopy for Detection of Lymphedema</u>

- 77. Hayes Health Technology Assessment. Bioelectrical Impendance (Bioimpedance) Analysis for Assessment of Lymphedema. HAYES, Inc. August 6, 2020. Annual Review March 17, 2023.
- 78. Stout Gergich NL, Pfalzer LA, McGarvey C, et al. Preoperative assessment enables the early diagnosis and successful treatment of lymphedema. Cancer. 2008;112(12):2809-2819.
- 79. National Lymphedema Network (NLN). Position Statement of the National Lymphedema Network. Screening and measurement for early detection of Lymphedema Diagnosis and Treatment of Lymphedema. http://www.lymphnet.org. Published April 2011.

AngelMed

- 80. AngelMed. What is the AngelMed Guardian System. Shrewsbury, NJ: Angel Medical Systems, Inc.; July 2012. Available: http://www.angel-med.com/index.php/patients-families/our-solution.html.
- 81. Hopenfeld B, John MS, Fischell DR, et al. The Guardian: an implantable system for chronic ambulatory monitoring of acute myocardial infarction. J Electrocardiol. 2009;42(6):481-6.
- 82. Rogers T, Steinvil A, Torguson R, Waksman R. The AngelMed Guardian system: Is there a role for implantable devices for early detection of coronary artery occlusion?

Cardiovasc Revasc Med. 2016 Dec;17(8):522-527. doi: 10.1016/j.carrev.2016.10.001. Epub 2016 Oct 8. PMID: 27847262.

83. Hayes Evidence Analysis Research Brief The AngelMed Guardian System for Management of Acute Coronary Syndrome. Hayes Inc. January 10, 2022.

Home Uterine Monitoring

- 84. HAYES Health Technology Assessment: Home Uterine Activity Monitoring. HAYES, Inc. January 3, 2008. Annual Review January 31, 2012.
- 85. Hayes Evidence Analysis Research Brief Invu by Nuvo (Nuvo Inc.) for Remote Pregnancy Monitoring. Hayes Inc. August 7, 2023.
- 86. American College of Obstetricians and Gynecologists (ACOG). Implementing telehealth in practice. ACOG Committee Opinion No. 798. American College of Obstetricians and Gynecologists. Obstet Gynecol 2020;135:e73–9.

Computerized Dynamic Posturography

- 87. Centers for Medicare and Medicaid (CMS) Local Coverage Article (LCA): Billing and Coding: Vestibular Function Testing (A56497) Effective Date: 01/01/2021 Available: MCD Search (cms.gov)
- 88. HAYES Evolving Evidence Review: Computerized Dynamic Posturography for Diagnosis of Vestibular Disorders. HAYES, IncDecember 7, 2022. Annual Review October 24, 2023

Electroretinography (ERG)

89. HAYES Health Technology Assessment: Pattern Electroretinography for Diagnosis of Glaucoma. HAYES, Inc. April 6, 2021. Annual Review June 15, 2023.

Radiofrequency Spectroscopy for intraoperative margin assessment

- 90. HAYES Health Technology Assessment. MarginProbe System (Dune Medical) For Intraoperative Assessment Of Surgical Margins In Patients With Breast Cancer. HAYES, Inc.. June 9, 2016. Annual Review May 29, 2018.
- 91. UpToDate, Inc. Techniques to reduce positive margins in breast-conserving surgery. Updated May 2019.

Drug-Eluting Devices

92. HayesEvidence Analysis Research Brief Dexamethasone Ophthalmic Insert (Dextenza) for Treatment of Postoperative Ocular Pain and Inflammation. HAYES, Inc.September 30, 2021.

- 93. Bhagav P, Trivedi V, Shah D, Chandran S. Sustained release ocular inserts of brimonidine tartrate for better treatment in open-angle glaucoma. 2011;1(2):161-174.
- 94. Franca JR, Foureaux G, Fuscaldi LL, et al. Bimatoprost-loaded ocular inserts as sustained release drug delivery systems for glaucoma treatment: In vitro and in vivo evaluation. PLoS One. 2014;9(4):e95461.

Iliopsoas tendon release (Tenotomy)

95. Hayes, Inc. Evidence Analysis Research Brief. Percutaneous Ultrasonic Tenotomy (Tenex Health TX System) for Treatment of Nonelbow or Non-Achilles Tendinopathy. HAYES, Inc. March 9, 2023.

Vocal Cord Paralysis Treatment

96. Hayes Inc. Health Technology Assessment Radiesse Voice Injectable Implant (Merz Aesthetics Inc.) For Treatment Of Glottic Insufficiency Including Vocal Cord Paralysis. Hayes Inc. December 3, 2013 Annual Review October 15, 2015.

Gastrointestinal Pathogen Nucleic Acid Detection Panels

97. Hayes Molecular Test Assessment: Multiplex Molecular Panels for Diagnosis of Gastrointestinal Infection. HAYES, Inc.; © 2021 Hayes, a symplr company. December 18, 2018. Annual Review October 31, 2022.

Pharmacogenetic testing for CYP2D6 gene variants for opioid treatment

- 98. <u>Hayes Clinical Utility Evaluation</u> Pharmacogenetic and Pharmacogenomic Testing for Opioid Treatment for Pain in Adults Selected Single-Gene Variants and Pharmacogenomic Panels. <u>Hayes, Inc. December 11, 2019. Annual Review: October 26, 2022.</u>
- 99. Hayes Clinical Utility Evaluation: Pharmacogenetic and Pharmacogenomic Testing to Improve Outcomes Related to Opioid Use Disorder Hayes, Inc. April 27, 2020. Annual Review June 30, 2023

Microsurgical Treatment of Lymphedema

100. HAYES Health Technology Assessment. Lymphovenous Anastomosis for the Physiological Microsurgical Treatment of Lymphedema. HAYES, Inc. June 9, 2020; Annual Review June 23, 2023.

Non-Contact Real-Time Fluorescent Wound Imaging (NCRFI)

101. Hayes Clinical Research Response MolecuLight i:X Imaging Device (MolecuLight). HAYES, Inc. March 16, 2023.

102. Hayes Health Technology Assessment. Endolumenal Functional Lumen Imaging Probe (EndoFLIP; Medtronic Inc.) For Evaluation Of Esophageal And Gastric Disorders. HAYES, Inc. June 14, 2019. Annual Review June 27, 2022.

Cryosurgical Tumor Ablation

National Comprehensive Cancer Network (NCCN).

Clinical Practice Guidelines in Oncology® v.2.2024. For additional information visit the NCCN website: National Comprehensive Cancer Network - Home (nccn.org)

103. Clinical Practice Guidelines in Oncology® v.2.2024. For additional information visit the NCCN website: National Comprehensive Cancer Network - Home (nccn.org)

104. National Institute of Health (NIH). National Cancer Institute (NCI) Cancer_Facts. Cryosurgery in Cancer Treatment: Questions and Answers. Available at: http://www.cancer.gov/cancertopics/factsheet/Therapy/cryosurgery

Adjustable Balloon Continence Devices

105. Hayes, Inc. Health Technology Assessment. ProACT Adjustable Continence Therapy (Uromedica) for treatment of post-surgical urinary incontinence in men. HAYES, Inc. April 17, 2020; Annual Review May 24, 2023.

CVAC Aspiration System

106. Hayes, Inc. Evidence Analysis Research Brief. CVAC Aspiration System (Calyxo, Inc.) for Treatment and Removal of Kidney Stones. HAYES, Inc. August 29, 2024.

107. Calyxo. CVAC System. Retrieved January 30, 2025, from <u>Calyxo CVAC System</u> <u>All-in-One Kidney Stone Treatment</u>.

Customer Product	Medical Management Requirements*
New York Products	·
HMO	Retrospective Review E&I
PPO in Plan	Retrospective Review E&I
PPO OOP	Retrospective Review E&I
POS in Plan	Retrospective Review E&I
POS OOP	Retrospective Review E&I
Essential Plan	Retrospective Review E&I
MVP Medicaid Managed Care	Retrospective Review E&I
MVP Child Health Plus	Retrospective Review E&I
MVP Harmonious Health Care Plan	Retrospective Review E&I
MVP Medicare Complete Wellness	Retrospective Review E&I
MVP Medicare Preferred Gold HMO POS	Retrospective Review E&I
MVP Medicare Secure HMO POS	Retrospective Review E&I
MVP Medicare Secure Plus HMO POS	Retrospective Review E&I
MVP Medicare WellSelect PPO	Retrospective Review E&I
MVP Medicare WellSelect Plus PPO	Retrospective Review E&I
MVP Medicare Patriot Plan PPO	Retrospective Review E&I
MVP SmartFund MSA	Potential for Retrospective Review
MVP DualAccess D-SNP HMO	Retrospective Review E&I
MVP DualAccess Complete D-SNP HMO	Retrospective Review E&I
MVP DualAccess Plus D-SNP HMO	Retrospective Review E&I
UVM Health Advantage Select PPO	Retrospective Review E&I
USA Care	Potential for Retrospective Review
Healthy NY	Retrospective Review E&I
MVP Premier	Retrospective Review E&I
MVP Premier Plus	Retrospective Review E&I
MVP Premier Plus HDHP	Retrospective Review E&I
MVP Secure	Retrospective Review E&I
MVP EPO	Retrospective Review E&I
MVP EPO HDHP	
	Retrospective Review E&I
Student Health Plans	Retrospective Review E&I
Vermont Products	See SPD
POS in Plan	Retrospective Review E&I
POS OOP	Retrospective Review E&I
MVP Medicare Preferred Gold HMO POS	Retrospective Review E&I
MVP Medicare Freiened Gold HMO FOS MVP Medicare Secure Plus HMO POS	Retrospective Review E&I
MVP SmartFund MSA	Potential for Retrospective Review
MVP VT HMO	Retrospective Review E&I
MVP VT HIMO MVP VT HDHP HMO	Retrospective Review E&I
MVP VT Plus HMO	Retrospective Review E&I
MVP VT Plus HDHP HMO	Retrospective Review E&I
MVP VI Plus HDHP HMO MVP Secure	·
	Retrospective Review E&I
ASO	See SPD

[♦] Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

*Medical Management Requirements

Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit
See SPD See Specific Plan Design

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Revision History:

06/01/2021 - Gastrointestingal Pathogen Nucleic Acid Detection Panels, Respiratory Pathogen Nucleic Acid Detection Panels and Pharmacogenetic testing for CYP2D6 gene variants for opioid treatment added to policy.

08/01/2021 - Removed Total Ankle Joint Replacement (27702) and added to coverage for all LOB, added Rupture of Membranes testing to coverage for Medicaid Managed Care (MMC) plans, moved transcatheter tricuspid valve replacement procedure (0569T, 0570T) from TAVR policy to this policy.

12/01/2021 – Add Genicular Nerve Rhizotomy/Peripheral Nerve Ablation for the Treatment of Osteoarthritic Knee Pain as experimental and investigational.

02/01/2022 – Added Medicare variations to investigational procedures for genicular nerve ablation, high intensity focused ultrasound (HIFU), and Dextenza for use in drug eluting stents. SpaceOAR moved into its own policy. Format of references updated to correspond to the investigational procedure that is addressed in the policy.

10/01/2022 - Added 0404T, 30468, 58674, 64640 to policy.

02/01/2023 - Added Percutaneous ultrasonic ablation of soft tissue utilizing Tenex treatment.

04/01/2023 - Moved 55880 to the Prostate Cancer Interventions Policy.

06/01/2023 - Added Non-Contact Real time Fluorescent Wound Imaging (0598T and 0599T) to policy.

12/1/2023 – Percutaneous Peripheral Nerve Stimulator added, CPT 64555 to policy. Removed A9291.

01/01/2024 - 0404T deleted, replaced with CPT code 58580.

06/01/2024 – Moved Percutaneous Peripheral Nerve Stimulator (CPT 64555) to the Electrical Stimulation policy. 58580 no longer investigational and removed from policy. Sonata system uses transcervical radiofrequency ablation for the treatment of uterine fibroids is no longer investigational.

08/01/2024 – Removed absorbable nasal implants (CPT 30468) and moved into the sinus surgery medical policy. ChemoFx In vitro chemosensitivity assays (CPT Code: 81535, 81536) has been removed and is now managed in the In Vitro Chemoresistance and Chemosensitivity Assays Payment Policy. OVA1™ Overa™ (CPT Code: 81503) has been moved to the Serum Tumor Markers for Malignancies Payment Policy. Removed the Autoimmune (rheumatoid arthritis), analysis of 12 biomarkers using immunoassays (CPT Code: 81490) and now managed in the Multi-biomarker for Rheumatoid Arthritis Payment Policy. Percutaneous Pulmonary Valve Implantation (CPT 33477) is no longer investigational with coverage criteria added to the Cardiac Procedures Medical Policy, Respiratory Pathogen Nucleic Acid Detection Panels (87632, 87633, 0115U) have been moved to the Pathogen Panel Testing Payment Policy. Respiratory Pathogen Nucleic Acid Detection Panels (0202U, 0223U, 0225U) have been moved to the Coronavirus Testing in the Outpatient Setting Payment Policy. Added and Low Level Laser Therapy (LLLT), (CPT Code: 97037) and High Resolution Esophageal Pressure Topography (EndoFlip; CPT code: 91299).

09/15/2024 – Removed HCPCS Code S3722 for dose optimization by area under the curve (AUC) analysis, for infusional 5-fluorouracil because this is now managed in a payment policy Therapeutic Drug Monitoring for 5-Fluorouracil.

10/01/2024 – Added cryosurgical tumor ablation (CPT codes: 20983, 47383). Removed CPT Code: 32994 ablation therapy for pulmonary tumors. Added language excluding adjustable balloon continence devices. Added coverage for 0509T to Medicare plans.

Investigational Procedures, Devices, Medical Treatments, and Tests

02/01/2025 - Added Gastrointestinal Manometry (Motility Testing) (CPT Codes 91117, 91020, 91022).

06/01/2025- Removed CardioMems from this policy and put into Ambulatory Holter Monitors, removed Transcatheter Tricuspid Valve Procedures and moved them in the Cardiac Procedures Medical Policy, added CVAC Aspiration System (Calyxo CVAC System) All-in-One Kidney Stone Treatment C9761).



Joint Replacement and Implant for Hallux Rigidus

Type of Policy: Surgical

Prior Approval Date: 04/04/2022

Approval Date: 03/04/2024

Effective Date: 06/01/2024

Related Polices:

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

CPT Codes: 28291- Hallux rigidus correction with cheilectomy, debridement and capsular release of the first metatarsophalangeal joint; with implant

HCPCS Codes:

L8641 - Metatarsal joint implant

L8642 - Hallux implant

Codes Requiring Retrospective Review:

N/A

Experimental/Investigational

N/A

Common Diagnosis Codes

ICD-10- CM Diagnosis Codes: M20.20, M20.21, M20.22

Common Procedure Codes

N/A

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

Most clinical presentations of the hallux (big toe) concern the metatarsal phalangeal joint (MTP). The underlying causes of the condition may be associated with osteoarthritis or rheumatoid arthritis, biomechanical instability, post traumatic degeneration, or other causes. Both types of arthritis often affect the first MTP located at the base of the big toe.

Hallux rigidus is a painful arthritic condition of the first metatarsalsophalangeal (MTP) joint located at the base of the big toe. It causes pain, limited range of motion, especially dorsiflexion, at the first MTP joint and periarticular bone orthoses. With time, it gets increasingly harder to bend the toe.

Non-surgical treatment is the first line treatment for Hallux rigidus. Conservative treatments include exercise, physiotherapy, supportive shoes worn alone or worn with soft/semi-rigid orthoses, non-steroidal anti-inflammatory drugs, and steroid injections.

Surgical procedures involving bony and/or soft tissue correction may be considered for patients with severe symptoms when conservative treatment is not effective. They include arthrodesis (fusion of the joint), arthroplasty, cheilectomy (trimming of the joint), Keller procedure (simple excision of the joint), osteotomy, and plantar release. Metatarsal phalangeal arthrodesis remains the gold standard for arthritis and salvage of the painful first MTP joint.

Documentation Requirements

Medical records must support medical necessity. Medical records must document type of implant (silastic) used.

Indications/Criteria

MVP covers partial and total prosthetic replacement arthroplasty (CPT code 28291, HCPCS code L8641) when both of the following criteria are met:

- Customer has severe disabling symptoms from hallux rigidus due to degenerative joint disease of the first MTP joint; and
- Failure of conservative medical management. Conservative medical management includes all of the following: exercise, physiotherapy, supportive shoes worn alone or worn with soft/semi-rigid orthoses, non-steroidal anti-inflammatory drugs, and steroid injections.

Exclusions

- Metatarsal phalangeal joint replacement for other indications, and for joints other than the first metatarsal phalangeal joint (e.g., tarsal metatarsal joint) is considered experimental and investigational because its value is unproven.
- Ceramic prostheses (e.g., the Moje implant) are experimental and investigational for replacement of the first metatarsal phalangeal joint and for other indications because their long-term effectiveness has not been established.
- Modular implants L8641 (e.g., the METIS prosthesis and the ToeFit-Plus prosthesis) are considered experimental and investigational for replacement of the first metatarsal phalangeal joint and for other indications due to the lack of long-term outcome data in the published medical literature.
- Interpositional arthroplasty with biologic spacers (L8658) (e.g., the InterPhlex interdigital implant).
- Total prosthetic replacement arthroplasty of the first MTP joint using total metallic implants are considered experimental and investigational for hallux rigidus, degenerative arthritis, and other indications involving the metatarsal phalangeal joints due to the lack of long-term outcome data in the published medical literature
- Metatarsophalangeal synthetic cartilage implant, consisting of biocompatible, molded cylindrical hydrogel (e.g., Cartiva Synthetic Cartilage Implants (Cartiva SCI)) is considered experimental and investigational as a treatment for metatarsophalangeal joint disorders including but not limited to hallux limitus or hallux rigidus.

Medicare

Based on review, there are no Medicare National Coverage Decisions (NCD) or Medicare Local Coverage Decisions (LCD) for metatarsal phalangeal joint replacement for hallux rigidus.

References (Updated 2024)

- 1. Brage ME, Ball ST. Surgical options for salvage of end-stage hallux rigidus. Foot Ankle Clin. 2002;7(1):49-73.
- National Institute for Health and Clinical Excellence (NICE). Metatarsalphalangeal joint replacement of the hallux. Interventional procedures guidance [IPG 140]. London, UK: NICE; November 2005. Available: https://www.nice.org.uk/guidance/IPG140
- 3. Leavitt KM, Nirenberg MS, Wood B, Yong RM. Titanium hemi-great toe implant: A preliminary study of its efficacy. J Foot Surg. 1991;30(3):289-293. Available: http://www.sciencedirect.com/science/article/pii/S0958259201907175

- 4. Gerbert J, Chang TJ. Clinical experience with two-component first metatarsal phalangeal joint implants. Clin Podiatr Med Surg. 1995;12(3):403-413.
- 5. Malviya A, Udwadia A, Doyle J. Pressfit ceramic arthroplasty of the first metatarsophalangeal joint: A short-term review. Acta Orthop Belg. 2004;70(5):455-460. http://actaorthopaedica.be/assets/990/10-Malviya_et_al.pdf
- 6. Vanore JV, Christensen JC, Kravitz SR, et al. Diagnosis and treatment of first metatarsophalangeal joint disorders. Section 1: Hallux valgus. Foot Ankle Surg. 2003;42(3):112-123.
- 7. Silva LF, Sousa CV, Rodrigues Pinto R, et al. Preliminary results from the Metis-Newdeal(®) total metatarsophalangeal prosthesis. Rev Bras Ortop. 2015;46(2):200-204. Available: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4799195/
- 8. Townley CO, Taranow WS. A metallic hemiarthroplasty resurfacing prosthesis for the hallux metatarsophalangeal joint. Foot Ankle Int. 1994;15(11):575-580. Available: https://www.ncbi.nlm.nih.gov/pubmed/7849971
- 9. Roukis TS, Townley CO. BIOPRO resurfacing endoprosthesis versus periarticular osteotomy for hallux rigidus: Short-term follow-up and analysis. 2003;42(6):350-358. Available: https://www.ncbi.nlm.nih.gov/pubmed/14688777
- 10. Weinfeld SB, Schon LC. Hallux metatarsophalangeal arthritis. Clin Orthop Relat Res. 1998;(349):9-19.
- 11. Raikin SM, Ahmad J, Pour AE, Abidi N. Comparison of arthrodesis and metallic hemiarthroplasty of the hallux metatarsophalangeal joint. J Bone Joint Surg Am. 2007;89(9):1979-1985. Available: https://www.ncbi.nlm.nih.gov/pubmed/17768195
- 12. Gibson JNA, Thomson CE. Arthrodesis or total replacement arthroplasty for hallux rigidus: A randomized controlled trial. Foot Ankle Int. 2005;26(9):680-690. https://www.ncbi.nlm.nih.gov/pubmed/16174497
- 13. Barwick TW, Talkhani IS. The MOJE total joint arthroplasty for 1st metatarso-phalangeal osteoarthritis: A short-term retrospective outcome study. Foot (Edinb). 2008;18(3):150-155. Available: http://europepmc.org/abstract/med/20307429
- 14. McGraw IW, Jameson SS, Kumar CS. Mid-term results of the Moje Hallux MP joint replacement. Foot Ankle Int. 2010;31(7):592-599. Available: http://journals.sagepub.com/doi/abs/10.3113/FAI.2010.0592?legid=spfai%3B31%2F7%2F592&patientinform-links=yes
- 15. Brewster M, McArthur J, Mauffrey C, et al. Moje first metatarsophalangeal replacement -- a case series with functional outcomes using the AOFAS-HMI score. J Foot Ankle Surg. 2010;49(1):37-42. Available: https://www.ncbi.nlm.nih.gov/pubmed/20123285

- 16. Gutteck N, Zeh A, Wohlrab D, Vasarhelyi A. One-stage aseptic revision of loosened metatarsophalangeal prosthesis. Orthopade. 2011;40(6):554-558.
- 17. Duncan NS, Farrar NG, Rajan RA. Early results of first metatarsophalangeal joint replacement using the ToeFit-Plus™ prosthesis. J Foot Ankle Surg. 2014;53(3):265-268. Available: https://www.ncbi.nlm.nih.gov/pubmed/24589137
- 18. Erkocak OF, Senaran H, Altan E, et al. Short-term functional outcomes of first metatarsophalangeal total joint replacement for hallux rigidus. Foot Ankle Int. 2013;34(11):1569-1579. https://pubmed.ncbi.nlm.nih.gov/23877170/
- Baumhauer JF, Singh D, Glazebrook M, et al. Prospective, randomized, multicentered clinical trial assessing safety and efficacy of a synthetic cartilage implant versus first metatarsophalangeal arthrodesis in advanced hallux rigidus. Foot Ankle Int. 2016; 37(5):457-469. Available: https://www.ncbi.nlm.nih.gov/pubmed/26922669
- 20. Daniels TR, Younger AS, Penner MJ, et al. Midterm outcomes of polyvinyl alcohol hydrogel hemiarthroplasty of the first metatarsophalangeal joint in advanced hallux rigidus. Foot Ankle Int. 2017; 38(3):243-247. Available: https://www.ncbi.nlm.nih.gov/pubmed/27909032
- 21. Ho B, Baumhauer J. Hallux rigidus. EFORT Open Rev. 2017; Jan; 2(1):13-20.
- 22. Younger ASE, Baumhauer JF. Polyvinyl alcohol hydrogel hemiarthroplasty of the great toe: technique and indications. Techniques in Foot and Ankle Surgery. 2013;12(3):164-169.
- 23. HAYES Medical Technology Directory™. Cartiva Synthetic Cartilage Implant (Cartiva SCI, Cartiva Inc.) for First Metatarsophalangeal Joint Arthroplasty. Health Technology Assessment ©2021 Hayes, a sympire company March 22, 2019, Annual Review: May 17, 2021 Available: www.hayesinc.com/
- 24. U.S. Food and Drug Administration (FDA) 510(k). Cartiva® Synthetic Cartilage Implant. Summary of Safety and Effectiveness. 510(k) No. P150017. Rockville, MD: FDA; April 20, 2016. Available: https://www.fda.gov/downloads/advisorycommittees/committeesmeetingmaterials/medicaldevices/medicaldevicesadvisorycommittee/orthopaedicandrehabilitationdevicespanel/ucm496457.pdf
- 25. Giannini S, Ceccarelli F, Faldini C, et al. What's new in surgical options for hallux rigidus? J Bone Joint Surg Am. 2004;86-A Suppl 2:72-83.

Customer Product	Medical Management Requirements*
New York Products	-
HMO	Prior Auth
PPO in Plan	Prior Auth
PPO OOP	Prior Auth
POS in Plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Prior Auth
MVP Child Health Plus	Prior Auth
MVP Harmonious Health Care Plan	Prior Auth
MVP Medicare Complete Wellness	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS MVP Medicare WellSelect PPO	Prior Auth Prior Auth
MVP Medicare WellSelect PPO MVP Medicare WellSelect Plus PPO	Prior Auth Prior Auth
MVP Medicare Wellselect Plus PPO MVP Medicare Patriot Plan PPO	Prior Auth Prior Auth
MVP DualAccess D-SNP HMO	Prior Auth
MVP DualAccess Complete D-SNP HMO	Prior Auth
MVP DualAccess Plus D-SNP HMO	Prior Auth
UVM Health Advantage Select PPO	Prior Auth
USA Care	Potential for Retrospective Review
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	
POS in Plan	Prior Auth
POS OOP	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Preferred Gold Timo POS MVP Medicare Secure Plus HMO POS	Prior Auth
MVP VT HMO	Prior Auth
MVP VT HIMO	Prior Auth Prior Auth
MVP VT Plus HMO	Prior Auth Prior Auth
MVP VT Plus HDHP HMO	Prior Auth Prior Auth
MVP VI Plus HDHP HMO MVP Secure	Prior Auth Prior Auth
ASO ASO	See SPD
ASU	

[♦] Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review.

Retro ReviewRetrospective Review RequiredNot CoveredService is not a covered benefit.See SPDSee Specific Plan Design

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MVP Health Care Medical Policy Revision History:

06/01/2022 – Annual Review; references and websites sections updated.

06/01/2024 – Annual Review; references and links checked. Updated language to cover partial implants.



Laser Treatment of Port Wine Stains, Hemangiomas, and Benign Skin Lesions

Type of Policy: Surgical

Prior Approval Date: 08/30/2024

Approval Date: 10/07/2024

Effective Date: 12/01/2024

Related Polices: N/A

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

N/A

Codes Requiring Retrospective Review

N/A

Experimental/Investigational

N/A

Common Diagnosis Codes

ICD-10- CM Diagnosis Codes: M51.36, M51.37, B07.9, D18.00, D18.01, D18.02, D18.03, D18.09, L71.0, L71.1, L71.8, Q82.5

Common Procedure Codes

11200, 11201, 11300, 11301, 11302, 11303, 11305, 11306, 11307, 11308, 11310, 11311, 11312, 11313, 11400-11471, 17106, 17107, 17108, 96904

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior authorization for some products may require retrospective review for plans that do not require prior authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Laser Treatment Port Wine Stains, Hemangiomas and Warts

Overview

Lasers are used to treat cutaneous vascular lesions (port wine stains) or benign tumors of the vascular endothelium (hemangiomas) by targeting oxyhemoglobin in cutaneous blood vessels. They produce a photothermal effect that alters tissue (lightens or blanches) as energy is absorbed and transformed into heat leading to the thermal destruction of the lesion while sparing surrounding tissue.

Laser treatment of a port wine stain (affect 0.3-0.5% of the general population) requires exposure of the affected area to a laser with a specific amount of energy at multiple sessions at six-to eight-week intervals until the desired degree of lightening has occurred.

Laser treatment for hemangiomas is usually administered at multiple sessions at four-to six-week intervals. Treatment is generally continued until the lesion resolves or stops responding.

Laser surgery for warts can be used for resistant warts that have not responded to other therapies. Treatment may be up to four sessions at one-month intervals if medically necessary.

Indications/Criteria

Port Wine Stains and Hemangiomas

Laser treatment of port wine stains and hemangiomas are considered medically necessary when there is medical documentation of a functional deficit (bleeding/infection/pain) that interferes with activities of daily living.

Treatment is considered medically necessary for patients with port wine stains or hemangiomas that are nodular or hypertrophic and are at high-risk for bleeding to prevent spontaneous hemorrhage.

Benign Skin Lesion Treatment and Removal Indications/Criteria

A benign skin lesion may be considered for surgical removal if one or more of the following conditions are presented and clearly documented in the medical record:

- the lesion has one or more of the following characteristics:
 - bleeding
 - intense itching
 - o pain
 - o change in physical appearance, for example, but not limited to:
 - reddening
 - pigmentary change

- enlargement
- increase in the number of lesions
- physical evidence of inflammation or infection (e.g., purulence, oozing, edema, erythema, etc.)
- lesion obstructs an orifice
- lesion clinically restricts eye function, for example, but not limited to:
 - o lesion restricts eyelid function
 - lesion causes misdirection of eyelashes or eyelid
 - o lesion restricts lacrimal puncta and interferes with tear flow
 - lesion touches globe

Examples of benign lesions include but are not limited to:

- sebaceous (epidermoid) cysts
- Skin tags
- Milia (keratin-filled cysts)
- Nevi (moles)
- Acquired Hyperkeratosis (keratoderma)
- Papilomas
- Hemangiomas
- Warts

Exclusions

- Requests not meeting criteria under Indications/Criteria of this policy.
- Elective treatment for aesthetic improvement of non-disabling physical defects.
- Laser and light therapies for the treatment of rosacea.
- Laser therapy for the removal of tattoos.

Medicare

There is currently a Local Coverage Article for removal of benign skin lesions which addresses removal of warts and port wine stains removal. For full Medicare coverage please refer to the following link: National Government Services Inc. Local Coverage Article: Removal of Benign Skin Lesions (A54602). Revision Effective Date: 05/07/2020. Available: MCD Search (cms.gov)

References (Updated 2024)

1. American Osteopathic College of Dermatology (AOCD). Hemangiomas. Available: https://www.aocd.org/page/Hemangiomas

- 2. Chen, JK, MD, Ghari, P, MD, Aguilar, G, PhD, et al. An overview of clinical experimental treatment modalities for port wine stains. American Academy of Dermatology, Inc., ©2012. J AM Acad Dermatol. Volumes 67, Number 2.
- 3. Metry, DW, MD, Levy, ML, MD, and Corona R, MD, DSc. Management of infantile hemangiomas. UpToDate Inc. April 2013. Available: https://www.uptodate.com/contents/infantile-hemangiomas-management
- 4. Laser Treatment of Acquired and Congenital Vascular Lesions, Nouri, K, MD, Medscape Reference Drugs, Diseases, and Procedures. Sep 2, 2011. Available: http://emedicine.medscape.com/article/1120509-overview
- 5. Mulhem, E, MD, Pinelis, A, MD. Treatment of nongenital cutaneous warts. © 2011American Family Physicians. Available: https://www.aafp.org/afp/2011/0801/p288.html
- 6. Micali, G, Dall'Oglio, F, Nasca, MR. Topical treatments for cutaneous warts: an update. © 2013 Expert Reviews Ltd. Expert Rev. Dermatol. 8(1), 15-17 (2013).
- 7. National Government Services Inc. Local Coverage Article: Removal of Benign Skin Lesions (A54602). Revision Effective Date: 05/07/2020. Available: https://www.cms.gov/

Customer Product	Medical Management Requirements*
New York Products	-
HMO	Potential for Retrospective Review
PPO in Plan	Potential for Retrospective Review
PPO OOP	Potential for Retrospective Review
POS in Plan	Potential for Retrospective Review
POS OOP	Potential for Retrospective Review
Essential Plan	Potential for Retrospective Review
MVP Medicaid Managed Care	Potential for Retrospective Review
MVP Child Health Plus	Potential for Retrospective Review
MVP Harmonious Health Care Plan	Potential for Retrospective Review
MVP Medicare Complete Wellness	Potential for Retrospective Review
MVP Medicare Preferred Gold HMO POS	Potential for Retrospective Review
MVP Medicare Secure HMO POS	Potential for Retrospective Review
MVP Medicare Secure Plus HMO POS	Potential for Retrospective Review
MVP Medicare WellSelect PPO	Potential for Retrospective Review
MVP Medicare WellSelect Plus PPO	Potential for Retrospective Review
MVP Medicare Patriot Plan PPO	Potential for Retrospective Review
MVP DualAccess D-SNP HMO	Potential for Retrospective Review
MVP DualAccess Complete D-SNP HMO	Potential for Retrospective Review
MVP DualAccess Plus D-SNP HMO	Potential for Retrospective Review
UVM Health Advantage Select PPO	Potential for Retrospective Review
USA Care	Potential for Retrospective Review
Healthy NY	Potential for Retrospective Review
MVP Premier	Potential for Retrospective Review
MVP Premier Plus	Potential for Retrospective Review
MVP Premier Plus HDHP	Potential for Retrospective Review
MVP Secure	Potential for Retrospective Review
MVP EPO	Potential for Retrospective Review
MVP EPO HDHP	Potential for Retrospective Review
MVP PPO	Potential for Retrospective Review
MVP PPO HDHP	Potential for Retrospective Review
Student Health Plans	Potential for Retrospective Review
ASO	See SPD
Vermont Products	
POS in Plan	Potential for Retrospective Review
POS OOP	Potential for Retrospective Review
MVP Medicare Preferred Gold HMO POS	Potential for Retrospective Review
MVP Medicare Secure Plus HMO POS	Potential for Retrospective Review
MVP VT HMO	Potential for Retrospective Review
MVP VT HDHP HMO	Potential for Retrospective Review
MVP VT Plus HMO	Potential for Retrospective Review
MVP Secure	Potential for Retrospective Review
ASO	See SPD

[♦] Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit
See SPD See Specific Plan Design

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Revision History:

06/01/2022 - Annual Review with removal of the wart treatment and section as this is duplicative and addressed in the criteria for benign skin lesions.

06/01/2024 – Annual Review, no changes to criteria, references up to date.

10/01/2024 – Removed CPT Codes: 17106, 17107, 17108 from prior authorization.

12/01/2024 - Completed annual review of fast-track changes effective 10/01/2024



Leadless Cardiac Pacemakers

Type of Policy: Medical

Prior Approval Date: 04/04/2022

Approval Date: 03/04/2024

Effective Date: 06/01/2024

Related Polices:

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

CPT Codes: 33274- Transcatheter insertion or replacement of permanent leadless pacemaker, right ventricular, including imaging guidance (e.g., fluoroscopy, venous ultrasound, ventriculography, femoral venography) and device evaluation (e.g., interrogation or programming), when performed

33275 - Transcatheter removal of permanent leadless pacemaker, right ventricular, including imaging guidance (eg, fluoroscopy, venous ultrasound, ventriculography, femoral venography), when performed

Experimental/Investigational Codes Requiring Retrospective Review

0795T, 0796T, 0797T, 0798T, 0799T, 0800T, 0801T, 0802T, 0803T, 0804T, 0823T, 0824T, 0825T, 0826T, C1605

Common Diagnosis Codes

N/A

Common Procedure Codes

N/A

Please refer to the product grid for detailed authorization requirements for specific plans. Code lists may not be all inclusive. Codes requiring prior-authorization for some products may be retrospectively reviewed for plans that do not require prior-authorization. Common diagnosis and procedure codes are included for

informational purposes. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

A leadless cardiac pacemaker system is a pulse generator with built-in battery and electrode for implantation in a cardiac chamber via a transfemoral catheter approach.

Leadless cardiac pacemakers are designed to achieve the same pacing results as a standard pacemaker, but the process for implanting the leadless pacemaker is different from standard pacemakers. The leadless pacemaker is placed via a catheter into the right ventricle. Unlike a standard pacemaker, a leadless pacemaker does not require creation of a surgical pocket for the pacemaker, and it requires no leads. The pacemaker battery life is equivalent to that of similar standard single chamber pacemakers. The advantage of a leadless pacemaker over a standard pacemaker is avoidance of a surgical scar or lump under the skin where the pacemaker sits. Additional potential advantages include avoidance of problems with lead placement and reduction in risk of infections.

Indications/Criteria

Due to the lack of evidence from the published peer-reviewed literature, the effectiveness and safety of leadless cardiac pacemaker has not been established, therefore, leadless cardiac pacemaker is considered investigational.

Medicaid Managed Care Variation

Medicaid does not cover leadless cardiac pacemakers.

Medicare Variation

Leadless cardiac pacemakers are covered through Coverage with Evidence Development (CED). CMS covers leadless pacemakers when all the following criteria are met:

- the procedures are performed in Food and Drug Administration (FDA) approved studies. CMS also covers, in prospective longitudinal studies, leadless pacemakers that are used in accordance with the FDA approved label for devices that have either:
 - o an associated ongoing FDA approved post-approval study; or
 - o completed an FDA post-approval study.

For full coverage details please refer to Medicare National Coverage Determination (NCD) for Leadless Pacemakers (20.8.4). Effective Date 01/18/2017. Publication No. 100-3. Available: https://www.cms.gov/

References (Reviewed 2024)

1. Reddy VY, Knops RE, Sperzel J, et al. Permanent leadless cardiac pacing: Results of the LEADLESS trial. Circulation. 2014;129(14):1466-1471.

- 2. Gillis AM, Russo AM, Ellenbogen KA, et al. HRS/ACCF expert consensus statement on pacemaker device and mode selection. J Am Coll Cardiol. 2012;60(7):682-703.
- 3. Reddy VY, Exner DV, Cantillon DJ, et al; LEADLESS II Study Investigators.

 Percutaneous implantation of an entirely intracardiac leadless pacemaker. N Engl
 J Med. 2015;373(12):1125-1135
- 4. Kessels S, Parsons J, Ellery B. Leadless pacemaker. Technology Brief: HealthPact Commonwealth of Australia. July 2015 Adelaide Health Technology Assessment (AHTA). Available: https://www.adelaide.edu.au/ahta/pubs/prioritisingsummaries/.
- 5. Miller MA, Neuzil P, Dukkipati SR, Reddy VY. Leadless cardiac pacemakers: Back to the future. J Am Coll Cardiol. 2015;66(10):1179-1189.
- Knops RE, Tjong FV, Neuzil P, et al. Chronic performance of a leadless cardiac pacemaker: 1-year follow-up of the LEADLESS trial. J Am Coll Cardiol. 2015;65(15):1497-1504.
- 7. Ritter P, Duray GZ, Steinwender C, et al; Micra Transcatheter Pacing Study Group. Early performance of a miniaturized leadless cardiac pacemaker: The Micra Transcatheter Pacing Study. Eur Heart J. 2015;36(37):2510-2519.
- 8. Sperzel J, Burri H, Gras D, et al. State of the art of leadless pacing. Europace. 2015;17(10):1508-1513.
- 9. Neuzil P, Reddy VY. Leadless cardiac pacemakers: Pacing paradigm change. Curr Cardiol Rep. 2015;17(8):68.
- 10. Kypta A, Blessberger H, Kammler J, et al. Leadless cardiac pacemaker implantation after lead extraction in patients with severe device infection. J Cardiovasc Electrophysiol. 2016;27(9):1067-1071.
- 11. Seriwala HM, Khan MS, Munir MB, et al. Leadless pacemakers: A new era in cardiac pacing. J Cardiol. 2016;67(1):1-5.
- 12. Arkles J, Cooper J. The emerging roles of leadless devices. Curr Treat Options Cardiovasc Med. 2016;18(2):14.
- 13. Meyer C, Jungen C, Gosau N, et al. Percutaneous implantable transcatheter pacemaker. Dtsch Med Wochenschr. 2016;141(8):574-578.
- 14. Hayes Health Technology Assessment. Micra Transcatheter Pacing System (Medtronic, Inc.). HAYES, Inc June 3, 2022. Annual Review July 11, 2023.
- 15. Hayes Evidence Analysis Research Brief. Aveir VR Leadless Pacemaker (Abbott) for Single-Chamber Pacemaker Indications. HAYES, Inc. March 6, 2023.

- 16. Medtronic, Inc. Micra Transcatheter Pacing System Post-Approval Registry. NCT02536118. Last updated February 1, 2021. Available: https://clinicaltrials.gov/ct2/show/NCT02536118.
- 17. U.S. Food and Drug Administration (FDA) Premarket Approval. Micra Transcatheter Pacemaker System. Summary of Safety and Effectiveness. No. P150033. Rockville, MD: FDA. April 6, 2016. Available: https://www.fda.gov/media/95861/download.
- 18. eMedNY. Provider Manuals. Physician Manual. New York State Medicaid. Procedure Code: Surgery. 2020. Available: https://www.emedny.org/ProviderManuals/Physician/index.aspx

Customer Product	Medical Management Requirements*	
New York Products		
HMO	Prior Auth	
PPO in Plan	Prior Auth	
PPO OOP	Prior Auth	
POS in Plan	Prior Auth	
POS OOP	Prior Auth	
Essential Plan	Prior Auth	
MVP Medicaid Managed Care	Prior Auth	
MVP Child Health Plus	Prior Auth	
MVP Harmonious Health Care Plan	Prior Auth	
MVP Medicare Complete Wellness	Prior Auth	
MVP Medicare Preferred Gold HMO POS	Prior Auth	
MVP Medicare Secure HMO POS	Prior Auth	
MVP Medicare Secure Plus HMO POS	Prior Auth	
MVP Medicare WellSelect PPO	Prior Auth	
MVP Medicare WellSelect Plus PPO	Prior Auth	
MVP Medicare Patriot Plan PPO	Prior Auth	
MVP DualAccess D-SNP HMO	Prior Auth	
MVP DualAccess Complete D-SNP HMO	Prior Auth	
MVP DualAccess Plus D-SNP HMO	Prior Auth	
UVM Health Advantage Select PPO	Prior Auth	
USA Care	Potential for Retrospective Review	
Healthy NY	Prior Auth	
MVP Premier	Prior Auth	
MVP Premier Plus	Prior Auth	
MVP Premier Plus HDHP	Prior Auth	
MVP Secure	•	
MVP Secure MVP Secure	Prior Auth	
MVP EPO HDHP	Prior Auth	
MVP PPO	Prior Auth	
MVP PPO HDHP	Prior Auth	
	Prior Auth	
Student Health Plans	Prior Auth	
ASO	See SPD	
Vermont Products		
POS in Plan	Prior Auth	
POS OOP	Prior Auth	
MVP Medicare Preferred Gold HMO POS	Prior Auth	
MVP Medicare Secure Plus HMO POS	Prior Auth	
MVP VT HMO	Prior Auth	
MVP VT HDHP HMO	Prior Auth	
MVP VT Plus HMO	Prior Auth	
MVP VT Plus HDHP HMO	Prior Auth	
MVP Secure	Prior Auth	
ASO	See SPD	

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review.

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Revision History:

06/01/2022 – Annual review with no changes to the indications or criteria, references and websites updated.

06/01/2024 – Annual review, no changes to criteria, references updated with new Hayes report.



Lenses for Medical Conditions of the Eye

Type of Policy: Medical

Prior Approval Date: 07/03/2023

Approval Date: 02/05/2024

Effective Date: 04/01/2024

Related Polices: Gas Permeable Scleral

Contact Lens

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

N/A

Codes Requiring Retrospective Review

CPT Codes:	Description:
V2787	Astigmatism correcting function of intraocular lens
V2788	Presbyopia correcting function of intraocular lens

Experimental/Investigational

N/A

Common Diagnosis Codes

ICD-10- CM Diagnosis Codes

H16.00, H16.01, H16.02, H16.03, H16.04, H16.05, H16.06, H16.07, H16.10, H16.11,

H16.12, H16.13, H16.14, H16.20, H16.21, H16.22, H16.23, H16.24, H16.25, H16.26,

H16.29, H16.30, H16.31, H16.32, H16.33, H16.39, H16.40, H16.41, H16.42, H16.43,

H16.44, H16.8, H16.9, H17.00, H17.10, H17.81, H17.82, H18.00, H18.01, H18.02, H18.03,

H18.04, H18.05, H18.06, H18.10, H18.20, H18.21, H18.22, H18.23, H18.30, H18.31,

H18.32, H18.33, H18.40, H18.41, H18.42, H18.43, H18.44, H18.45, H18.46, H18.49,

H18.50, H18,51, H18.52, H18.53, H18.54, H18.55, H18.59, H18.60, H18.61, H18.62,

H18.70, H18.71, H18.72, H18.73, H18.79, H18.81, H18.82, H18.83, H18.89, H18.9, H21.2, H21.26, H21.29, H26.0, H27.0, H27.03, H27.00, H27.01, H27.02, H50.0, H50.3, H50.4, H53.0, H53.03, H53.00, H53.01, H53.02, H53.04

Common Diagnosis Codes associated with this policy have been provided for informational purposes only. The list of codes may not be all-inclusive and may be updated to reflect any applicable revisions to the ICD-10 code sets and/or medical necessity guidelines applied in this policy.

Common Procedure Codes

CPT Codes:	Description:
66982	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique
66983	Intracapsular cataract extraction with insertion of intraocular lens prosthesis (1 stage procedure)
66984	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (e.g., irrigation and aspiration or phacoemulsification); without endoscopic cyclophotocoagulation
66985	Insertion of intraocular lens prosthesis (secondary implant), not associated with concurrent cataract removal
66986	Exchange of intraocular lens
92310	Prescription of optical and physical characteristics of and fitting of contact lens, with medical supervision of adaptation; corneal lens, both eyes, except for aphakia
92311	Prescription of optical and physical characteristics of and fitting of contact lens, with medical supervision of adaptation; corneal lens for aphakia, 1 eye
92312	Prescription of optical and physical characteristics of and fitting of contact lens, with medical supervision of adaptation; corneal lens for aphakia, both eyes
92314	Prescription of optical and physical characteristics of contact lens, with medical supervision of adaptation and direction of fitting by independent technician; corneal lens, both eyes except for aphakia
92315	Prescription of optical and physical characteristics of contact lens, with medical supervision of adaptation and direction of fitting by independent technician; corneal lens for aphakia, 1 eye

Prescription of optical and physical characteristics of contact lens, with medical supervision of adaptation and direction of fitting by independent technician; corneal lens for aphakia, both eyes
Replacement of contact lens
Fitting of spectacle prosthesis for aphakia; monofocal
Fitting of spectacle prosthesis for aphakia; multifocal
Prosthesis service for aphakia, temporary (disposable or loan, including materials)
Repair and refitting spectacles; spectacle prosthesis for aphakia
Frames, purchases
Contact lens, PMMA, spherical, per lens
Contact lens, gas permeable, spherical, per lens
Contact lens, hydrophilic, spherical, per lens
Contact lens, hydrophilic, toric, or prism ballast, per lens
Contact lens, hydrophilic, bifocal, per lens
Contact lens, hydrophilic, extended wear, per lens
Anterior chamber intraocular lens
Iris supported intraocular lens
Posterior chamber intraocular lens

Non-Covered HCPCS Code for Medicare:

HCPCS Code	Description
V2025	Deluxe frame
V2787	Astigmatism correcting function of intraocular lens
V2788	Presbyopia correcting function of intraocular lens

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

MVP may provide coverage for lenses, frames and contact lenses under the eye wear benefit or vision care plan through participating opticians/dispensers. Please check the benefit plan descriptions for details. This policy outlines when lenses, frames, and contact lenses would be covered under the medical benefit for specific medical circumstances as outlined in this medical policy.

One of the most common indications is for the coverage of intraocular lens implants for cataract surgery. Cataracts are the hardening or opacification (clouding) of the normally transparent crystalline lens within the eye and usually occur as part of the aging process but may be congenital, traumatic, or related to other systemic diseases or medications. Intraocular lenses are used to replace the natural lens and restore the eye's optical focusing power.

Indications/Criteria

MVP will cover the cost of contact lenses or eyeglass lenses for a diagnosis of:

- Cataracts
- Pediatric aphakia (congenital absent lens)
- Pediatric aniridia
- Pediatric amblyopia
- Pediatric estropia
- Corneal erosions/ulcers
- Keratoconus, keratoglobus and other corneal ectatic disorders

For treatment of keratoconus, keratoglobus and other corneal conditions with scleral contact lenses, see the Gas Permeable Scleral Contact Lens medical policy.

MVP will cover children (age 18 and under) with accommodative esotropia and amblyopia with long-term stabilization of ocular alignment through prescription hyperopic spectacles.

Contact lenses, eyeglass lenses, and frames after cataract surgery are covered.

The customer may be responsible for applicable cost share such as co-payments, coinsurance, and/or deductibles which are specific to each customer's contract.

For post-surgical indications, a maximum of four (4) sets of lenses per year will be covered for infants and children through age four (4). From age five (5) to adult, a maximum of two (2) sets of lenses per year will be covered.

Standard fixed monofocal intraocular lens (IOL) implants are covered following cataract surgery.

Exclusions

- Contact lenses or eyeglass lenses for conditions other than specified above are not covered.
- Disposable contact lenses, sunglasses, tinting of lenses, progressive lenses, and safety glasses required for employment or sports will not be covered, even if prescribed.
- Loss or injury to the lenses is not covered.
- There will be no additional payment for lenses considered to be not medically necessary including, but not limited to, presbyopia-correcting intraocular lenses, astigmatism-correcting intraocular lenses, accommodating intraocular lenses, and multifocal intraocular lenses.
- Radial keratotomy and keratoplasty to treat refractive defects.

Medicare Variation

The following pertains to Medicare Customers only:

• One (1) pair of eyeglasses or contact lenses will be covered for an adult after each cataract surgery with a conventional intraocular lens (IOL) implant.

Presbyopia-Correcting Intraocular Lenses (P-C IOLs) and Astigmatism-Correcting Intraocular Lenses (A-C IOLs)

- Medicare customers have the choice to receive the presbyopia-correcting intraocular lens (P-C IOL) that not only replaces the lens clouded by cataracts but also allows the eye to focus on near, intermediate, and far vision, minimizing the need for a corrective lens or an astigmatism intraocular lens (A-C IOL). These customers may request insertion of the presbyopia-correcting intraoperative lens or an astigmatism-correcting intraoperative lens in place of a conventional IOL following cataract surgery. In this case, the presbyopia-correcting intraoperative lens or astigmatism-correcting intraoperative lens and associated services for fitting one lens are considered partially covered. Code V2788 was established for reporting non-covered charges associated with the insertion of a presbyopia-correcting intraoperative lens and code V2787 was established for reporting non-covered charges associated with the insertion of an astigmatism-correcting intraoperative lens. Providers may report these codes on claims to reflect the appropriate lens when inserted in lieu of the conventional intraoperative lens in conjunction with correcting cataract surgery.
- MVP will pay the amount normally paid for the insertion of a conventional intraoperative lens. The customer is responsible for payment of that portion of the facility and physician charge for the presbyopia-correcting intraoperative lens or an astigmatism-correcting intraoperative lens and associated services and supplies attributable to the presbyopia-correcting functionality or astigmatism-correcting

functionality that exceed the charge for insertion of a conventional intraoperative lens following cataract surgery. Medicare strongly encourages facilities and physicians to issue a Notice of Exclusion from Medicare Benefits to beneficiaries in order to clearly identify the non-payable aspects of a presbyopia-correcting intraoperative lens insertion.

- Medicare does not cover radial keratotomy and keratoplasty to treat refractive defects.
- HCPCS Code V2025 is not covered for Medicare Products

There is a Medicare National Coverage Determination (NCD) for Refractive Keratoplasty. (80.7) and Intraocular Lenses (IOLs) (80.12). Available: https://www.cms.gov/medicare-coverage-database/search.aspx

Based on review, there are no Local Coverage Determinations (LCD) for Medical Conditions of the Eye.

There are several CMS transmittals regarding Presbyopia-Correcting (P-C IOLS (Intraocular Lenses)) and Astigmatism-Correcting Intraocular Lenses (A-C IOLs). For the CMS transmittals please refer to the **References** section of the policy.

References (Updated 2023)

- Centers for Medicare and Medicaid Services. CMS Ruling. Requirements for Determining Coverage of Presbyopia-Correcting Intraocular Lenses that Provide Two Distinct Services for the Patient: (1) Restoration of Distance Vision Following Cataract Surgery, and (2) Refractive Correction of Near and Intermediate Vision with Less Dependency on Eyeglasses or Contact Lenses. Ruling No. 05-01 Date: May 3, 2005. Available at: http://www.cms.hhs.gov/Rulings/downloads/CMSR0501.pdf.
- Centers for Medicare and Medicaid Services. CMS Ruling. Ruling Requirements for Determining Payment Made for Insertion of Astigmatism-Correcting Intraocular Lenses following Cataract Surgery. Ruling No. 1536-R Date January 22, 2007. Available at: https://www.cms.gov/Regulations-and-guidance/Guidance/Transmittals/downloads/R1228CP.pdf.
- 3. Centers for Medicare and Medicaid Services. CMS Recognized Presbyopia-Correcting (PC) IOLs and Astigmatism-Correcting (AC) IOLs CMS Recognized Presbyopia-Correcting (PC) IOLs and Astigmatism-Correcting (AC) IOLs
- 4. American Academy™ of Ophthalmology. EyeWiki® Penny A. Asbell M.D. M, Theodora Petratos, M.D.; et al. Keratoconus, August 2015. Available: http://eyewiki.aao.org/Keratoconus
- 5. American Academy of Ophthalmology. Guidelines. Preferred Practice Pattern®. Accessed May 2023. Available at URL address:

- https://www.aao.org/guidelinesbrowse?filter=Guidelines&sub=ONE.ContentTypes.Pr eferredPracticePatternGuideline
- 6. de Silva SR, Evans JR, Kirthi V, et al. Multifocal versus monofocal intraocular lenses after cataract extraction. Cochrane Database Syst Rev. 2016(9):CD003169.
- 7. Ong HS, Evans JR, Allan BD. Accommodative intraocular lens versus standard monofocal intraocular lens implantation in cataract surgery. Cochrane Database Syst Rev. 2014;(5):CD009667.
- 8. Department of Health and Human Services. Centers for Medicare and Medicaid Services. Medicare Learning Network. Medicare Vision Services. ICN 907165 January 2017. Available: https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/VisionServices-FactSheet_ICN907165.pdf
- Centers for Medicare and Medicaid Services. National Coverage Determination (NCD) for Intraocular Lenses (IOLs) (80.12) Effective 05/19/1997. Available: www.cms.gov
- 10. Mohney BG. Common forms of childhood esotropia. Ophthalmology 2001;108(4):805-9. https://www.uptodate.com/contents/causes-of-horizontal-strabismus-in-children
- 11. Allaboutvision.com. Conditions/Cataracts/Intraocular Lenses. IOLs: Choosing the best implant for cataract surgery. Page updated June 15, 2022. Accessed May 2023. Available at URL address: https://www.allaboutvision.com/conditions/iols.htm

Customer Product	Medical Management Requirements*
New York Products	•
HMO	Retrospective Review
PPO in Plan	Retrospective Review
PPO OOP	Retrospective Review
POS in Plan	Retrospective Review
POS OOP	Retrospective Review
Essential Plan	Retrospective Review
MVP Medicaid Managed Care	Retrospective Review
MVP Child Health Plus	Retrospective Review
MVP Harmonious Health Care Plan	Retrospective Review
MVP Medicare Complete Wellness	Retrospective Review
MVP Medicare Preferred Gold HMO POS	Retrospective Review
MVP Medicare Secure HMO POS	Retrospective Review
MVP Medicare Secure Plus HMO POS	Retrospective Review
MVP Medicare WellSelect PPO	Retrospective Review
MVP Medicare WellSelect Plus PPO	Retrospective Review
MVP Medicare Patriot Plan PPO	Retrospective Review
MVP DualAccess D-SNP HMO	Retrospective Review
MVP DualAccess Complete D-SNP HMO	Retrospective Review
MVP DualAccess Plus D-SNP HMO	Retrospective Review
UVM Health Advantage Select PPO	Retrospective Review
USA Care PPO	Potential for Retrospective Review
Healthy NY	Retrospective Review
MVP Premier	Retrospective Review
MVP Premier Plus	Retrospective Review
MVP Premier Plus HDHP	Retrospective Review
MVP Secure	Retrospective Review
MVP EPO	Retrospective Review
MVP EPO HDHP	Retrospective Review
MVP PPO	Retrospective Review
MVP PPO HDHP	Retrospective Review
Student Health Plans	Retrospective Review
ASO	See SPD
Vermont Products	300 0. 2
POS In Plan	Retrospective Review
POS OOP	Retrospective Review
MVP Medicare Preferred Gold HMO POS	Retrospective Review
MVP Medicare Secure Plus HMO POS	Retrospective Review
MVP VT HMO	Retrospective Review
MVP VT HDHP HMO	Retrospective Review
MVP VT Plus HMO	Retrospective Review
MVP VT Plus HDHP HMO	Retrospective Review
MVP Secure	Retrospective Review
ASO	See SPD
AJU	JEE JED

[♦] Note: Prior authorization requirements for HDHP products are the same as the base product (e.g., HDHP HMO auth requirements are the same as listed for HMO).

*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit
See SPD See Specific Plan Design

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Revision History:

10/01/2021 – Annual review with no change to the indications or criteria. Updated overview section clarified coverage for pediatric eye conditions and added statement to see the Gas Permeable Contact Lenses medical policy for coverage of these lens for keratoconus and other corneal conditions.

10/01/2023 - Annual review, references updated.

04/01/2024 – added overview for intraocular lenes, added statement for what IOL are covered, removed monofocal from the exclusions and added accommodating. Updated Medicare variation with Medicare language. No changes to indications or coverage.



Light Therapy for Seasonal Affective Disorder

Type of Policy: DME

Prior Approval Date: 10/04/2021

Approval Date: 08/07/2023

Effective Date: 10/01/2023

Related Polices: N/A

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

N/A

Codes Requiring Retrospective Review

HCPCS codes	Description
E0203	Therapeutic lightbox, minimum 10,000 lux, table top model
A4634	Replacement bulb for therapeutic light box, tabletop model

Experimental/Investigational

N/A

Common Diagnosis Codes

ICD-10- CM Diagnosis Codes: F33.9

Common Procedure Codes:

CPT Code: 90899

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are

subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

Seasonal effective disorder (SAD) is a type of depression that follows a seasonal pattern. It typically occurs and recurs during specific seasons, most commonly in the fall and winter months, when there is less sunlight. SAD is believed to be caused by reduced sunlight which affects mood and sleep symptoms include sadness, low energy, changes in appetite and sleep problems. Treatment options include light therapy, therapy, medication, and lifestyle adjustments.

Light therapy is a treatment for seasonal affective disorder that involves exposure to bright artificial light. Therapy typically uses a special light box that emits a bright light mimicking natural sunlight. By sitting in front of the light box for a specific amount of time each day, usually in the morning, it helps to regulate the body's internal clock and is proposed to improve mood.

Indications/Criteria

A light emitting device for the treatment of seasonal affective disorder (SAD) does not conform to the definition of durable medical equipment and, therefore, does not meet coverage criteria for DME.

Exclusions

N/A

Medicare:

Therapeutic light box (E0203) is considered not reasonable and necessary and noncovered.

References (Reviewed 2023)

- 1. Lam, R.W., Levitt, A.J., Levitan, R.D., Enns, M.W., Morehouse, R., Michalak, E.E., Tam, E.M., The CAD-SAD Study: A randomized controlled trial of the effectiveness of light therapy and fluoxetine in patients with winter seasonal affective disorder. Am J Psychiatry 2006; 163:805-812.
- 2. Golden, R.N., Gaynes, B.N., Ekstrom, R.D., Hamer, R.M., Jacobsen, F.M., Suppes, T., Wisner, K.L., Nemeroff, C.B., The efficacy of light therapy in the treatment of mood disorders: A review and meta-analysis of evidence. Am J Psychiatry 2005; 162:656-662.
- 3. Morgan AJ, Jorm AF. Self-help interventions for depressive disorders and depressive symptoms: a systematic review. Ann Gen Psychiatry. 2008 Aug 19;7:13.

- 4. Freeman MP, Fava M, Lake J, Trivedi MH, Wisner KL, Mischoulon D. Complementary and alternative medicine in major depressive disorder: the American Psychiatric Association Task Force report. J Clin Psychiatry. 2010 Jun;71(6):669-81.
- 5. Centers for Medicare and Medicaid Services (CMS) Medicare Benefit Policy Manual Chapter 15 Covered Medical and Other Health Services Durable Medical Equipment Reference List: Chapter 1, Part 4, Section: 280.1 Available: Medicare National Coverage Determinations Manual (cms.gov)

Customer Product	Medical Management Requirements*	
New York Products	-	
HMO	Retrospective Review	
PPO in Plan	Retrospective Review	
PPO OOP	Retrospective Review	
POS in Plan	Retrospective Review	
POS OOP	Retrospective Review	
Essential Plan	Retrospective Review	
MVP Medicaid Managed Care	Retrospective Review	
MVP Child Health Plus	Retrospective Review	
MVP Harmonious Health Care Plan	Retrospective Review	
MVP Medicare Complete Wellness	Retrospective Review	
MVP Medicare Preferred Gold HMO POS	Retrospective Review	
MVP Medicare Secure HMO POS	Retrospective Review	
MVP Medicare Secure Plus HMO POS	Retrospective Review	
MVP Medicare WellSelect PPO	Retrospective Review	
MVP Medicare WellSelect Plus PPO	Retrospective Review	
MVP Medicare Patriot Plan PPO	Retrospective Review	
MVP DualAccess D-SNP HMO	Retrospective Review	
MVP DualAccess Complete D-SNP HMO	Retrospective Review	
MVP DualAccess Plus D-SNP HMO	Retrospective Review	
UVM Health Advantage Select PPO	Retrospective Review	
USA Care PPO	Potential for Retrospective Review	
Healthy NY	Retrospective Review	
MVP Premier	Retrospective Review	
MVP Premier Plus	Retrospective Review	
MVP Premier Plus HDHP	Retrospective Review	
MVP Secure	Retrospective Review	
MVP EPO	Retrospective Review	
MVP EPO HDHP	Retrospective Review	
MVP PPO	Retrospective Review	
MVP PPO HDHP	Retrospective Review	
Student Health Plans	Retrospective Review	
ASO	See SPD	
Vermont Products		
POS in Plan	Retrospective Review	
POS OOP	Retrospective Review	
MVP Medicare Preferred Gold HMO POS	Retrospective Review	
MVP Medicare Secure Plus HMO POS	Retrospective Review	
MVP VT HMO Retrospective Review		
MVP VT HDHP HMO	Retrospective Review	
MVP VT Plus HMO Retrospective Review		
IVP VT Plus HDHP HMO Retrospective Review		
MVP Secure Retrospective Review		
ASO	See SPD	

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Review History:

12/01/2021 - Annual Review with no changes to the indications/criteria.

10/01/2023 – Annual review with no changes to the indications/criteria. Overview updated, added Medicare section, references reviewed.



Liposuction for Lipedema

Type of Policy: Surgical/Medical

Prior Approval Date: 08/01/2022

Approval Date: 07/01/2024

Effective Date: 10/01/2024

Related Polices: Panniculectomy and Abdominoplasty

Cosmetic and Reconstructive Services

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

CPT Code:	Description:
15876	Suction assisted lipectomy; head and neck
15877	Suction assisted lipectomy; trunk
15878	Suction assisted lipectomy; upper extremity
15879	Suction assisted lipectomy; lower extremity

Codes Requiring Retrospective Review

N/A

Experimental/Investigational/Cosmetic

15832	Excision, excessive skin and subcutaneous tissue (includes lipectomy); thigh
15833	Excision, excessive skin and subcutaneous tissue (includes lipectomy); leg
15834	Excision, excessive skin and subcutaneous tissue (includes lipectomy); hip
15835	Excision, excessive skin and subcutaneous tissue (includes lipectomy); buttock

15836	Excision, excessive skin and subcutaneous tissue (includes lipectomy);
	arm
15837	Excision, excessive skin and subcutaneous tissue (includes lipectomy);
	forearm or hand
15839	Excision, excessive skin and subcutaneous tissue (includes lipectomy);
	other area

Common Diagnosis Codes

Common Diagnosis Codes associated with this policy have been provided for informational purposes only. The list of codes may not be all-inclusive and may be updated to reflect any applicable revisions to the ICD-10 code set and/or medical necessity guidelines applied in this policy.

E65 – Localized adiposity

E88.2 - Lipomatosis, not elsewhere classified

Common Procedure Codes

CPT Codes: N/A

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

Lipedema is a rare adipose disorder characterized as the abnormal deposition of fat with associated edema. It occurs almost exclusively in women. It is often misdiagnosed as obesity or lymphedema. Lipedema is a distinct entity that must be differentiated from obesity and lymphedema, although it may progress to involve the venous and lymphatic systems, which increases the difficulty of its diagnosis. Physical examination will help differentiate lipedema from lymphedema; patients with lipedema will not generally have pitting edema while lymphedema may have pitting edema. Patients with lipedema usually have normal lymphatic function, whereas patients with lymphedema may have dermal backflow and lack of uptake in lymph nodes.

Lipedema treatment options include conservative and surgical (e.g., liposuction) treatments. Conservative treatment includes promoting a healthy lifestyle through diet and exercise, complete decongestive therapy (i.e., manual lymphatic massage, bandaging, and skin care) as well as emotional, psychological, and social support. When conservative treatment fails, liposuction may be considered.

Indications/Criteria

Liposuction, (i.e., water jet-assisted liposuction, micro-cannular) or lipectomy for the treatment of lipedema is considered medically necessary when ALL of the following criteria are met:

- Pain in the affected areas on palpation; and
- Tenderness on palpation; and
- Easy bruising; and
- Nodularity of fat deposits in lipedema affected areas (dimpled or orange peel texture); and
- Physical function impairment (i.e., difficulty ambulating or performing activities of daily living); and
- Absence of pitting edema from lipedema (no "pitting" when finger or thumb pressure is applied to the area of fat); and
- Negative Stemmer sign, unless the individual has coexisting lymphedema (Stemmer sign is negative when a fold of skin can be pinched and lifted up at the base of the second toe or at the base of the middle finger); and
- Lack of improvement in lipedema-affected areas following medically supervised weight loss modalities; and
- Lack of improvement in swelling with limb elevation; and
- Lack of response to at least six or more consecutive months of medical management (i.e., conservative treatment with compression garments and manual lymph drainage)

All other applications of liposuction or lipectomy not meeting the criteria as indicated in this policy are considered cosmetic and therefore not medically necessary.

Exclusions

Suction assisted lipectomy done solely for cosmetic purposes is non-covered.

Medicare and Medicaid

There was no National Coverage Determination (NCD) or Local Coverage Determination (LCD) found. Therefore, coverage criteria in this policy applies to all Medicare and Medicaid Managed Care plans.

References (Reviewed 2024)

1. Buck DW 2nd, Herbst KL. Lipedema: A relatively common disease with extremely common misconceptions. Plast Reconstr Surg Glob Open. 2016;4(9):e1043. Published 2016 Sep 28.

- 2. Goss JA, Greene AK. Sensitivity and Specificity of the Stemmer Sign for Lymphedema: A Clinical Lymphoscintigraphic Study. Plast Reconstr Surg Glob Open. 2019 Jun 25;7(6):e2295.
- 3. Herbst KL. Rare adipose disorders (RADs) masquerading as obesity. Acta Pharmacol Sin. 2012 Feb;33(2):155-72.
- 4. Jensen MD, Ryan DH, Apovian CM et al. National Heart, Lung and Blood Institute (NHLBI). Managing overweight and obesity in adults. Systematic evidence review from the Obesity Expert Panel, 2013.
- 5. Kelly AS, Barlow SE, Rao G, et al. Severe obesity in children and adolescents: identification, associated health risks, and treatment approaches: a scientific statement from the American Heart Association. Circulation. 2013 Oct 8;128(15):1689-712.
- 6. Peprah K, MacDougall D. Liposuction for the treatment of lipedema: A review of clinical effectiveness and guidelines [Internet]. Ottawa (ON): Canadian Agency for Drugs and Technologies in Health; 2019 Jun 7.
- 7. Witte T, Dadras M, Heck FC, et al. Water-jet-assisted liposuction for the treatment of lipedema: Standardized treatment protocol and results of 63 patients. J Plast Reconstr Aesthet Surg. 2020 Sep;73(9):1637-1644.
- 8. Wold LE, Hines EA Jr, Allen EV. Lipedema of the legs; a syndrome characterized by fat legs and edema. Ann Intern Med. 1951 May;34(5):1243-50.
- 9. Wollina U, Heinig B. Treatment of lipedema by low-volume micro-cannular liposuction in tumescent anesthesia: Results in 111 patients. Dermatol Ther. 2019 Mar;32(2):e12820.

Customer Product	Medical Management Requirements*
New York Products	
HMO	Prior Auth
PPO in Plan	Prior Auth
PPO OOP	Prior Auth
POS in Plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Prior Auth
MVP Child Health Plus	Prior Auth
MVP Harmonious Health Care Plan	Prior Auth
MVP Medicare Complete Wellness	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP Medicare WellSelect PPO	Prior Auth
MVP Medicare WellSelect Plus PPO	Prior Auth
MVP Medicare Patriot Plan PPO	Prior Auth
MVP DualAccess D-SNP HMO	Prior Auth
MVP DualAccess Complete D-SNP HMO	Prior Auth
MVP DualAccess Plus D-SNP HMO	Prior Auth
UVM Health Advantage Select PPO	Prior Auth
USA Care	Potential for Retrospective Review
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	300 31 2
POS in Plan	Prior Auth
POS OOP	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP VT HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD
AND	

[♦] Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

*Medical Management Requirements

Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review.

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

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MVP Health Care Medical Policy Revision History:

10/01/2022 – New policy adopted.

10/1/2024 – Annual review, no change to criteria.



Lymphedema Compression Garments Compression Stockings

Type of Policy: DME

Prior Approval Date: 12/04/2023

Approval Date: 03/21/2024

Effective Date: 04/01/2024

Related Polices: Pneumatic Compression Devices

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

A6593 - Accessory for gradient compression garment or wrap with adjustable straps, not otherwise specified

A6609 - Gradient compression bandaging supply, not otherwise specified

A9999 - Miscellaneous DME supply or accessory, not otherwise specified

A9900 - Miscellaneous DME supply, accessory, and/or service component of another HCPCS code

See MVP Durable Medical Equipment (DME) Prior Authorization List

https://www.mvphealthcare.com/utilization

Codes Requiring Retrospective Review

N/A

Experimental/Investigational

N/A

Common Diagnosis Codes

187.2 – Venous insufficiency

Lymphedema Compression Garments Compression Stockings

183.001 – 183.899 – Varicose veins

189.0 – 189.9 – Other noninfective disorders of lymphatic vessels and lymph nodes

195.1 – Orthostatic hypotension

197.2 – Postmastectomy lymphedema syndrome

Q82.0 – Hereditary lymphedema

Common Diagnosis Codes associated with this policy have been provided for informational purposes only. The list of codes may not be all-inclusive and may be updated to reflect any applicable revisions to the ICD-10 code set and/or medical necessity guidelines applied in this policy.

Common Procedure Codes

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HCPCS Codes: A4465, A6518, A6519, A6520, A6521, A6522, A6523, A6524, A6525, A6526, A6527, A6528, A6529, A6530, A6531, A6532, A6533, A6534, A6535, A6536, A6537, A6538, A6539, A6540, A6541, A6544, A6545, A6549, A6552, A6553, A6554, A6555, A6556, A6557, A6558, A6559, A6560, A6561, A6562, A6563, A6564, A6565, A6566, A6567, A6568, A6569, A6570, A6571, A6572, A6573, A6574, A6575, A6576, A6577, A6578, A6579, A6580, A6581, A6582, A6583, A6584, A6585, A6586, A6587, A6588, A6589, A6593, A6594, A6595, A6596, A6597, A6598, A6599, A6600, A6601, A6602, A6603, A6604, A6605, A6606, A6607, A6608, A6609, A6610, A6611, S8420, S8421, S8422, S8423, S8424, S8425, S8426, S8427, S8428
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Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

Lymphedema is a chronic condition characterized by the accumulation of lymph fluid in tissues, typically in the arms or legs. It occurs when the lymphatic system, which helps remove waste and excess fluid from the body, is impaired or damaged. The most common cause of lymphedema is the removal or damage of lymph nodes and vessels often as a result of surgery or radiation therapy for cancer. Lymphedema compression garments are used for the purpose of preventing an increase in lymphedema and maintaining the reduction of lymphedema after treatment.

Lymphedema compression appliances include lymphedema compression garments, sleeves, gloves, and non-elastic binders. Gradient compression stockings or garments are made of elastic compression material used to provide static compression to promote venous and/or lymphatic circulation. Gradient compression wraps, bandaging rolls and supplies are also used to promote venous and/or lymphatic circulation.

Surgical stockings, also known as compression stockings or support stockings, are specialized hosiery garments designed to provide graduated compression to the legs. They are commonly used to improve blood circulation, reduce swelling, and prevent blood clots in the lower extremities. These stockings are commonly prescribed for individuals who have conditions like venous insufficiency, varicose veins, deep vein thrombosis (DVT), or those who have undergone surgery. They can be worn during and after surgical procedures to support recovery and minimize the risk of blood clots.

Surgical and gradient compression stockings have the greatest amount of compression at the ankle and gradually decrease as the garment comes up the leg towards the heart. Compression stockings will have at least 18 mmHg of compression to a maximum of 50 mmHg. There are many different compression stocking lengths available, such as above the knee, thigh length, below the knee, and full length. There are also many types of surgical stockings ranging in size and custom made. Compression stockings or garments are also known by various brand names such as Sigvaris, Mediven, Juzo, Jobst, Tribute (Solaris), and others.

A sleeve may be needed for lymphedema of the arm and a glove or gauntlet may also be used if lymphedema is present in the hand. The compression garment may be prefabricated or custom fabricated for adequate graduated compression. Non-elastic binders provide static compression of the extremity without the use of elastic, but use wraps, adjustable velcro, or buckle straps.

Indications/Criteria:

Unless otherwise stipulated in the benefit plan language, compression stockings and compression garments are covered under the core medical benefits of the plan. Graduated-compression garments (18 mmHg to 50 mmHg) are considered medically necessary for the following indications:

- Venous insufficiency
- Ulceration due to chronic venous insufficiency
- Varicose veins
- Phlebitis/Thrombophlebitis
- Deep vein thrombosis (DVT) prophylaxis during pregnancy and postpartum, or immobilization due to surgery, trauma or debilitation;
- Orthostatic hypotension
- Edema following surgery, fracture, burns or other trauma.
- Postmastectomy lymphedema

Coverage is for both standard and custom fitted gradient compression garments of the extremities when the above criteria is met.

Custom compression stockings/garments are covered when:

- There is vascular impairment that requires compression garments.
- The customer's limb/body measurements are outside the manufacturer's parameters for ready-made or off-the-shelf garments.

Use of zippered gradient compression stockings is covered when:

- Customer meets coverage criteria for custom compression stockings/garments. The presence of an open wound or inability to don/doff non-zippered stockings if caregivers are not available.
- Detailed documentation of customer's dexterity/ability to don/doff zippered stockings if caregivers are not available.

A lymphedema compression garment for the upper extremities (e.g., sleeve, gauntlet, or stocking) is considered medically necessary for the treatment of chronic lymphedema and intractable lymphedema of the upper extremity subsequent to lymph node dissection related to cancer surgery. Custom lymphedema garments are covered when the customer's limb/body measurements are outside the manufacturer's parameters for the ready-made or off-the-shelf garments.

Non-elastic binders (e.g., Reidsleeve, Circaid) are covered for lymphedema which has failed a four (4) week course of treatment including a compression bandage garment, exercise and elevation of the limb.

Coverage for lymphedema compression treatment items, when medically necessary, includes the following:

- Standard daytime gradient compression garments
- Custom daytime gradient compression garments
- Nightime gradient compression garments
- Gradient compression wraps
- Accessories, such as zippers, linings, paddings, or fillers, necessary for the effective use of a gradient compression garment or wrap
- Compression bandaging systems and supplies

Custom-fitted or non-standard garments are uniquely sized and shaped to fit the exact dimensions of the affected extremity of a person to give accurate gradient compression to treat lymphedema. Gradient compression garments are designed differently for daytime or nighttime use. Daytime garments give a higher level of compression. Nighttime garments offer milder compression and are less snug against the skin.

The frequency limitations for replacement of lymphedema compression treatment items are:

- Once every 6 months for 3 gradient compression garments or wraps with adjustable straps per each affected extremity or part of the body
- Once every 2 years for 2 nighttime garments per each affected extremity or part of the body

A gradient compression stocking, below the knee, is a covered benefit for all MVP customers when it is used in the treatment of an open venous stasis ulcer.

The following gradients may be covered:

- 30-40mm/Hg (A6531); or
- 40-50mm/hg (A6532).

A non-elastic gradient compression wrap described by code A6545 is a covered benefit for all MVP customers when it is used in the treatment of an open venous stasis ulcer that is below the knee.

Exclusions

Gradient compression stockings are a disposable supply. If a product excludes coverage for a disposable supply, it is not covered, and medical policy criteria do not apply.

MVP Medicaid Managed Care (including CHP/HARP plans)

Effective April 1, 2023, providers are no longer able to bill MVP Managed Medicaid or HARP members for pharmacy and pharmacy related durable medical equipment and supplies because NYS Medicaid covers these items. This includes certain surgical stockings including A4495, A4500, and A4510 as designated by the New York State Department of Health.

The full list of codes that must be billed to Medicaid Fee-For-Service is located at https://www.emedny.org/ProviderManuals/Pharmacy/index.aspx - See the OTC and Supply Fee Schedule.

Providers should bill these directly to New York State Medicaid Fee-For-Service using the Medicaid member client identification number (CIN) after 04/01/2023. Claims submitted directly to MVP for items that are carved out to Fee-For-Service will deny as not a covered benefit.

Covered for venous or lymphatic impairment.

Non-Custom

- Prefabricated elastic support garment that applies varying pressure gradients to an area.
- Prefabricated garments are available in various sizes, and different levels of compression.

Lymphedema Compression Garments Compression Stockings - Prefabricated garments with appropriate level of compression (determined by the ordering provider) should be requested before custom is considered if the member's limb measurements fit within the size ranges specified by the manufacturers of the garment. Various manufacturers should be explored.

Custom

- Custom-made gradient compression stockings/garments are fabricated to the exact specifications of an individual.
- Custom made are considered medically necessary when the degree of gradient pressure is one that cannot be provided in a prefabricated garment, or the measurements fall outside the ranges of prefabricated garments.
- Custom HCPCS codes and fees include zippered compression garments.
 Documentation Requirements
 - A physician's fiscal order indicating the specific level of compression in mm/Hg, specific style, type, and hosiery knit, and any additional accessories/options
 - Ordering provider's letter of medical necessity should include: medical history, related diagnoses, duration and extent of current symptoms, any neurological involvement of affected limbs, ambulation status and degree of assistance required.
 - Current and previous decompression treatment modalities utilized and member's compliance and medical outcomes
 - Detailed limb/body measurements obtained from a certified fitter or LANA certified therapist, and date measured. Indicate the location and degree of edematous lobules, if present

Medicaid coverage for lymphedema garments and compression stockings is for 2 pairs twice per year, one to wash and one to wear.

MVP Medicare Plans Variation:

Medicare Advantage Plans cover compression treatment items only for the treatment of lymphedema, including postmastectomy lymphedema.

These items, include lymphedema compression garments for the arms and legs, and must be prescribed by a physician (or a physician assistant, nurse practitioner, or a clinical nurse specialist).

A lymphedema compression garment for the upper extremities (e.g., sleeve, gauntlet, or stocking) is considered medically necessary for the treatment of chronic lymphedema and intractable lymphedema of the upper extremity after lymph node dissection related to cancer surgery. Custom lymphedema garments are covered when the customer's limb/body measurements are outside the manufacturer's parameters for the readymade or off-the-shelf garments.

Coverage for lymphedema compression treatment items, when medically necessary, includes the following:

- Standard daytime gradient compression garments
- Custom daytime gradient compression garments
- Nighttime gradient compression garments
- Gradient compression wraps
- Accessories, such as zippers, linings, paddings, or fillers, necessary for the effective use of a gradient compression garment or wrap
- Compression bandaging systems and supplies

A gradient compression stocking, below the knee, is a covered benefit for all MVP Medicare customers when it is used in the treatment of an open venous stasis ulcer.

The following gradients may be covered:

- 30-40mm/Hg (A6531); or
- 40-50mm/hg (A6532).

A non-elastic gradient compression wrap described by code A6545 is a covered benefit for all MVP Medicare customers when it is used in the treatment of an open venous stasis ulcer that is below the knee.

For additional information see the Noridian Healthcare Solutions Durable Medical Equipment Medicare Administrative Contractor, Local Coverage Article (LCA) A54563. Revision Effective Date: 05/01/2021. Available: MCD Search (cms.gov)

Medicare Learning Network (MLN) Matters® Articles MM13286, November 9, 2023, Effective Date: January 1, 2024 Available: lymphedema-compression-treatment-items-implementation.pdf

References (Reviewed 2023):

1. Noridian Healthcare Durable Medical Equipment Medicare Administrative Contractor, LCD for Surgical Dressings (L33831). Revision Effective Date05/01/2021. Available: https://med.noridianmedicare.com/web/jddme/policies/lcd/active

- 2. Noridian Healthcare Solutions Durable Medical Equipment Medicare Administrative Contractor, Local Coverage Article (LCA) A54563. Revision Effective Date: 05/01/2021. Available: MCD Search (cms.gov)
- 3. New York State Medicaid Program. Durable Medical Equipment Orthotics, Prosthetics, and Supplies. Prcedure Codes and Coverage Guidelines. Version 2022 1 (06/01/2022) Available: www.emedny.org/ProviderManuals/index.html
- 4. Federal Consolidated Appropriations Act, 2023. H.R. 2617-2 Title IV Section 4133 Available: <u>BILLS-117hr2617enr.pdf</u> (congress.gov)
- 5. Medicare Learning Network (MLN) Matters® Articles MM13286, November 9, 2023, Effective Date: January 1, 2024 Available:

 https://www.cms.gov/files/document/mm13286-lymphedema-compression-treatment-items-implementation.pdf

Customer Product	Medical Management Requirements*			
New York Products				
НМО	Prior Auth			
PPO In Plan	Prior Auth			
PPO OOP	Prior Auth			
POS In Plan	Prior Auth			
POS OOP	Prior Auth			
Essential Plan	Prior Auth			
MVP Medicaid Managed Care	Prior Auth			
MVP Child Health Plus	Prior Auth			
MVP Harmonious Health Care Plan	Prior Auth			
MVP Medicare Complete Wellness	Prior Auth			
MVP Medicare Preferred Gold HMO POS	Prior Auth			
MVP Medicare Secure HMO POS	Prior Auth			
MVP Medicare Secure Plus HMO POS	Prior Auth			
MVP Medicare WellSelect PPO	Prior Auth			
MVP Medicare WellSelect Plus PPO	Prior Auth			
MVP Medicare Patriot Plan PPO	Prior Auth			
MVP DualAccess D-SNP HMO	Prior Auth			
MVP DualAccess Complete D-SNP HMO	Prior Auth			
MVP DualAccess Plus D-SNP HMO	Prior Auth			
UVM Health Advantage Select PPO	Prior Auth			
Healthy NY	Prior Auth			
MVP Premier	Prior Auth			
MVP Premier Plus	Prior Auth			
MVP Premier Plus HDHP	Prior Auth			
MVP Secure	Prior Auth			
MVP EPO	Prior Auth			
MVP EPO HDHP	Prior Auth			
MVP PPO	Prior Auth			
MVP PPO HDHP	Prior Auth			
Student Health Plans	Prior Auth			
ASO	See SPD			
Vermont Products				
POS In Plan	Prior Auth			
POS OOP	Prior Auth			
MVP Medicare Preferred Gold HMO POS	Prior Auth			
MVP Medicare Secure Plus HMO POS	Prior Auth			
MVP VT HMO	Prior Auth			
MVP VT HDHP HMO	Prior Auth			
MVP VT Plus HMO	Prior Auth			
MVP VT Plus HDHP HMO	Prior Auth			
MVP Secure	Prior Auth			
ASO	See SPD			

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g., HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Revision History:

12/01/2022 – Annual review; added postmastectomy lymphedema to indications; added clarification language for MVP CHP and Medicare plan exclusions.

01/01/2023 – Added coverage to Child Health Plans (CHP).

01/01/2024 – Added Medicare Advantage Plan coverage of certain lymphedema compression treatment items: A4465, A6520, A6521, A6522, A6523, A6524, A6525, A6526, A6527, A6528, A6529, A6530, A6531, A6532, A6533, A6534, A6535, A6536, A6537, A6538, A6539, A6540, A6541, A6544, A6545, A6549, A6552, A6553, A6554, A6555, A6556, A6557, A6558, A6559, A6560, A6561, A6562, A6563, A6564, A6565, A6566, A6567, A6568, A6569, A6570, A6571, A6572, A6573, A6574, A6575, A6576, A6577, A6578, A6579, A6580, A6581, A6582, A6583, A6584, A6585, A6586, A6587, A6588, A6589, A6593, A6594, A6595, A6596, A6597, A6598, A6599, A6600, A6601, A6602, A6603, A6604, A6605, A6606, A6607, A6608, A6609, A6610. Added prior authorization to A6593 and A6609.

04/01/2024 - update to reflect carve out to original Medicaid of burn garments and surgical stockings and to be consistent with new Medicaid policy coverage guidelines which were just introduced effective 4/1/24.



Magnetoencephalography and Magnetic Source Imaging

Type of Policy: Imaging/Radiology

Prior Approval Date: 06/06/2022

Approval Date: 06/03/2024

Effective Date: 08/01/2024

Related Polices: N/A

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

N/A

Codes Requiring Retrospective Review

N/A

Experimental/Investigational

N/A

Common Diagnosis Codes

95965, 95966, 95967, S8035Common Procedure Codes

N/A

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

Magnetoencephalography involves external monitoring of the weak magnetic fields associated with electrical activity within the brain; changes in this neuromagnetic field provide information about brain function. The functional data can be combined with structural data obtained by magnetic resonance imaging. This combined technique is known as magnetic source imaging.

Indications/Criteria

Magnetoencephalography (MEG) and magnetic source imaging (MSI) is considered medically necessary when all the following criteria are met:

- pre-surgical evaluation of individuals with intractable focal epilepsy to identify and localize area(s) of epileptiform activity when other neurological imaging studies (electroencephalography [EEG], PET or SPECT, MRI) designed to localize a focus area are indeterminate; and
- must be ordered by a neurosurgeon or neurologist.

Exclusions

Any indication not listed in the Indications/Criteria section.

Medicare

No National Coverage Determination (NCD) or Local Coverage Determination (LCD) noted.

References (Reviewed 2024)

- 1. Medical Advisory Secretariat. Functional brain imaging: an evidence-based analysis. Ontario Health Technology Assessment Series 2006; 6(22). Available: www.hqontario.ca/.
- 2. American Academy of Neurology. Magnetoencephalography (MEG) Model Policy. © 2016 American Academy of Neurology. Available: www.aan.com/.
- 3. Lau M, Yam D, Burneo JG. A systematic review on MEG and its use in the presurgical evaluation of localization-related epilepsy. Epilepsy Res. 2008 May;79(2-3):97-104. Epub 2008 Mar 19.
- 4. American College of Radiology. ACR Appropriateness Criteria®. Seizure and epilepsy. Date of origin 1996. Last review date: 2011. Available: http://www.acr.org/Quality-Safety/Appropriateness-Criteria.
- 5. Krumholz A, Wiebe S, Gronseth G, Shinnar S, Levisohn P, Ting T, et al. Quality Standards Subcommittee of the American Academy of Neurology; American Epilepsy Society. Practice Parameter: evaluating an apparent unprovoked first seizure in adults (an evidence-based review): report of the Quality Standards Subcommittee of the

- American Academy of Neurology and the American Epilepsy Society. Neurology. 2007 Nov 20;69(21):1996-2007.
- 6. Knowlton RC, Elgavish RA, Limdi N, Bartolucci A, Ojha B, Blount J, et al. Functional imaging: I. Relative predictive value of intracranial electroencephalography. Ann Neurol. 2008a Jul;64(1):25-34.
- 7. Knowlton RC, Elgavish RA, Bartolucci A, Ojha B, Limdi N, Blount J, et al. Functional imaging: II. Prediction of epilepsy surgery outcome. Ann Neurol. 2008b Jul;64(1):35-41.
- 8. Bagic A, Funke ME, Ebersole J; ACMEGS Position Statement Committee. American Clinical MEG Society (ACMEGS) position statement: The value of magnetoencephalography (MEG)/magnetic source imaging (MSI) in noninvasive presurgical evaluation of patients with medically intractable localization-related epilepsy. J Clin Neurophysiol. 2009;26(4):290-293.
- 9. Sutherling WW, Mamelak AN, Thyerlei D, et al. Influence of magnetic source imaging for planning intracranial EEG in epilepsy. Neurology. 2008 Sep 23; 71(13):990-6.
- 10. Centers for Medicare & Medicaid Services, Billing and Coding: Independent Diagnostic Testing Facilities (IDTF) A58559. January 1, 2022. Available: https://www.cms.gov.
- 11. Hayes Health Evidence Research Brief Review. Magnetoencephalography And Magnetic Source Imaging Of The Brain. HAYES, Inc.; © 2023 Hayes, a symplr company. October 8, 2012.

Customer Product	Medical Management Requirements*		
New York Products			
НМО	Potential for Retrospective Review		
PPO in Plan	Potential for Retrospective Review		
PPO OOP	Potential for Retrospective Review		
POS in Plan	Potential for Retrospective Review		
POS OOP	Potential for Retrospective Review		
Essential Plan	Potential for Retrospective Review		
MVP Medicaid Managed Care	Potential for Retrospective Review		
MVP Child Health Plus	Potential for Retrospective Review		
MVP Harmonious Health Care Plan	Potential for Retrospective Review		
MVP Medicare Complete Wellness	Potential for Retrospective Review		
MVP Medicare Preferred Gold HMO POS	Potential for Retrospective Review		
MVP Medicare Secure HMO POS	Potential for Retrospective Review		
MVP Medicare Secure Plus HMO POS	Potential for Retrospective Review		
MVP Medicare WellSelect PPO	Potential for Retrospective Review		
MVP Medicare WellSelect Plus PPO	Potential for Retrospective Review		
MVP Medicare Patriot Plan PPO	Potential for Retrospective Review		
MVP DualAccess D-SNP HMO	Potential for Retrospective Review		
MVP DualAccess Complete D-SNP HMO	Potential for Retrospective Review		
MVP DualAccess Plus D-SNP HMO	Potential for Retrospective Review		
UVM Health Advantage Select PPO	Potential for Retrospective Review		
USA Care	Potential for Retrospective Review		
Healthy NY	Potential for Retrospective Review		
MVP Premier	Potential for Retrospective Review		
MVP Premier Plus	Potential for Retrospective Review		
MVP Premier Plus HDHP	Potential for Retrospective Review		
MVP Secure	Potential for Retrospective Review		
MVP EPO	Potential for Retrospective Review		
MVP EPO HDHP	Potential for Retrospective Review		
MVP PPO	Potential for Retrospective Review		
MVP PPO HDHP	Potential for Retrospective Review		
Student Health Plans	Potential for Retrospective Review		
ASO	See SPD		
Vermont Products			
POS in Plan	Potential for Retrospective Review		
POS OOP	Potential for Retrospective Review		
MVP Medicare Preferred Gold HMO POS	Potential for Retrospective Review		
MVP Medicare Secure Plus HMO POS	Potential for Retrospective Review		
MVP VT HMO	Potential for Retrospective Review		
MVP VT HDHP HMO	Potential for Retrospective Review		
MVP VT Plus HMO	Potential for Retrospective Review		
MVP VT Plus HDHP HMO	Potential for Retrospective Review		
MVP Secure	Potential for Retrospective Review		
ASO	See SPD		

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Revision History:

08/01/2022 - Annual review; added neurologist to providers that can order MEG and MSI.

08/01/2024 – Annual review; removed CPT Codes 95965, 95966, 95967, S8035 from retrospective review.



Mechanical Stretching Devices

Type of Policy: DME

Prior Approval Date: 11/07/2022

Approval Date: 11/04/2024

Effective Date: 02/01/2025

Related Polices: Durable Medical Equipment

Temporomandibular Joint

Dysfunction Vermont

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

HCPCS Codes:

E1800 – Dynamic adjustable elbow extension and flexion device, includes soft interface material

E1802- Dynamic adjustable forearm pronation/supination device, includes soft interface material

E1803 – Dynamic adjustable elbow extension only device, includes soft interface material

E1804 - Dynamic adjustable elbow flexion only device, includes soft interface material

E1805- Dynamic adjustable wrist extension and flexion device, includes soft interface material

E1807 – Dynamic adjustable wrist extension only device, includes soft interface material

E1808 - Dynamic adjustable wrist flexion only device, includes soft interface material

E1810 -Dynamic adjustable knee extension and flexion device, includes soft interface material

E1812 - Dynamic knee, extension/flexion device with active resistance control

- E1813 Dynamic adjustable knee extension only device, includes soft interface material
- E1814 Dynamic adjustable knee flexion only device, includes soft interface material
- E1815 Dynamic adjustable ankle extension and flexion device, includes soft interface material
- E1816-Static progressive stretch ankle device, flexion and/or extension, with or without range of motion adjustment, includes all components and accessories
- E1822 Dynamic adjustable ankle extension only device, includes soft interface material
- E1823 Dynamic adjustable ankle flexion only device, includes soft interface material
- E1825-Dynamic adjustable finger extension and flexion device, includes soft interface material
- E1826 Dynamic adjustable finger extension only device, includes soft interface material
- E1827 Dynamic adjustable finger flexion only device, includes soft interface material
- E1828 Dynamic adjustable toe extension only device, includes soft interface material
- E1829 Dynamic adjustable toe flexion only device, includes soft interface material
- E1830-Dynamic adjustable toe extension and flexion device, includes soft interface material
- E1831-Static progressive stretch toe device, extension and/or flexion, with or without range of motion adjustment, includes all components and accessories
- E1832 Static progressive stretch finger device, extension and/or flexion, with or without range of motion adjustment, includes all components and accessories
- E1840-Dynamic adjustable shoulder flexion/abduction/rotation device, includes soft interface material
- E1841- Static progressive stretch shoulder device, with or without range of motion adjustment, includes all components and accessories

Codes Subject to Retrospective Review

HCPCS Codes:

- E1700-Jaw motion rehabilitation system
- E1701-Replacement cushions for jaw motion rehabilitation system, package of 6
- E1702-Replacement measuring scales for jaw motion rehabilitation system, package of 200
- L2861-Addition to lower extremity joint, knee or ankle, concentric adjustable torsion style mechanism for custom fabricated orthotics only, each

L3891 - Addition to upper extremity joint, wrist or elbow, concentric adjustable torsion style mechanism for custom fabricated orthotics only, each

Experimental/Investigational

HCPCS Codes:

E1815- Dynamic adjustable ankle extension/flexion device, includes soft interface material

E1816- Static progressive stretch ankle device, flexion and/or extension, with or without range of motion adjustment, includes all components and accessories

E1822 – Dynamic adjustable ankle extension only device, includes soft interface material

E1823 – Dynamic adjustable ankle flexion only device, includes soft interface material

E1828 – Dynamic adjustable toe extension only device, includes soft interface material

E1829 - Dynamic adjustable toe flexion only device, includes soft interface material

E1830- Dynamic adjustable toe extension/flexion device, includes soft interface material

E1831- Static progressive stretch toe device, extension and/or flexion, with or without range of motion adjustment, includes all components and accessories

E1840- Dynamic adjustable shoulder flexion/abduction/rotation device, includes soft interface material

E1841- Static progressive stretch shoulder device, with or without range of motion adjustment, includes all components and accessories

L2861- Addition to lower extremity joint, knee or ankle, concentric adjustable torsion style mechanism for custom fabricated orthotics only, each

L3891- Addition to upper extremity joint, wrist or elbow, concentric adjustable torsion style mechanism for custom fabricated orthotics only, each

Common Diagnosis Codes

N/A

Common Procedure Codes

E1801, E1806, E1811, E1818, E1821

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive.

Overview

A dynamic splint is a spring loaded, adjustable device designed to provide a low-load, prolonged stretch to joints while a patient is asleep or at rest. The goal of dynamic

splinting is to increase range of motion to a joint in individuals with limited range of motion due to fractures, dislocations, surgery, contractures, immobilization, or other non-traumatic conditions. Dynamic splints are available for extension or flexion of the elbow, wrist, fingers, knee, ankle, and toes. There are several types of dynamic splints which include static progressive stretch, low-load prolonged duration stretch, and patient-actuated serial stretch devices.

Static progressive stretch (SPS) devices (HCPCS codes E1801, E1806, E1811, E1816, E1818, E1821, E1831, E1841) hold the joint in a set position but allow for manual modification of the joint at any angle and may allow for active motion without resistance (inelastic traction). This device does not exert stress on the tissue unless the angle is set to the joint's limitation.

Low-load prolonged-duration (LLPS) stretch devices (HCPCS code E1800, E1812, E1805, E1810, E1812, E1815, E1820, E1825, E1830, E1840) permit resisted active and passive motion (elastic traction) within a limited range. The device maintains a set level of tension by means of incorporated springs.

Patient-actuated serial stretch (PASS) devices provide a low- to high-level load to the joint using pneumatic or hydraulic systems that can be adjusted by the patient.

Jaw stretch devices (HCPCS codes E1700, E1701, E1702) are devices that open the jaw to stretch the oral-facial tissues and mobilize the temporomandibular joint (TMJ). It is proposed to prevent and treat trismus and scarring or fibrosis from radiation therapy, surgery, and trauma.

Indications/Criteria

<u>Low-load Prolonged-duration Stretch Device (LLPS) and Static Progressive Stretch (SPS)</u>
<u>Device</u>

Low-load prolonged-duration stretch (LLPS) and static progressive stretch (SPS) devices for use in the management of contractures of the finger, wrist, elbow, or knee are covered when the following criteria are met:

- as part of a formal physical therapy/occupational therapy rehabilitation program for customers with either:
 - documented signs and symptoms of significant motion stiffness or loss that interferes with function or activities of daily living following immobilization of a joint due to injury or post-operative period (not more than four months after injury or surgery); or
 - 2. prior documented history of motion stiffness or loss in a joint and have had additional surgical procedures performed to improve motion to that joint and are in the acute post-operative period of up to 12 weeks following surgery;

 and documented signs and symptoms of significant motion stiffness or loss from a contracture that interferes with function or activities of daily living when a formal physical therapy/occupational therapy rehabilitation program has failed to improve range of motion.

Coverage is allowed for a two-month initial rental period with a four-month maximum rental period. Documentation of current range of motion is required for any additional rental beyond the initial two months. If range of motion has improved with use of the dynamic splinting device, but there is still additional range that is lacking, then two additional months of rental will be allowed.

Exclusions

- Any indication not listed in the Indications/Criteria section.
- Dynamic splints for contractures of the finger, wrist, elbow, or knee with no significant improvement in motion after a four-month period are considered experimental and investigational because there is not enough proof in medical information or research by specialists that describe the value or effectiveness for their use after this amount of time.
- Custom dynamic splints using concentric adjustable torsion style mechanisms for the lower extremities and upper extremities are experimental and investigational. Their use in reduction of chronic or acute contractures does have enough proof in medical information or research by specialists that describe their value or effectiveness over the use of the prefabricated dynamic splints (L2861, L3891).
- There is insufficient evidence in the peer-reviewed literature that patient-actuated serial stretch (PASS) devices results in proven beneficial outcomes and is, therefore, considered investigational. This includes, but may not be limited to:
 - o ERMI Elbow Extensionator
 - o ERMI Knee Extensionator
 - o ERMI Knee/Ankle Flexionator
 - o ERMI Shoulder Flexionator
- There is insufficient evidence in the peer-reviewed literature that low-load prolongedduration and static progressive stretch devices for the use in the management of contractures of the shoulder, ankle, or toe results in proven beneficial outcomes and is, therefore, considered investigational.
- There is insufficient evidence in the peer-reviewed literature that jaw stretch devices (E1700, E1701, E1702) result in proven beneficial outcomes and are, therefore, considered investigational.

Vermont Variation

Jaw stretch devices are covered for the treatment of temporomandibular joint disorders.

Medicare Variation:

Jaw stretch devices (E1700, E1701, E1702) are considered medically necessary and covered for the treatment of temporomandibular joint disorders for Medicare customers.

Medicare does not have a National Coverage Determination (NCD) for jaw motion rehabilitation system. Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) do not exist at this time.

References (Updated 2025)

- 1. American Academy of Physical Medicine and Rehabilitation (AAPM&R). Contractures. PM&R knowledge Now. Updated July 30, 2020. Available: https://now.aapmr.org/contractures/.
- 2. Atos Medical. The TheraBite® System. Available: https://www.craniorehab.com/therabite-jaw-motion-rehab-system.
- 3. Bonutti PM, Marulanda GA, McGrath MS, Mont MA, Zywiel MG. Static progressive stretch improves range of motion in arthrofibrosis following total knee arthroplasty. Knee Surg Sports Traumatol Arthrosc. 2010 Feb;18(2):194-9.
- 4. Bonutti, PM, McGrath, MS., Ulrich, SD., McKenzie, SA. Seyler, TM., Mont, MA. Static progressive stretch for the treatment of knee stiffness. Knee. 2008 August; 15(4):272-6.
- 5. Branch TP, Karsch RE, Mills TJ, Palmer MT. Mechanical therapy for loss of knee flexion. Am J Orthop. 2003;32(4):195-200.
- 6. Bressel E, McNair PJ. The effect of prolonged static and cyclic stretching on ankle joint stiffness, torque relaxation, and gait in people with stroke. *Phys Ther*. 2002;82(9):880-887.
- 7. Bruner A, Whittemann A, Jester A, Blumenthal K, Germann G. Dynamic splinting after extensor tendon repair in zones V to VII. J Hand Surg (Br). 2003;28B(3):224-7.
- 8. Cetin, A, Dancer, F, Keck, A, Cetin, M. Rehabilitation of flexor tendon injuries by use of a combined regimen of modified Kleinert and modified Duran techniques. American Journal of Physical Medicine and Rehabilitation. 2001 Oct; 80(10):721-8.
- 9. Chester, DL., Beale, S, Beverridge, L, Nancarrow, JD, Titley, OM, A prospective, controlled, randomized trial comparing early active extension with passive extension using a dynamic splint in the rehabilitation of repaired extensor tendons. The Journal of Hand Surgery: Journal of the British Society for Surgery of the Hand. 2002; 27N (3):283-8.

- 10. Cohen EG, Deschler DG, Walsh K, Hayden RE. Early use of a mechanical stretching device to improve mandibular mobility after composite resection: a pilot study. Arch Phys Med Rehabil. 2005 Jul;86(7):1416-9.
- 11. CranioRehab, Inc. OraStretch Press Jaw motion Rehab System. Available: http://www.craniorehab.com/Jaw-Motion-Rehab-System-Comparison_ep_38-1.html
- 12. Dempsey AL, Mills T, Karsch RM, Branch TP. Maximizing total end range time is safe and effective for the conservative treatment of frozen shoulder patients. Am J Phys Med Rehabil. 2011;90(9):738-745.
- 13. Doornberg, JN, Ring, D, Jupiter, JB, Static progressive splinting for posttraumatic elbow stiffness. Journal of Orthopedic Trauma. 2006 Jul; 20(6):400-4.
- 14. ERMI Inc. Getting Motion Without Surgery. 2013. Available: https://www.ermi-motion.com/
- 15. Farmer, SE, Woolam, PJ, Patrick, JH, Roberts, AP, Bromwich, W. Dynamic orthoses in the management of joint contracture. The Journal of Bone and Joint Surgery [Br]. 2005 Mar; 87(3):291-5.
- 16. Gaspar PD, Willis FB. Adhesive capsulitis and dynamic splinting: a controlled, cohort study. BMC Musculoskelet Disord. 2009;10:111.
- 17. Harvey, L, Herbert, R, Crosbie, J. Does stretching induce lasting increases in joint ROM? A systematic review. Physiotherapy Research International. 2002; 7(1):1-13.
- 18. Hayes Medical Technology Directory. Mechanical stretching devices for the treatment of joint contractures of the extremities. Copyright © 2020 Hayes, a TractManager Company. May 9, 2018. Annual Review: May 9, 2022. Available: www.hayesinc.com
- 19. Hewitt, B, Shakespeare, D. Flexion vs. extension: a comparison of post-operative total knee arthroplasty mobilization regimes. Knee. 2001 Dec; 8(4):305-9.
- 20. John MM, Kalish S, Perns SV, Willis FB. Dynamic splinting for postoperative hallux limitus: a randomized, controlled trial. JAm Podiatr Med Assoc. 2011;101(4):285-288.
- 21. John MM, Kalish S, Perns SV, Willis FB. Dynamic splinting for postoperative hallux limitus: A randomized, controlled trial. J Am Podiatr Med Assoc. 2011;101(4):285-288.
- 22. Katalinic OM, Harvey LA, Herbert RD, et al. Stretch for the treatment and prevention of contractures. Cochrane Database Syst Rev. 2010 Sep 8;(9):CD007455.
- 23. Katalinic OM, Harvey LA, Herbert RD, Moseley AM, Lannin NA, Schurr K. Stretch for the treatment and prevention of contractures. Cochrane Database Syst Rev. 2010 Sep 8;(9):CD007455.

- 24. Khandwala AR, Webb J, Harris SB, Foster AJ, Elliot D. A comparison of dynamic extension splinting and controlled active mobilization of complete divisions of extensor tendons in zones 5 and 6. *J Hand Surg Br.* 2000;25(2):140-146.
- 25. Khandwala, AR, Blair J, Harris, SB, Foster, AJ, Elliot, D. A comparison of dynamic extension splinting and controlled active mobilization of complete divisions of extensor tendons in zones 5 and 6. The Journal of Hand Surgery: Journal of the British Society for Surgery of the Hand. 2000 Apr; 25(2): 140-6.
- 26. Lai JM, Francisco GE, Willis FB. Dynamic splinting after treatment with botulinum toxin type-A: a randomized controlled pilot study. Adv Ther. 2009;26(2):241-248.
- 27. Legislative Council of the General Assembly for the State of Vermont (2007) §4089g. Craniofacial Disorders.
- 28. Lindenhovius AL, Doornberg JN, Brouwer KM, Jupiter JB, Mudgal CS, Ring D. A prospective randomized controlled trial of dynamic versus static progressive elbow splinting for posttraumatic elbow stiffness. J Bone Joint Surg Am. 2012 Apr 18;94(8):694-700.
- 29. Maloney GE, Mehta N, Forgione AG, Aawawi KH, AS-Badawi EA, Driscoll SE. Effect of a passive jaw motion device on pain and range of motion in TMJ patients not responding to flat plane intraoral appliances. Cranio. 2002 Jan;20(1): 55-66.
- 30. Maloney GE, Mehta N, Forgione AG, Zawawi KH, Al-Badawi EA, Driscoll SE. Effect of a passive jaw motion device on pain and range of motion in TMJ patients not responding to flat plane intraoral appliances. Cranio. 2002 Jan;20(1):55-66.
- 31. Postans N, Wright P, Bromwich W, et al. The combined effect of dynamic splinting and neuromuscular electrical stimulation in reducing wrist and elbow contractures in six children with cerebral palsy. Prosthet Orthot Int. 2010;34(1):10-19.
- 32. Rose KJ, Burns J, Wheeler DM, North KN. Interventions for increasing ankle range of motion in patients with neuromuscular disease. Cochrane Database Syst Rev. 2010;(2):CD006973.
- 33. Sharma NK, Loudon JK. Static progressive stretch brace as a treatment of pain and functional limitations associated with plantar fasciitis: a pilot study. *Foot Ankle Spec.* 2010;3(3):117-124.
- 34. Shulman DH et al. Treating trismus with dynamic splinting: a cohort, case series. Adv Ther. 2008;25(1): 9-16.
- 35. Steffan, TM, Mollinger, LA., Low-load, prolonged stretch in the treatment of knee flexion contractures in nursing home residents. Physical Therapy. 1995; 75:888-97.
- 36. Stubblefield MD et al. A preliminary report on the efficacy of a dynamic jaw opening device (dynasplint trismus system) as part of the multimodal treatment of trismus in patients with head and neck cancer. Arch Phys Med Rehabil. 2010;91(8): 1278-1282.

- 37. Treatment of Recalcitrant Plantar Fasciitis: The Ankle Dorsiflexion Dynasplint. Orthopedics.2002;25(11): 1273-5.
- 38. Zatarain LA, Smith DK, Deng J, Gilbert J, Dietrich MS, et al. A Randomized Feasibility Trial to Evaluate Use of the Jaw Dynasplint to Prevent Trismus in Patients With Head and Neck Cancer Receiving Primary or Adjuvant Radiation-Based Therapy. Integr Cancer Ther. 2018 Jun 1:1534735418784363.

Customer Product	Medical Management Requirements*	
New York Products		
HMO	Prior Auth	
PPO in Plan	Prior Auth	
PPO OOP	Prior Auth	
POS in Plan	Prior Auth	
POS OOP	Prior Auth	
Essential Plan	Prior Auth	
MVP Medicaid Managed Care	Prior Auth	
MVP Child Health Plus	Prior Auth	
MVP Harmonious Health Care Plan	Prior Auth	
MVP Medicare Complete Wellness	Prior Auth	
MVP Medicare Preferred Gold HMO POS	Prior Auth	
MVP Medicare Secure HMO POS	Prior Auth	
MVP Medicare Secure Plus HMO POS	Prior Auth	
MVP Medicare WellSelect PPO	Prior Auth	
MVP Medicare WellSelect Plus PPO	Prior Auth	
MVP Medicare Patriot Plan PPO	Prior Auth	
MVP DualAccess D-SNP HMO	Prior Auth	
MVP DualAccess Complete D-SNP HMO	Prior Auth	
MVP DualAccess Plus D-SNP HMO	Prior Auth	
UVM Health Advantage Select PPO	Prior Auth	
USA Care PPO	Potential for Retrospective Review	
Healthy NY	Prior Auth	
MVP Premier	Prior Auth	
MVP Premier Plus	Prior Auth	
MVP Premier Plus HDHP	Prior Auth	
MVP Secure	Prior Auth	
MVP EPO	Prior Auth	
MVP EPO HDHP	Prior Auth	
MVP PPO	Prior Auth	
MVP PPO HDHP	Prior Auth	
Student Health Plans	Prior Auth	
ASO	See SPD	
Vermont Products		
POS in Plan	Prior Auth	
POS OOP	Prior Auth	
MVP Medicare Preferred Gold HMO POS	Prior Auth	
MVP Medicare Secure Plus HMO POS	Prior Auth	
MVP VT HMO	Prior Auth	
MVP VT HDHP HMO	Prior Auth	
MVP VT Plus HMO	Prior Auth	
MVP VT Plus HDHP HMO	Prior Auth	
MVP Secure	Prior Auth	
ASO	See SPD	

[♦] Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Revision History

02/01/2023 – Annual Review; prior authorization removed from E1801, E1806, E1811, E1818.

01/01/2025 – Added prior authorization to E1803, E1804, E1807, E1808, E1813, E1814, E1822, E1823, E1826, E1827, E1828, E1829.

02/01/2025 – Annual Review, references updated, no changes to indications or criteria.



Medical Policy Development, Implementation and Review Process

Type of Policy: N/A

Prior Approval Date: 01/03/2022

Approval Date: 02/05/2024

Effective Date: 04/01/2024

Related Polices: Pharmacy Programs

Administration

Evaluation of New Technology, Procedures, Behavioral Health

Services, and Programs

Objective

The purpose of medical policies is to provide criteria for determining coverage for new and existing technologies including medical/surgical procedures, drugs, behavioral health procedures, and medical devices.

The process for evaluating pharmaceuticals can be found in the Pharmacy Programs Administration Policy.

Policy

Medical policies are based on the most recent evidence-based literature and research available. The indications/criteria and the exclusions/limitations listed within each medical policy should not be considered all inclusive. Medical Directors review indications for any service on an individual basis for medical necessity taking into consideration the individual circumstances of the customer and the capabilities of the local delivery system.

The MVP Medical Affairs Department is responsible for research and assessment of new and existing medical technologies, drugs, devices, and behavioral health treatments. The Medical Affairs Department develops and modifies policies with consideration of input from network providers. All medical policies are approved through the organization's Quality Improvement structure.

If there are any conflicts between medical policy guidelines and applicable contract language, the contract language takes precedence. Medical policy is not intended to override the health insurance contract that defines the insured's benefits, nor is it intended to dictate to providers how to practice medicine.

Procedure

Standard Review of New Medical Policies

1. Requests for the development of a new medical policy or evaluation of technology may come from internal or external sources.

Internal sources include:

- Sales/Marketing based upon product development;
- Customer Care Center based on benefit questions from customers;
- Case/Disease Management staff based on customer issues during care management;
- Utilization Management based on recurring authorization issues;
- Behavioral Health based on new standards of care;
- Provider Services, Provider Network, and Utilization Management based on practitioner trends;
- Medical Policy Task Force based on ongoing review of the medical literature; and
- Pharmacy Management based on new technology or standards of care related to medication therapies.

External sources include:

- contracted at-risk entities and hospital delivery systems;
- CTAAB (Community Technology Assessment Advisory Board);
- plan providers;
- regional IPAs;
- physician hospital organizations;
- eviCore©; and
- physician organizations

Internal and external requests for policy development or technology assessment are referred to the Chairman of the Medical Policy Task Force. (See the Evaluation of New Technology, Procedures, Behavioral Health Services and Programs Policy in the Benefits Interpretation Manual.

- 2. An extensive review of the medical literature is completed. Information is obtained from various sources. Examples include:
 - Contracted research company (Hayes Inc.);
 - Centers for Medicare and Medicaid Services (CMS) Policy and Coverage Analysis, National Coverage Determinations (NCD) and Local Coverage Determinations (LCD);
 - Peer-reviewed publications;
 - Internet Websites (i.e., Physician On-line, UpToDate, MEDLINE, AIDSLINE, CANCERLINK);
 - National Institute of Health (NIH), Centers for Disease Control (CDC), and Food and Drug Administration (FDA);
 - Evidence-based clinical practice guidelines developed by national organizations and other recognized authorities such as the American Medical Association, American College of Physicians, the American College of Obstetricians and Gynecologists, American Psychiatric Association (APA) and American Academy of Child and Adolescent Psychiatry.
 - 3. Specialty and panel physician opinion is sought. Providers are consulted virtually, electronically, and through written communication.
 - 4. A policy is drafted and reviewed by the Medical Policy Task Force. The draft policy is sent for internal and external review. This review typically is done over a 14-day period. External opinions are sought from at-risk entities, panel physicians. Internal opinions are sought from a variety of areas including opinions from the Regional and IPA/Provider Organization Medical Directors, Quality, Pharmacy, Utilization Management, Operations, the Legal Department and Professional Relations.
 - 5. Comments provided during the External and Internal Review are considered by the Medical Policy Task Force and incorporated into the policy as deemed appropriate.
 - 6. The updated policy is presented to the Medical Management Committee for review and recommendation.
 - 7. Policies recommended by the Medical Management Committee are presented to the Quality Improvement Committee for review and approval at the next Quality Improvement Committee meeting.
 - 8. New and revised policies are communicated to practitioners by Provider Bulletin/Newsletter or FastFax memo after approval by the Quality Improvement Committee. Upon request, copies of a benefit interpretation used to make a determination are forwarded to the requesting provider.

Standard Review of Existing Medical Policies

All existing medical policies are reviewed at least annually by a Medical Director, undergo 14-day review and are presented to the Medical Management Committee and the Quality Improvement Committee. Input from MVP internal departments, panel providers including experts in selected specialties, and the Medical Policy Task Force is sought to determine which policies require a full comprehensive review. A comprehensive review will be done on each policy at least once every two years but may occur any time when new evidence is available in the medical literature.

- 1. The policies identified for comprehensive review follow the same review process documented for new medical policies (14-day review and MMC and QIC committee process) when there has been a significant change in medical evidence or change in criteria. The policies that are reviewed during the comprehensive process and are not changed by medical evidence or do not have a significant change in criteria, content or wording, may be endorsed by two senior level Medical Directors.
- 2. Policies recommended by the Medical Management Committee are communicated to the Quality Improvement Committee at the next Quality Improvement Committee meeting.
- 3. Policy approval is communicated throughout the organization and appropriate medical management activities are implemented. Appropriate notice is given to plan providers.
- 4. New or revised clinical review criteria for any gender-affirming treatments, must be submitted to New York State Office of Mental Health no later than 60 days prior to the date of implementation. New or revised review criteria for any gender-affirming treatments in any MVP medical policies may not be implemented without prior approval from New York State Office of Mental Health.

Fast Track Review of New and Existing Medical Policies

An expedited review of a new medical policy or revisions to an existing policy is necessary for the following:

- when the standard review time would be detrimental to MVP customers;
- clarification of an existing policy interpretation;
- coverage of a technology that is not available in a medical policy or in the customer contract; or
- Government mandates.

Policies appropriate for Fast Track Review may come from internal or external sources including:

- Customer Services or Customer Appeals;
- Legal;

- Medical Directors;
- Utilization Management;
- ongoing review of the medical literature;
- Pharmacy Management; or
- Network Providers.

Process for Fast Track

- 1. Two MVP Healthcare Medical Directors will review the medical policy, and the clinical information prepared by staff. Appropriate provider review will be obtained.
- 2. The proposed benefit interpretation will be sent to all Medical Directors via email for immediate review with an expected date of reply not to exceed 10 business days.
- 3. After Medical Director Review, revisions will be incorporated in the medical policy as appropriate.
- 4. The medical policy will be implemented with provisional approval.

The policy will then follow the standard comprehensive review process and will be presented to the Medical Management Committee for recommendation and the Quality Improvement Committee for full approval.

Revision History:

04/01/2022 - updated medical literature references that are reviewed, removed references to senior medical director.

04/01/2024 – Annual review; added contract references to overview, removed external sources that no longer exist, updated external review sources.



Mental Health Services – Behavioral Health Inpatient Mental Health Residential Treatment Center Crisis Residence Programs

Type of Policy: Behavioral Health

Prior Approval Date: 02/05/2024

Provisional Approval 03/21/2025

Date:

Provisional Effective

Date:

04/01/2025

Related Polices: InterQual Criteria Behavioral Health

Policies

Substance Use Disorder Treatment

Codes Requiring Notification / Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

Service	Revenue / CPT / HCPCs Code(s)
Inpatient Mental Health	0114, 0124, 0134, 0154, 0204
Residential Treatment Center	1001, H0017, H0018, H0019

Codes Requiring Retrospective Review

N/A

Experimental/Investigational

N/A

Common Diagnosis Codes

N/A

Common Procedure Codes

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N/A

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

"Mental illness," also referred to as a mental disorder or a psychiatric disorder, is defined as a syndrome characterized by clinically significant disturbance in cognition, emotion regulation, or behavior that is usually associated with significant distress or disability in social, occupational, or other important activities. A diagnosis of mental illness is made by a mental health professional using the most recent edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM.

MVP Health Care uses Change Healthcare's InterQual® criteria for Inpatient Mental Health, Mental Health Residential Treatment Center, and Crisis Residence Program treatment determinations. Use of the Adult and Geriatric Psychiatry criteria is intended for patients age 18 or older presenting with a predominant symptom of a psychiatric disorder. The Child and Adolescent Psychiatry criteria are used for patients who are ages 4 through 17 and presenting with a predominant symptom of a psychiatric disorder, unless otherwise specified within a specific level of care.

Indications/Criteria

MVP provides coverage for inpatient and residential treatment and/or services for mental health care in the following settings:

- A psychiatric center or inpatient facility under the jurisdiction of the New York
 State Office of Mental Health;
- A state or local government run psychiatric inpatient facility;
- A part of a Hospital providing inpatient mental health care under an operating certificate issued by the New York State Commissioner of Mental Health;
- A comprehensive psychiatric emergency program;
- A Facility providing inpatient mental health care that has been issued an operating certificate by the New York State Commissioner of Mental Health;
- Residential treatment facilities defined in New York Mental Hygiene Law Section 1.03
- Residential treatment facilities that are a part of a comprehensive care center for eating disorders identified pursuant to New York Mental Hygiene Law Article 30; and, in other states, to similarly licensed or certified Facilities. In the absence of a similarly licensed or certified Facility, the Facility must be accredited by the Joint

Mental Health Services Page 2 of 11

Commission on Accreditation of Health Care Organizations, or a national accreditation organization recognized by MVP.

Inpatient and residential treatment is subject to medical necessity. This policy lists mental health treatment and services reviewed utilizing Change Healthcare InterQual® criteria.

Inpatient Mental Health

The Inpatient criteria are used for a customer who has been admitted or is expected to be admitted to an inpatient unit. Inpatient refers to acute psychiatric treatment in an acute care or psychiatric hospital inpatient unit or a state psychiatric hospital. Inpatient treatment is provided 24 hours a day, 7 days a week by or under the direction of a psychiatrist, a psychiatric nurse practitioner, or a psychologist when legally authorized by the state. Inpatient is recommended for patients who are an acute danger to themselves or others or who are unable to provide required self—care and lack available support. Inpatient Mental Health is reviewed using the following subsets of criteria:

- InterQual® BH: Child and Adolescent Psychiatry, Level of Care Inpatient
- InterQual® BH: Adult and Geriatric Psychiatry, Level of Care Inpatient

Residential Treatment Center

The Residential Treatment Center criteria are used for a customer presenting with severe and persistent mental illness, an eating disorder, autism spectrum disorder or intellectual disability, who has been admitted or is expected to be admitted to a psychiatric residential treatment center. A psychiatric residential treatment center refers to a licensed residential facility that is nonhospital–based and provides voluntary, non–acute short–term 24–hour individualized interdisciplinary treatment to a group of individuals. The treatment and supervision is provided by paid staff unrelated to the individual. Residential Treatment Center is reviewed using the following subsects of criteria:

- InterQual® BH: Child and Adolescent, Level of Care Residential Treatment Center
- InterQual® BH: Adult and Geriatric, Level of Care Residential Treatment Center

In addition to considering InterQual criteria as a guideline for determining if inpatient or residential level of care is medically necessary, the following apply:

- For diagnoses that frequently can be evaluated and treated as outpatient or at an alternative level of care, the medical record must support that an alternative level of care is inappropriate.
- If appropriate care can be provided in a less intense level of care setting that is available, then a higher level of care is considered not medically necessary.

Exclusions

• Inpatient provider visits are not covered if the admission is not approved.

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- Inpatient admissions of which discharge also occurs on the same day.
- Inpatient admissions to facilities operated by the federal, state, or other governmental agencies.
- Inpatient and or Residential treatment provided in a setting not listed in Indications/Criteria above.
- Inpatient and/or Residential treatment or services that are determined to be not medically necessary

New York (excluding ASO and Medicare) Variation

As approved by the NY Office of Mental Health (OMH), MVP utilizes a supplemental risk assessment, together with InterQual, when establishing medical necessity for mental health Inpatient or Residential Treatment Center services. This risk assessment takes into consideration several factors impacting an individual's environmental stress and support in the recovery environment, treatment and recovery history, and acceptance and engagement in treatment (to include caregivers for children/adolescents). Each risk factor is assigned a point value, based on a low, moderate, or high-risk tiering. Low risk factors are considered protective factors, therefore do not indicate an increased risk, and are assigned a point value of zero (0). Moderate to high risk factors that are present must be included as a core component of the current treatment plan. To meet criteria for Residential Treatment Center, there must be an overall risk score of three (3) points. To meet criteria for Inpatient, there must be an overall risk score of four (4) points or greater.

Adult Risk Assessment

	Factors		
Domain	Low Risk	Moderate Risk	High Risk
	0 pts	1 pt each	2 pts each
Level of stress and support in the recovery environment	Support systems are local and accessible/adequate to meet customer's holistic needs	Unsuccessful attempts to live independently, with family or significant other	Lives in a high-risk environment, such as abusive, unsanitary, or illegal situations
	Recent change in job or living environment	No transportation available	Homeless or imminent risk of homelessness

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	T	Т	
	No support needed or resources are readily available and utilized	Support system available but not local	High risk drug use exposure in current living situation
	Transportation available		Recent diagnosis of a life-threatening condition in self or family customer
	Support system able to provide required care and supervision during non-program hours		Recent death of significant other
			Jailed or incarcerated and lacks residence post discharge
			Support system unavailable
			Unable to ensure safety or high-risk environment
Treatment and recovery history	Prior recent successful treatment(s) in managing symptoms with good adherence over a significant period of time	No prior treatment – first episode of illness	Unable to maintain and/or manage medication(s) or symptoms
		Prior recent successful treatment(s) in managing symptoms with good adherence but only for limited periods of time	Unable to manage symptoms and/or medication(s) outside of a controlled environment
			Symptoms are not controlled despite optimal medication management

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Engagement and recovery	The customer understands and	The customer waxes	The customer is
status	accepts his/her illness and/or any current functional impairments	and wanes in participation of recovery program	unable to follow instruction or negotiate needs
	The customer participates fully in treatment and recommendations	The customer lacks knowledge of coping skills	The customer is unwilling or refuses to accept responsibility in recovery process

Children/Adolescent Risk Assessment

Domain	Factors			
Domain	Low Risk	Moderate Risk	High Risk	
Level of stress	Support systems	Unsuccessful	Lives in a high-risk	
and support in	are local and	attempts to live	environment, such as	
the recovery	accessible/adequate	independently or	abusive, unsanitary,	
environment	to meet parent and child's holistic needs	with family or with foster care	or illegal situations	
	Stable housing available	Primary support not feeling safe with the child in the home	Homeless or imminent risk of homelessness	
	Recent change in living environment (moved, changed schools)	Interactions by primary support escalating child's behavior	High risk drug use exposure in current living situation	
	No support needed or resources are readily available and utilized and home environment is safe	Support from caregiver(s) inconsistently available	Recent diagnosis of a life-threatening condition in self or family customer	
	Support system able to provide required care and supervision during non-program or treatment hours		Recent death of parent, sibling, or significant other	

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- International Care International			<u>, </u>
			Suspected abuse within the home environment
			Support unavailable or unable to manage intensity of symptoms
			Intentional sabotage of treatment by support person
Treatment and recovery history	Prior recent successful treatment(s) in managing symptoms with good adherence over a significant period of time	No prior treatment – first episode of illness	Poor impulse control with harm to self or others and unresponsive to adult intervention
		Prior recent successful treatment(s) in managing symptoms with good adherence but only for limited periods of time	Unable to manage symptoms and/or medications outside of a controlled environment
			Symptoms unresponsive despite optimal treatment and management
Acceptance and engagement in child/adolescent AND caregivers	The customer and caregiver(s) understand and accept illness and/or any current functional limitations	Customer and/or caregiver waxes and wanes in participation of recovery program	Unsuccessful in implementing interventions to support improved school functioning and performance
	Participates fully in treatment plan and recommendations	Customer and/or caregiver lacks knowledge of coping skills	Imminent risk of school failure

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outbursts)

MVP Medicaid Managed Care (MMC) and CHP Variation

MVP provides coverage for <u>Crisis Residence Programs</u> licensed pursuant to the Office of Mental Health Part 598 regulations:

- Children's Crisis Residences (Under age 21)
- Residential Crisis Support (Ages 18+)

MVP Health Care Medical Policy

• Intensive Crisis Residence (Ages 18+)

Crisis Residence Programs provide voluntary, short term residential crisis support services to individuals experiencing a mental health crisis or challenges in daily life that create a risk for escalation of symptoms that cannot be managed in the individual's home and community without onsite supports. Crisis Residence Programs are reviewed using the following subsets of criteria:

- For individuals up to age 21, InterQual® BH: Child and Adolescent Psychiatry, Residential Crisis Program.
- For individuals age 21+, InterQual® BH: Adult and Geriatric Psychiatry, Residential Crisis Program

Medicare and Dual Access D-SNP Variation

Inpatient Hospitals or Facilities providing mental health treatment and/or services must be enrolled in Federal Medicare.

Residential Treatment Centers and Crisis Residence Programs are not covered by Medicare Managed Care.

For customers enrolled in an MVP Dual Access D-SNP Plan, Crisis Residence Programs are covered under their Medicaid Plan. For those enrolled in an MVP Medicaid Managed Care Plan, Crisis Residence is covered per the MMC Variation above.

Note: InterQual® Criteria is consistent with Centers for Medicare and Medicaid Services (CMS) NY and VT Local Coverage Determination (LCD) L33624 for Psychiatric Inpatient Hospitalization.

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For providers directly contracted with MVP, the complete Change Healthcare InterQual® criteria can be found in the provider self-service application under resources. For all other providers and customers, a copy of the criteria can be requested by contacting MVP customer care at 1-800-568-0458.

References (Reviewed 2024)

- 1. InterQual[®] Clinical Decision Support Criteria. Change Healthcare, LLC, Copyright © 2023 Change Healthcare Corporation.
- 2. New York State Office of Mental Health Division of Managed Care Medicaid Managed Care Crisis Intervention, Residential Crisis Services.
- 3. New York State Office of Mental Health Crisis Residence Program Guidance June 2, 2021. Available: https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&cad=rja&uact=8&ved=2ahUKEwiOmtaFm4f1AhVDTd8KHcLLDa8QFnoECAkQAQ&url=https%3A%2F%2Fomh.ny.gov%2Fomhweb%2Fbho%2Fdocs%2Fcrisis-residence-program-quidance.pdf&usq=AOvVaw2nlBFVHmnwuoDyPt8x-r_6
- 4. American Psychiatric Association (March 2022). Diagnostic and statistical manual of mental disorders: DSM-5. Washington, DC: American Psychiatric Association.
- 5. New York State Office of Mental Health, Guiding Principles for the Review and Approval of Clinical Review Criteria for Mental Health Services, November 25, 2019; Revised June 15, 2022. Available: https://omh.ny.gov/omhweb/bho/omh_mnc_guiding_principles.pdf

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	Medical Management Requirements*			
Customer Product	Inpatient	Residential Treatment Center	Crisis Residence Programs	
New York Products		Center		
HMO	Notification Required	Notification Required	Not Covered	
PPO in Plan	Notification Required	Notification Required	Not Covered	
PPO OOP	Notification Required	Notification Required	Not Covered	
POS in Plan	Notification Required	Notification Required	Not Covered	
POS OOP	Notification Required	Notification Required	Not Covered	
Essential Plan	Notification Required	Notification Required	Not Covered	
MVP Medicaid Managed Care (incl. IBP)	Notification Required	Not Covered	Potential for Retro Review	
MVP Child Health Plus	Notification Required	Notification Required	Potential for Retro Review	
MVP Harmonious Health Care Plan (incl. IBP)	Notification Required	Not Covered	Potential for Retro Review	
MVP Medicare Complete Wellness	Notification Required	Not Covered	Not Covered	
MVP Medicare Preferred Gold HMO POS	Notification Required	Not Covered	Not Covered	
MVP Medicare Secure HMO POS	Notification Required	Not Covered	Not Covered	
MVP Medicare Secure Plus HMO POS	Notification Required	Not Covered	Not Covered	
MVP Medicare WellSelect PPO	Notification Required	Not Covered	Not Covered	
MVP Medicare WellSelect plus PPO	Notification Required	Not Covered	Not Covered	
MVP Medicare Patriot Plan PPO	Notification Required	Not Covered	Not Covered	
MVP DualAccess D-SNP HMO	Notification Required	Not Covered	Not Covered	
MVP DualAccess Complete D-SNP HMO	Notification Required	Not Covered	Not Covered	
MVP DualAccess Plus D-SNP HMO	Notification Required	Not Covered	Not Covered	
UVM Health Advantage Select PPO	Notification Required	Not Covered	Not Covered	
USA Care	Notification Required	Not Covered	Not Covered	
Healthy NY	Notification Required	Notification Required	Not Covered	
MVP Premier	Notification Required	Notification Required	Not Covered	
MVP Premier Plus	Notification Required	Notification Required	Not Covered	
MVP Premier Plus HDHP	Notification Required	Notification Required	Not Covered	
MVP Premier	Notification Required	Notification Required	Not Covered	
MVP Premier Plus	Notification Required	Notification Required	Not Covered	
MVP Premier Plus HDHP	Notification Required	Notification Required	Not Covered	
MVP Secure	Notification Required	Notification Required	Not Covered	
MVP EPO	Notification Required	Notification Required	Not Covered	
MVP EPO HDHP	Notification Required	Notification Required	Not Covered	
MVP PPO	Notification Required	Notification Required	Not Covered	
MVP PPO HDHP	Notification Required	Notification Required	Not Covered	
Student Health Plans	Notification Required	Notification Required	Not Covered	
ASO	See SPD	See SPD	See SPD	
Vermont Products				
POS in Plan	Notification Required	Notification Required	Not Covered	
POS OOP	Notification Required	Notification Required	Not Covered	

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MVP Medicare Preferred Gold HMO POS	Notification Required	Not Covered	Not Covered
MVP Medicare Secure Plus HMO POS	Notification Required	Not Covered	Not Covered
MVP VT HMO	Notification Required	Notification Required	Not Covered
MVP VT HDHP HMO	Notification Required	Notification Required	Not Covered
MVP VT Plus HMO	Notification Required	Notification Required	Not Covered
MVP VT Plus HDHP HMO	Notification Required	Notification Required	Not Covered
MVP Secure	Notification Required	Notification Required	Not Covered
ASO	See SPD	See SPD	See SPD

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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MVP adheres to the most recent version of NYS guidance as it pertains to inpatient admissions at in-network OMH licensed hospitals or facilities for the treatment of a mental health condition of an individual under the age of 18.

*Medical Management Requirements

Notification Required Notification Required, may be subject to Concurrent Review

Prior Auth Prior Authorization Required

Potential for Retro Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Revision History:

04/01/2022 – Annual Review; removed procedure codes that do not require prior authorization. Overview and Indications and Criteria section rewritten to indicate reviews based on Change Health InterQual®. Added covered settings to the Indications/Criteria. Updated the Medicaid Managed Care variation with indications/criteria for Crisis Residence Programs and the use of InterQual® criteria. Added prior authorization to H0019 and T2034.

04/01/2024 – Annual Review. Added supplemental risk assessment for mental health Inpatient or Residential Treatment Center services. References checked and updated.

2/28/2025 - Removed notification from Crisis Residence Programs; potential for retro review starting 3/1/2025.

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Minimally Invasive Anti-Reflux Procedures and Peroral Endoscopic Myotomy (POEM) Procedures

Type of Policy: Surgical/Medical

 Prior Approval Date:
 02/05/2024

 Approval Date:
 05/06/2024

 Effective Date:
 08/01/2024

Related Polices:

Investigational Procedures, Devices, Medical Treatments and Tests

Experimental or Investigational Procedures,

Behavioral Health Services, Drugs and Treatments,

Off-Label use of FDA Approved Drugs, and Clinical Trials

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

43497	Lower esophageal myotomy, transoral (ie, peroral endoscopic myotomy [POEM])
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Codes Requiring Experimental/Investigational Retrospective Review:

	Description
	Esophagogastroduodenoscopy, flexible, transoral; with
43210	esophagogastric fundoplasty, partial or complete, includes
	duodenoscopy when performed
	Esophagogastroduodenoscopy, flexible, transoral; with delivery of
43257	thermal energy to the muscle of lower esophageal sphincter and/or
	gastric cardia, for treatment of gastroesophageal reflux disease
	Laparoscopy, surgical, esophageal sphincter augmentation procedure,
43284	placement of sphincter augmentation device (ie, magnetic band),
	including cruroplasty when performed
43285	Removal of esophageal sphincter augmentation device

43289	Unlisted laparoscopy procedure, esophagus
43499	Unlisted procedure, esophagus
43659	Unlisted laparoscopy procedure, stomach

Common Diagnosis Codes

K21.0; K21.9

Common Diagnosis Codes associated with this policy have been provided for informational purposes only. The list of codes may not be all-inclusive and may be updated to reflect any applicable revisions to the ICD-10 code set and/or medical necessity quidelines applied in this policy.

Common Procedure Codes

CPT Codes: 43180

HCPCS Codes: none

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

Gastroesophageal reflux (GERD) is defined as symptoms (e.g., heartburn, regurgitation, pain, and dysphagia) and/or tissue damage that results from the abnormal reflux of gastric contents into the esophagus. Initial treatment of GERD is geared toward reducing esophageal refluxes by using medical therapies (dietary and lifestyle modifications, medications). Surgery may also be considered. There are now minimally invasive surgical techniques that are transendoscopic. Endoscopic therapies can be classified into three categories: thermal methods, endoscopic suturing/stapling, and injection of implants made up of inert biocompatible material.

Thermal procedures (Stretta®) often utilize an endoscope and radiofrequency ablation to create thermal lesions at the gastroesophageal junction.

Endoscopic gastroplasty or gastroplication (EndoCinch ™ Suturing Device, the Sew-Right Device, the Syntheon ARD Plicator ™, and the NDO Plicator ™ System) involves the suturing of the lower esophageal sphincter, to strengthen and lengthen the sphincter.

The insertion of inert, biocompatible material can be injected at or above the cardia or below into the lower esophageal folds. Types of material injected are polymethylmethacrylate (PMMA), Plexiglas microspheres, hydrogel prosthesis (Gatekeeper System), polymer (Enteryx ®), and pyrolytic carbon coated beads (Duraphere).

Endoluminal fundoplication (ELF, EsophyX ™), also known as transesophageal (or transoral) incisionless fundoplication (TIF), is designed to restore the anti- reflux barrier by recreating the valve at the GE Junction.

Achalasia is a rare motility disorder that effects the esophagus; there is degeneration of the muscle and nerves in the esophagus. Achalasia is defined by the reduction or absence of primary peristaltic waves in the distal two thirds of the esophagus, incomplete or no relaxation of the lower esophageal sphincter (LES) during swallowing and increased resting LES tone. The cause of primary or idiopathic achalasia is unknown, secondary achalasia is due to diseases that affect the esophageal motor control. Symptoms of achalasia include dysphagia, heartburn, difficulty belching, chest pain, regurgitation of undigested food and liquid, and weight loss.

Three types of achalasia based on the Chicago Classification:

- Type I (classic achalasia) Incomplete LES relaxation, aperistalsis and absence of esophageal pressurization. Swallowing results in no significant change in esophageal pressurization and has 100% failed peristalsis with a distal contractile integral (DCI, an index of the strength of distal esophageal contraction) < 100 mmHg.
- Type II Incomplete LES relaxation, aperistalsis and panesophageal pressurization in at least 20% of swallows. Swallowing results in simultaneous pressurization that spans the entire length of the esophagus. Type II achalasia has 100% failed peristalsis and pan-esophageal pressurization with ≥ 20 percent of swallows.
- Type III (spastic achalasia) Incomplete LES relaxation and premature contractions (distal latency [DL] < 4.5 seconds) in at least 20% of swallows. Swallowing results in abnormal, lumen-obliterating contractions or spasms. Type III achalasia has no normal peristalsis and premature (spastic contractions with DCI >450 mmHg-sec-cm with ≥ 20 percent of swallows.

Peroral endoscopic myotomy (POEM) procedures are proposed as a minimally invasive intervention to treat achalasia. It is the equivalent of Heller myotomy. The POEM involves an endoscope through the esophagus, incision into the mucosa, and cutting the muscle fibers in the lower esophagus and proximal stomach.

Eckardt score evaluates the symptoms of achalasia takes into consideration weight loss; dysphagia, retrosternal pain and regurgitation with meals.

Indications/Criteria

Peroral endoscopic myotomy (POEM – CPT code: 43497) is covered for:

- age > 18 years; and
- Eckardt symptom score greater than 3; and

- Documentation of failed medical management;
- And one of the following using esophageal monometry:
 - o diagnosis of achalasia type III; or
 - type I or II achalasia with documentation of failed Pneumatic Dilation
 (PD)

Exclusions

Endoluminal fundoplication (e.g., ELF, EsophyX ™) and transoral incisionless fundoplication (TIF): Based upon review and assessment of peer-reviewed literature, Endoluminal fundoplication (e.g., ELF, EsophyX ™) and transoral incisionless fundoplication (TIF), as treatments of GERD have not been medically proven to be effective and, therefore, are considered experimental and investigational.

Endoscopic gastroplasty/gastroplication (e.g., EndoCinch, Sew- Right, Plicator System, Syntheon ARD Plicator): Based upon review and assessment of peer-reviewed literature, Endoscopic gastroplasty/gastroplication, as a treatment of GERD has not been medically proven to be effective and, therefore, is considered experimental and investigational.

Injection/implantation of biocompatible material (e.g., endoscopic submucosal implantation of Plexiglas beads, Durasphere®, Enteryx or use of the Gatekeeper System) as a treatment of GERD: Based upon review and assessment of peer-reviewed literature, injection/implantation of biocompatible material have not been medically proven to be effective and, therefore, are considered experimental and investigational.

LINX® Reflux Management System (Torax Medical, Shoreview, MN): Based upon review and assessment of peer-reviewed literature, use of a magnetic esophageal ring (e.g., LINXTM Reflux Management System) in the treatment of gastroesophageal reflux disease (GERD) has not proven to be medically effective and is therefore considered experimental and investigational.

Medigus Ultrasonic Surgical Endostapler (**MUSE**) endostapling: Based upon review and assessment of peer-reviewed literature, use of a Medigus Ultrasonic Surgical Endostapler (MUSE) endostapling in the treatment of gastroesophageal reflux disease (GERD) has not proven to be medically effective and is therefore considered experimental and investigational.

Stretta® (**Restech**): Based upon review and assessment of peer-reviewed literature, use of a Stretta in the treatment of gastroesophageal reflux disease (GERD) has not proven to be medically effective and is therefore considered experimental and investigational.

Peroral endoscopic myotomy (POEM) for ANY indication other than achalasia is considered experimental, and investigational.

Each of the following peroral endoscopic myotomy (POEM) procedures is considered experimental, and investigational:

- Diverticular peroral endoscopic myotomy (D-POEM)
- Gastric peroral endoscopic myotomy (G-POEM)
- Zenker peroral endoscopic myotomy (Z-POEM)

Medicare Variation

Transoral incisional fundoplication surgery (TIF-EsophyX [™] - 43210) is covered with ICD-10 diagnosis codes:

- -Gastro-esophageal reflux (GERD) disease with esophagitis, without bleeding (K21.00); or
- -Gastro-esophageal reflux disease without esophagitis (K21.9).

Not Covered for:

- A. any patient who has recurrent symptoms or other evidence of failure following a prior TIF. These procedures (repeat TIF) would be considered investigational at this time.
- B. any patient with a hiatal hernia greater than 2 cm, except where the hernia has been reduced to 2 cm or less by a successful laparoscopic hernia reduction procedure prior to the TIF procedure. (Based on FDA approval).
- C. any GERD patients with BMI > 35, esophagitis LA grade > B, Barrett's esophagus > 2 cm, and presence of achalasia or esophageal ulcer or has not been on an appropriate trial of proton pump inhibitors.

References (Reviewed 2024)

- American Society of General Surgeons. Position statement: Transoral fundoplication. 2016. Accessed June 2, 2020. Available at URL address: https://theasgs.org/position-statements/american-society-ofgeneral-surgeons-asgs-position-statement-transoral-fundoplication/
- 2. Barbieri LA, Hassan C, Rosati R, Romario UF, Correale L, Repici A. Systematic review and meta-analysis: Efficacy and safety of POEM for achalasia. United European Gastroenterol J. 2015 Aug;3(4):325-34. doi: 10.1177/2050640615581732. PMID: 26279840; PMCID: PMC4528214.
- 3. Bazerbachi F, Krishnan K, Abu Dayyeh BK. Endoscopic GERD therapy: a primer for the transoral incisionless fundoplication procedure. Gastrointest Endosc. 2019 Sep;90(3):370-383. doi: 10.1016/j.gie.2019.05.028. Epub 2019 May 18. PMID: 31108091.
- 4. Brewer Gutierrez OI, Ichkhanian Y, Spadaccini M, Vosoughi K, Repici A, Khashab MA. Zenker's Diverticulum Per-Oral Endoscopic Myotomy Techniques: Changing

- Paradigms. Gastroenterology. 2019 Jun;156(8):2134-2135. doi: 10.1053/j.gastro.2019.02.045. Epub 2019 Mar 7. PMID: 30851303.
- 5. Centers for Medicare & Medicaid Services. Local Coverage Article: Billing and Coding: Select Minimally Invasive GERD Procedures (A56863) Effective Date: 10/01/2020 Available: https://www.cms.gov
- 6. Centers for Medicare & Medicaid Services. Local Coverage Determination (LCD): Select Minimally Invasive GERD Procedures (L35080) Effective Date: 04/15/2021. Available: https://www.cms.gov
- 7. Chimukangara M, Jalilvand AD, Melvin WS, Perry KA. Long-term reported outcomes of transoral incisionless fundoplication: an 8-year cohort study. Surg Endosc. 2019 Apr;33(4):1304-1309. doi: 10.1007/s00464-018-6403-x. Epub 2018 Aug 27. PMID: 30167944; PMCID: PMC6461469.
- 8. Chimukangara M, Jalilvand AD, Melvin WS, Perry KA. Long-term reported outcomes of transoral incisionless fundoplication: an 8-year cohort study. Surg Endosc. 2019 Apr;33(4):1304-1309. doi: 10.1007/s00464-018-6403-x. Epub 2018 Aug 27. PMID: 30167944; PMCID: PMC6461469.
- Costantini A, Familiari P, Costantini M, Salvador R, Valmasoni M, Capovilla G, Landi R, Mangiola F, Provenzano L, Briscolini D, Merigliano S, Costamagna G. Poem Versus Laparoscopic Heller Myotomy in the Treatment of Esophageal Achalasia: A Case-Control Study from Two High Volume Centers Using the Propensity Score. J Gastrointest Surg. 2020 Mar;24(3):505-515. doi: 10.1007/s11605-019-04465-w. Epub 2019 Dec 17. PMID: 31848870.
- 10. Crespin OM, Liu LWC, Parmar A, Jackson TD, Hamid J, Shlomovitz E, Okrainec A. Safety and efficacy of POEM for treatment of achalasia: a systematic review of the literature. Surg Endosc. 2017 May;31(5):2187-2201. doi: 10.1007/s00464-016-5217-y. Epub 2016 Sep 15. PMID: 27633440.
- 11. Das B, Reddy M, Khan OA. Is the Stretta procedure as effective as the best medical and surgical treatments for gastro-oesophageal reflux disease? A best evidence topic. Int J Surg. 2016 Jun 30:19-24. doi: 10.1016/j.ijsu.2016.03.062. Epub 2016 Apr 5. PMID: 27058112.
- 12. Hayes, Inc. Hayes Comparative Effectiveness Review: Endoscopic Therapy for Gastroesophageal Reflux Disease. Hayes © 2021 Hayes, a symplr company. December 7, 2017. (Annual Review January 24, 2022). Archived July 31, 2023.
- 13. Hayes, Inc. Hayes Health Technology Report. Magnetic Sphincter Augmentation (LINX Reflux Management System) For Treatment Of Gastroesophageal Reflux Disease. Hayes © 2021 Hayes, a symplr company. December 6, 2021. (Annual Review February 3, 2021).

- 14. Hayes Inc. Hayes Health Technology. Magnetic Sphincter Augmentation With LINX Reflux Management System (Ethicon Inc.) for Treatment of Gastroesophageal Reflux Disease. Hayes Inc. August 26,2022 (Annual Review August 25, 2023).
- 15. Hayes, Inc. Hayes Comparative Effectiveness Review. Peroral Endoscopic Myotomy for Treatment of Esophageal Achalasia. Hayes © 2021 Hayes, a symplr company. December 3, 2021 (Annual review April 16, 2021).
- 16. Hayes, Inc. Hayes Health Technology Assessment. Stretta (Respiratory Technology Corp.) Radiofrequency Treatment for Gastroesophageal Reflux Disease. Hayes, Inc. May 5, 2023.
- 17. Hayes, Inc. Hayes Health Technology Assessment. Transoral Incisionless Fundoplication 2.0 With EsophyX (EndoGastric Solutions Inc.) for Treatment of Gastroesophageal Reflux. Hayes Inc. May 9, 2023.
- 18. He S, Xu F, Xiong X, Wang H, Cao L, Liang N, et al. Stretta procedure versus proton pump inhibitors for the treatment of nonerosive reflux disease: A 6-month follow-up. Medicine (Baltimore). 2020 Jan;99(3):e18610
- 19. Kahrilas PJ, Katzka D, Richter JE. Clinical Practice Update: The Use of Per-Oral Endoscopic Myotomy in Achalasia: Expert Review and Best Practice Advice From the AGA Institute. Gastroenterology. 2017 Nov;153(5):1205-1211. doi: 10.1053/j.gastro.2017.10.001. Epub 2017 Oct 6. PMID: 28989059; PMCID: PMC5670013.
- 20. Laurino-Neto RM, Herbella F, Schlottmann F, Patti M. EVALUATION OF ESOPHAGEAL ACHALASIA: FROM SYMPTOMS TO THE CHICAGO CLASSIFICATION. Arq Bras Cir Dig. 2018;31(2):e1376. doi: 10.1590/0102-672020180001e1376. Epub 2018 Jul 2. PMID: 29972404; PMCID: PMC6044194.
- 21. Lee Y, Brar K, Doumouras AG, Hong D. Peroral endoscopic myotomy (POEM) for the treatment of pediatric achalasia: a systematic review and meta-analysis. Surg Endosc. 2019 Jun;33(6):1710-1720. doi: 10.1007/s00464-019-06701-5. Epub 2019 Feb 14. PMID: 30767141.
- 22. Li H, Peng W, Huang S, Ren Y, Peng Y, Li Q, Wu J, Fu X, Tang X. The 2 years' long-term efficacy and safety of peroral endoscopic myotomy for the treatment of achalasia: a systematic review. J Cardiothorac Surg. 2019 Jan 3;14(1):1. doi: 10.1186/s13019-018-0811-9. PMID: 30606216; PMCID: PMC6318943.
- 23. Park CH, Jung DH, Kim DH, Lim CH, Moon HS, Park JH, Jung HK, Hong SJ, Choi SC, Lee OY; Achalasia Research Group of the Korean Society of Neurogastroenterology and Motility. Comparative efficacy of per-oral endoscopic myotomy and Heller myotomy in patients with achalasia: a meta-analysis.

- Gastrointest Endosc. 2019 Oct;90(4):546-558.e3. doi: 10.1016/j.gie.2019.05.046. Epub 2019 Jun 10. PMID: 31443929.
- 24. Patel DA, Lappas BM, Vaezi MF. An Overview of Achalasia and Its Subtypes. Gastroenterol Hepatol (N Y). 2017;13(7):411-421.
- 25. Schiefke I, Zabel-Langhennig A, Neumann S, Feisthammel J, Moessner J, Caca K. Long term failure of endoscopic gastroplication (EndoCinch). Gut. 2005 Jun;54(6):752-8. doi: 10.1136/gut.2004.058354. PMID: 15888777; PMCID: PMC1774515.
- 26. Schlottmann F, Herbella FA, Patti MG. Understanding the Chicago Classification: From Tracings to Patients. J Neurogastroenterol Motil. 2017;23(4):487-494. doi:10.5056/jnm17026
- 27. Tefas C, Ababneh R, Tanţău M. Peroral Endoscopic Myotomy Versus Heller Myotomy for Achalasia: Pros and Cons. Chirurgia (Bucur). 2018 Mar-Apr;113(2):185-191. doi: 10.21614/chirurgia.113.2.185. PMID: 29733014.
- 28. Vaezi, Michael F. MD, PhD, MSc, FACG1; Pandolfino, John E. MD, MS, FACG2; Yadlapati, Rena H. MD, MHS (GRADE Methodologist)3; Greer, Katarina B. MD, MS4; Kavitt, Robert T. MD, MPH5 American Gastroenterological Association Clinical Guidelines: Diagnosis and Management of Achalasia, The American Journal of Gastroenterology: September 2020 Volume 115 Issue 9 p 1393-1411 doi: 10.14309/ajq.000000000000000731

Customer Product	Medical Management Requirements*
New York Products	
НМО	Retrospective Review
PPO in Plan	Retrospective Review
PPO OOP	Retrospective Review
POS in Plan	Retrospective Review
POS OOP	Retrospective Review
Essential Plan	Retrospective Review
MVP Medicaid Managed Care	Retrospective Review
MVP Child Health Plus	Retrospective Review
MVP Harmonious Health Care Plan	Retrospective Review
MVP Medicare Gold Giveback	Retrospective Review
MVP Medicare Preferred Gold HMO POS	Retrospective Review
MVP Medicare Secure HMO POS	Retrospective Review
MVP Medicare Secure Plus HMO POS	Retrospective Review
MVP Medical WellSelect PPO	Retrospective Review
MVP Medicare WellSelect Plus PPO	Retrospective Review
MVP Medicare Patriot Plan PPO	Retrospective Review
MVP DualAccess D-SNP HMO	Retrospective Review
MVP DualAccess Complete D-SNP HMO	Retrospective Review
MVP DualAccess Plus D-SNP HMO	Retrospective Review
UVM Health Advantage Select PPO	Retrospective Review
UVM Health Advantage Secure PPO	Retrospective Review
UVM Health Advantage Preferred PPO	Retrospective Review
USA Care	Retrospective Review
Healthy NY	Retrospective Review
MVP Premier	Retrospective Review
MVP Premier Plus	Retrospective Review
MVP Premier Plus HDHP	Retrospective Review
MVP Secure	Retrospective Review
MVP EPO	Retrospective Review
MVP EPO HDHP	Retrospective Review
MVP PPO	Retrospective Review
MVP PPO HDHP	Retrospective Review
Student Health Plans	Retrospective Review
ASO	See SPD
Vermont Products	
POS in Plan	Retrospective Review
POS OOP	Retrospective Review
MVP Medicare Preferred Gold HMO POS	Retrospective Review
MVP Medicare Secure Plus HMO POS	Retrospective Review
UVM Health Advantage Select PPO	Retrospective Review
UVM Health Advantage Secure PPO	Retrospective Review
UVM Health Advantage Preferred PPO	Retrospective Review
MVP VT HMO	Retrospective Review
MVP VT HDHP HMO	Retrospective Review
MVP VT Plus HMO	Retrospective Review
MVP VT Plus HDHP HMO	Retrospective Review
MVP Secure	Retrospective Review
ASO	See SPD
h	300 3. 2

[♦] Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

*Medical Management Requirements

Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review.

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

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Revision History:

04/01/2022 – New policy effective. CPT Code 43497 added to prior authorization.

04/01/2024 – Annual review. References updated.

08/01/2024 – remove CPT Code 43180 – procedure from experimental and investigational review.



Molecular Markers in Fine Needle Aspirates of the Thyroid

(Afirma®)

(RosettaGX Reveal™)

(ThyraMIR™)

(ThyGeNEXT®) oncogene mutational panel

Type of Policy: Medical

Prior Approval Date: 05/02/2022

Approval Date: 05/06/2024

Effective Date: 08/01/2024

Related Polices:

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

N/A

Codes Requiring Retrospective Review

CPT Codes:

84999 - Unlisted chemistry procedure

81445 - Targeted genomic sequence analysis panel, solid organ neoplasm, DNA analysis, and RNA analysis when performed, 5-50 genes (eg, ALK, BRAF, CDKN2A, EGFR, ERBB2, KIT, KRAS, NRAS, MET, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, if performed

81479 - Unlisted molecular pathology procedure

81546- Oncology (thyroid), mRNA, gene expression analysis of 10,196 genes, utilizing fine needle aspirate, algorithm reported as a categorical result (eg, benign or suspicious)

0018U- Oncology (thyroid), microRNA profiling by RT-PCR of 10 microRNA sequences, utilizing fine needle aspirate, algorithm reported as a positive or negative result for moderate to high risk of malignancy (ThyraMIR™)

0026U - Oncology (thyroid), DNA and mRNA of 112 genes, next-generation sequencing, fine needle aspirate of thyroid nodule, algorithmic analysis reported as a categorical result ("Positive, high probability of malignancy" or "Negative, low probability of malignancy") (Thyroseq Genomic Classifier)

0245U - Oncology (thyroid), mutation analysis of 10 genes and 37 RNA fusions and expression of 4 mRNA markers using next-generation sequencing, fine needle aspirate, report includes associated risk of malignancy expressed as a percentage (ThyGeNEXT® Thyroid Oncogene Panel)

Experimental/Investigational

N/A

Common Diagnosis Codes

ICD-10- CM Diagnosis Codes: N/A

Common Diagnosis Codes associated with this policy have been provided for informational purposes only. The list of codes may not be all-inclusive and may be updated to reflect any applicable revisions to the ICD-10 code set and/or medical necessity quidelines applied in this policy.

Common Procedure Codes

N/A

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

Thyroid cancer is most commonly found on routine physical examination as a palpable thyroid nodule. A fine-needle aspiration (FNA) biopsy is usually performed to rule out malignancy. In some cases, the nodules are not clearly benign or malignant based on fine-needle aspiration results alone. Those patients with cytologically indeterminate nodules are often referred for diagnostic surgery, though most of these nodules are benign.

The Afirma® Thyroid FNA Analysis combines cytopathology by Thyroid Cytopathology Partners (TCP) with Afirma's Gene Expression Classifier (GEC) measures the expression of 142 genes and applies a multi-dimensional algorithm to reclassify a nodule with cytopathology indeterminate diagnosis as benign or suspicious.

The RosettaGX Reveal test is a quantitative reverse transcription PCR (qRT-PCR)-based profiling test that measures microRNA expression levels in RNA extracted from stained thyroid fine-needle aspiration (FNA) biopsy smears or cell blocks. A proprietary algorithm classifier combines linear discriminant analysis steps and a K Nearest Neighbor classifier step to differentiate thyroid nodules as benign or suspicious for malignancy. In addition, the test measures the hsa-miR-375 marker for medullary carcinoma.

Thyroid microRNA (miRNA) GEC (RosettaGX Reveal) measures the expression levels of microRNAs to supposedly classify thyroid nodules with indeterminate FNA cytopathology.

ThyraMIR is a 7 gene panel with microRNA (miRNA) gene expression classifier, which evaluates the expression of 10 miRNAs and should be used in combination with ThyGeNext (previously called ThyGenX) oncogene mutational panel to better assess the risk of thyroid nodules being either benign or malignant and help reduce unnecessary surgeries in conjunction with all other available clinical data.

The ThyGeNext Thyroid Oncogene Panel is a Next Generation Sequencing panel designed to be used in patients with indeterminate thyroid FNA results. The panel includes sequencing of 8 genes associated with papillary thyroid carcinoma (PTC) and follicular carcinomas.

The ThyroSeq® v.2 Next Generation Sequencing (NGS) panel includes sequencing of more than 60 genes and per manufacturer's website is indicated when FNA cytology indicates atypical of uncertain significance (AUS) or follicular lesion of undetermined significance (FLUS), follicular neoplasm (FN) or suspicious for follicular neoplasm, or suspicious for malignancy. Per the UPMC laboratory, the test targets variant detection by next-generation sequencing in thyroid FNA and tissue samples and offers simultaneous sequencing and detection in > 1000 hotspots of 14 thyroid cancer-related genes and for 42 types of gene fusions known to occur in thyroid cancer.

Indications/Criteria

Afirma Genomic Sequencing Classifier (Afirma® by Veracyte, Inc.) (CPT code 81546) for thyroid follicular neoplasm, Hürthle cell neoplasm, anaplastic thyroid carcinoma, atypia of undetermined significance (AUS) or follicular lesion of undetermined significance (FLUS) is considered medically necessary.

Exclusions

microRNA Expression Classifier (RosettaGX Reveal™) test to differentiate cytologically indeterminate thyroid nodules as benign, suspicious for malignancy, or as having a high risk for medullary carcinoma is considered experimental/investigational. The evidence does not support the impact of patient outcomes and physician decision making to evaluate clinical utility.

ThyraMIR (CPT Code 81479, 0018U) is a microRNA (miRNA) gene expression classifier which evaluates the expression of 10 miRNAs is considered experimental/investigational. The evidence is insufficient to determine the effects of the technology on health outcomes.

Thyroid microRNA (miRNA) gene expression classifier (GEC) (eg, RosettaGX Reveal, ThyraMIR) (CPT Code 81479) alone or in combination with a thyroid cancer mutational panel (eg, ThyGeNEXT) is considered experimental/investigational. The evidence is insufficient to determine the effects of the technology on health outcomes.

ThyGeNEXT Thyroid Oncogene Panel (previously known as ThyGenX) (CPT Code 81445, 0245U) is considered experimental/investigational. The evidence is insufficient to determine the effects of the technology on health outcomes.

The ThyroSeq Genomic Classifier (CBLPath, Inc.) (0026U) test is considered experimental/investigational. The evidence is insufficient to determine the effects of the technology on health outcomes.

Medicare

Molecular testing coverage indications are as follows:

- ThyraMIR, ThyGeNEXT and Afirma services will be considered reasonable and necessary for patients with any of the following conditions:
 - o An indeterminate pathology on fine needle aspiration
 - Patients with one or more thyroid nodules with a history or characteristics suggesting malignancy such as:
 - Nodule growth over time
 - Family history of thyroid cancer
 - Hoarseness, difficulty swallowing or breathing
 - History of exposure to ionizing radiation
 - Hard nodule compared with rest of gland consistency
 - Presence of cervical adenopathy

ThyraMIR is used as a companion test to ThyGeNEXT when ThyGenNEXT results are inconclusive.

RosettaGX Reveal thyroid MicroRNA test, an assay used for the classification of indeterminate thyroid nodules, will be considered reasonable and necessary when the conditions outlined above for ThyraMIR, ThyGenNEXT and Afirma are met.

ThyroSeq (0026U) is a test utilized to better define the need for thyroid surgery and the type of such surgery. ThyroSeq will be considered reasonable and necessary when the conditions outlined above for ThyraMir, ThyGenNEXT and Afirma are met.

For full Medicare coverage details please refer to the following LCD website for Medicare Customers: Novitas Solutions, Inc. Local Coverage Determination (LCD) Biomarkers for Oncology (L35396) Revision Effective Date:12/13/2020. Available: Home-Centers for Medicare & Medicaid Services | CMS There are no Medicare National Coverage Determinations for Molecular Markers in Fine Needle Aspirates of the Thyroid available.

References (Updated 2024)

- 1. The National Comprehensive Cancer Network, Thyroid Carcinoma. Clinical Practice Guidelines in Oncology, Version 3.2021 October 15, 2021. Available: www.nccn.org
- 2. Afirma® Genomic Sequencing Classifier. © 2017 Veracyte, Inc. Available: https://www.afirma.com/physicians/
- 3. Alexander EK, Kennedy GC, Baloch ZW, et al. Preoperative diagnosis of benign thyroid nodules with indeterminate cytology. N Engl J Med. 2012 Aug 23; 367(8):705-15.
- 4. Alexander EK, Schorr M, Klopper J, et al. Multicenter clinical experience with the Afirma gene expression classifier. J Clin Endocrinol Metab. 2014 Jan; 99(1):119-25.
- 5. Duick DS, Klopper JP, Diggans JC, et al. The impact of benign gene expression classifier test results on the endocrinologist-patient decision to operate on patients with thyroid nodules with indeterminate fine-needle aspiration cytopathology. Thyroid. 2012 Oct; 22(10):996-1001.
- 6. Ferris RL, Baloch Z, Bernet V, et al. American Thyroid Association statement on surgical application of molecular profiling for thyroid nodules: current impact on perioperative decision making. Thyroid. 2015 Jul;25(7):760-8. Available: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4519104/
- 7. Walsh PS, Wilde JI, Tom EY, et al. Analytical performance verification of a molecular diagnostic for cytology-indeterminate thyroid nodules. J Clin Endocrinol Metab. 2012 Dec; 97(12):E2297-306.
- 8. Nikiforov YE, Ohori NP, Hodak SP, Carty SE, LeBeau SO, Ferris RL, Yip L, Seethala RR, Tublin ME, Stang MT, Coyne C, Johnson JT, Stewart AF, Nikiforova MN. Impact of mutational testing on the diagnosis and management of patients with cytologically indeterminate thyroid nodules: a prospective analysis of 1056 FNA samples. J Clin Endocrinol Metab. 2011 Nov; 96(11):3390-7.
- 9. Ohori NP, Nikiforova MN, Schoedel KE, LeBeau SO, Hodak SP, Seethala RR, Carty SE, Ogilvie JB, Yip L, Nikiforov YE. Contribution of molecular testing to thyroid fineneedle aspiration cytology of "follicular lesion of undetermined significance/atypia of undetermined significance". Cancer Cytopathol. 2010 Feb 25; 118(1):17-23.

- 10. Chudova D, Wilde JI, Wang ET, Wang H, Rabbee N, Egidio CM, et al. Molecular classification of thyroid nodules using high-dimensionality genomic data. *J Clin Endocrinol Metab*. 2010; 95:5296-5304.
- 11. Rivera, M., Ricarte-Filho, J., Knauf, J., et al. Molecular genotyping of papillary thyroid carcinoma follicular variant according to its histological subtypes (encapsulated vs infiltrative) reveals distinct BRAF and RAS mutation patterns. Mod Pathol 2010; 23:1191-1200.
- 12. Nikiforov YE, Steward DL, Robinson-Smith TM, Haugen BR, Klopper JP, Zhu Z, Fagin JA, Falciglia M, Weber K, Nikiforova MN. Molecular testing for mutations in improving the fine-needle aspiration diagnosis of thyroid nodules. Clin Endocrinol Metab. 2009 Jun; 94(6):2092-8.
- 13. Hodak SP, Rosenthal DS; American Thyroid Association Clinical Affairs Committee. Information for clinicians: commercially available molecular diagnosis testing in the evaluation of thyroid nodule fine-needle aspiration specimens. Thyroid. 2013 Feb; 23(2):131-4.
- 14. Giordano, TJ. Et al. Molecular testing for oncogemic gene mutations in thyroid lesions: a case –control validation study in 413 postsurgical specimens. Hum Path 2014: 45:1339-1347. Available: http://www.ncbi.nlm.nih.gov/pubmed/24830619.
- 15. Theoharis C., et al. The molecular diagnosis and management of thyroid neoplasms. Curr Opin Oncol 2012; 24:35-41. Available: http://www.ncbi.nlm.nih.gov/pubmed/22123232
- 16. Haugen BR, Alexander EK, Bible KC, et al. 2015 American Thyroid Association management guidelines for adult patients with thyroid nodules and differentiated thyroid cancer: the American Thyroid Association Guidelines Task Force on thyroid nodules and differentiated thyroid cancer. Thyroid. 2016;26(1):1-133. Available: https://www.ncbi.nlm.nih.gov/pubmed/26462967
- 17. Lithwick-Yanai G, Dromi N, Shtabsky A, et al. Multicentre validation of a microRNA-based assay for diagnosing indeterminate thyroid nodules utilising fine needle aspirate smears. J Clin Pathol. Epub ahead of print. October 26, 2016. Available: http://jcp.bmj.com/content/early/2016/12/08/jclinpath-2016-204089.long.
- 18. Cantara S, Marzocchi C, Pilli T, Cardinale S, Forleo R, Castagna MG, Pacini F. Molecular Signature of Indeterminate Thyroid Lesions: Current Methods to Improve Fine Needle Aspiration Cytology (FNAC) Diagnosis. Int J Mol Sci. 2017 Apr 6;18(4). pii: E77 Available: https://www.ncbi.nlm.nih.gov/pubmed/283834805.
- 19. Rosetta Genomics Ltd. RosettaGX Reveal™. Results Summary Thyroid microRNA Classifier. 2016a. Available: http://rosettagx.com/files/forms-reports/14689598714216cf0b60f35da2a3b5862dff3fada1.pdf.

- 20. Rosetta Genomics Ltd. RosettaGX™ Thyroid Test Requisition Form. 2016b. Available: http://rosettagx.com/files/requisition-forms/146914153541753b1ee695ec64efbc4cdf05da2556.pdf.
- 21. Rosetta Genomics Ltd. RosettaGX Reveal™. 2016c. Available: http://rosettagx.com/testing-services/thyroid
- 22. Labourier E, Shifrin A, Busseniers AE, et al. Molecular testing for mirna, mrna, and DNA on fine-needle aspiration improves the preoperative diagnosis of thyroid nodules with indeterminate cytology. The Journal of clinical endocrinology and metabolism. 2015;100(7):2743-2750.
- 23. Valderrabano P, Leon ME, Centeno BA, et al. Institutional prevalence of malignancy of indeterminate thyroid cytology is necessary but insufficient to accurately interpret molecular marker tests. European journal of endocrinology. 2016;174(5):621-629.
- 24. Wylie D, Beaudenon-Huibregtse S, Haynes BC, Giordano TJ, Labourier E. Molecular classification of thyroid lesions by combined testing for mirna gene expression and somatic gene alterations. The journal of pathology Clinical research. 2016;2(2):93-103.
- 25. Interpace Diagnostics © 2020 Interpace Biosciences, Inc. All rights reserved. Available: Home ThyGeNEXT® + ThyraMIR® (thygenext-thyramir.com)
- 26. Shifrin AL, Fischer M, Paul T, et al. Mutational analysis of metastatic lymph nodes from papillary thyroid carcinoma in adult and pediatric patients. Surgery. 2017;161(1):176-187.
- 27. Hayes Molecular Test Assessment. ThyGeNEXT and ThyraMIR (Interpace Diagnostics Group Inc.) HAYES, Inc.; © 2021 Hayes, a symplr company. July 10, 2019. Annual Review August 11, 2021.
- 28. Hayes Molecular Test Assessment. ThyroSeq v3 (University of Pittsburgh Medical Center, CBLPath Inc.) HAYES, Inc.; © 2021 Hayes, a symplr company. May 9, 2019. Annual Review October 19, 2021.
- 29. Hayes Molecular Test Assessment. Afirma Genomic Sequencing Classifier (Veracyte Inc.) HAYES, Inc.; © 2021 Hayes, a symplr company. April 7, 2021
- 30. UpToDate, Inc. Diagnostic approach to and treatment of thyroid nodules. http://www.uptodate.com. Updated March 2017. Accessed April 24, 2017.
- 31. UpToDate, Inc. Oncogenes and tumor suppressor genes in thyroid nodules and nonmedullary thyroid cancer. http://www.uptodate.com. Updated March 2017.
- 32. Nikiforov YE, Carty SE, Chiosea SI, et al. Highly accurate diagnosis of cancer in thyroid nodules with follicular neoplasm/suspicious for a follicular neoplasm

- cytology by ThyroSeq v2 next-generation sequencing assay. Cancer. 2014;120(23):3627-3634.
- 33. Nikiforov YE, Carty SE, Chiosea SI, et al. Impact of the Multi-Gene ThyroSeq Next-Generation Sequencing Assay on cancer diagnosis in thyroid nodules with atypia of undetermined significance/follicular lesion of undetermined significance cytology. Thyroid. 2015;25(11):1217-1223.
- 34. Nikiforova MN, Wald AI, Roy S, Durso MB, Nikiforov YE. Targeted next-generation sequencing panel (ThyroSeq) for detection of mutations in thyroid cancer. J Clin Endocrinol Metab. 2013;98(11):E1852-E1860.
- 35. Cibas ES, Ali SZ; NCI Thyroid FNA State of the Science Conference. The Bethesda System for Reporting Thyroid Cytopathology. Am J Clin Pathol. 2009;132(5):658-665. Available: https://academic.oup.com/ajcp/article-lookup/doi/10.1309/AJCPPHLWMI3JV4LA
- 36. Cibas ES1, Ali SZ; NCI Thyroid FNA State of the Science Conference.Am J Clin Pathol. 2009 Nov;132(5):658-65. doi: 10.1309/AJCPPHLWMI3JV4LA.The Bethesda System For Reporting Thyroid Cytopathology. Available: 2009060286.indd (thyroid-cancer.net)

Customer Product	Medical Management Requirements*
New York Products	
НМО	Retrospective Review
PPO in Plan	Retrospective Review
PPO OOP	Retrospective Review
POS in Plan	Retrospective Review
POS OOP	Retrospective Review
Essential Plan	Retrospective Review
MVP Medicaid Managed Care	Retrospective Review
MVP Child Health Plus	Retrospective Review
MVP Harmonious Health Care Plan	Retrospective Review
MVP Medicare Gold Giveback	Retrospective Review
MVP Medicare Preferred Gold HMO POS	Retrospective Review
MVP Medicare Secure HMO POS	Retrospective Review
MVP Medicare Secure Plus HMO POS	Retrospective Review
MVP Medicare WellSelect PPO	Retrospective Review
MVP Medicare WellSelect Plus PPO	Retrospective Review
MVP Medicare Patriot Plan PPO	Retrospective Review
MVP DualAccess D-SNP HMO	Retrospective Review
MVP DualAccess Complete D-SNP HMO	Retrospective Review
MVP DualAccess Plus D-SNP HMO	Retrospective Review
UVM Health Advantage Select PPO	Retrospective Review
UVM Health Advantage Secure PPO	Retrospective Review
UVM Health Advantage Preferred PPO	Retrospective Review
Healthy NY	Retrospective Review
MVP Premier	Retrospective Review
MVP Premier Plus	Retrospective Review
MVP Premier Plus HDHP	Retrospective Review
MVP Secure	Retrospective Review
MVP EPO	Retrospective Review
MVP EPO HDHP	Retrospective Review
MVP PPO	Retrospective Review
MVP PPO HDHP	Retrospective Review
Student Health Plans	Retrospective Review
ASO	See SPD
Vermont Products	
POS in Plan	Retrospective Review
POS OOP	Retrospective Review
MVP Medicare Preferred Gold HMO POS	Retrospective Review
MVP Medicare Secure Plus HMO POS	Retrospective Review
UVM Health Advantage Select PPO	Retrospective Review
UVM Health Advantage Secure PPO	Retrospective Review
UVM Health Advantage Preferred PPO	Retrospective Review
MVP VT HMO	Retrospective Review
MVP VT HDHP HMO	Retrospective Review
MVP VT Plus HMO	Retrospective Review
MVP VT Plus HDHP HMO	Retrospective Review
MVP Secure	Retrospective Review
ASO	See SPD

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

*Medical Management Requirements

Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

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Revision History

04/01/2021 - Updated policy to reflect new code and name change for ThyGeNext (previously called ThyGenX).

08/01/2022 - Annual review; added anaplastic thyroid carcinoma to coverage indications for Afirma.

08/01/2024 – Annual review; no changes to the indications or criteria.



Needle-Free Insulin Injectors

Type of Policy: DME

Prior Approval Date: 11/01/2021

Approval Date: 02/05/2024

Effective Date: 04/01/2024

Related Polices: N/A

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

N/A

Codes Subject to Retrospective Review

HCPCS code	Description	
A4210	Needle-free injection device, each	

Experimental/Investigational

Experimental codes are not covered.

N/A

Common Diagnosis Codes

N/A

Common Procedure Codes

N/A

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy.

Overview

These injectors are needle-free devices that inject insulin, under pressure, through the skin and into the subcutaneous tissue. They deliver a micro-fine jet of insulin when the tip is placed against the injection site and the button is pressed.

Indications/Criteria

Needle-free insulin injectors are considered not medically necessary as there are other alternatives for insulin administration available.

Medicare Variation

Medical supplies directly associated with delivering insulin to the body, including syringes, needles, alcohol swabs, gauze, and insulin injection delivery devices not otherwise covered under Medicare Part B, such as insulin pens, pen supplies, and needle-free syringes, can satisfy the definition of a Part D drug.

Exclusions

See Medicare Variation above.

References (Reviewed 2023)

- Arora A, Hakim I, Baxter J, Ratjmasomgham R, Srinivasan R, Fletcher DA, Mitragotri S. Needle-free delivery of macromolecules across the skin by nanoliter-volume pulsed microjets. Biomolecular Science and Engineering, University of California, Santa Barbara, CA. Proc Natl Acad Sci U.S.A. 2007 Mar 13; 104(11): 4255-60. Epub 2007 Mar 6. PubMed – MEDLINE.
- 2. Baxter, J, Mitragotri, S. Needle-free liquid jet injections: Mechanisms and applications. Expert Rev Med Devices. 2006 Sept; 3(5):565-74.
- 3. Cefalu WT. Concept, strategies, and feasibility of noninvasive insulin delivery. Diabetes Care. 2004 Jan;27(1):239-46. doi: 10.2337/diacare.27.1.239. PMID: 14693996.
- 4. Centers for Medicare & Medicaid Services. Medicare Coverage of Diabetes Supplies and Services. Available: https://www.medicare.gov/Pubs/pdf/11022-Medicare-Diabetes-Coverage.pdf
- 6. Centers for Medicare & Medicaid Services. Medicare Prescription Drug Benefit Manual. Chapter 6 Part D Drug and Formulary Requirements. (Rev.18,01-15-16).

- 7. Hayes Inc. Hayes Health Technology Assessment: Needle-Free Insulin Injection Systems. Hayes © 2021 Hayes, a symplr company. December 26, 2010 (Archived January 26, 2016) Annual Review January 10, 2014.
- 8. Reutens, AT., et al. A pilot study to examine the tolerability and device preference in type 1 diabetes of insulin as part administered by InsuJet compared with subcutaneous injection. Diabetes Technol Ther. 2013
- 9. Szmuk P, Szmuk E, Ezri T. Use of needle-free injection systems to alleviate needle phobia and pain at injection. University of Texas Medical School, Houston, TX. Outcome Research Institute, Louisville, Kentucky, U.S.A. Expert Rev Pharmacoecon Outcomes Res. 2005 Aug; 5(4) 467-77.

Customer Product	Medical Management Requirements*
New York Products	
HMO	Retrospective Review
PPO in Plan	Retrospective Review
PPO OOP	Retrospective Review
POS in Plan	Retrospective Review
POS OOP	Retrospective Review
Essential Plan	Retrospective Review
MVP Medicaid Managed Care	Retrospective Review
MVP Child Health Plus	Retrospective Review
MVP Harmonious Health Care Plan	Retrospective Review
MVP Medicare Complete Wellness	Retrospective Review
MVP Medicare Preferred Gold HMO POS	Retrospective Review
MVP Medicare Secure HMO POS	Retrospective Review
MVP Medicare Secure Plus HMO POS	Retrospective Review
MVP Medicare WellSelect PPO	Retrospective Review
MVP Medicare WellSelect Plus PPO	Retrospective Review
MVP Medicare Patriot Plan PPO	Retrospective Review
MVP DualAccess D-SNP HMO	Retrospective Review
MVP DualAccess Complete D-SNP HMO	Retrospective Review
MVP DualAccess Plus D-SNP HMO	Retrospective Review
UVM Health Advantage Select PPO	Retrospective Review
USA Care PPO	Potential for Retrospective Review
Healthy NY	Retrospective Review
MVP Premier	Retrospective Review
MVP Premier Plus	Retrospective Review
MVP Premier Plus HDHP	Retrospective Review
MVP EPO	Retrospective Review
MVP EPO HDHP	Retrospective Review
MVP PPO	Retrospective Review
MVP PPO HDHP	Retrospective Review
Student Health Plans	Retrospective Review
ASO	See SPD
Vermont Products	
POS in Plan	Retrospective Review
POS OOP	Retrospective Review
MVP Medicare Preferred Gold HMO POS	Retrospective Review
MVP Medicare Secure Plus HMO POS	Retrospective Review
Gold AnyWhere PPO	Retrospective Review
MVP VT HMO	Retrospective Review
MVP VT HDHP HMO	Retrospective Review
MVP VT Plus HMO	Retrospective Review
MVP VT Plus HDHP HMO	Retrospective Review
ASO	See SPD

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

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MVP Health Care Medical Policy Review History:

02/01/2022 – Annual review with no changes to the indications or criteria in the policy.

04/01/2024 – Annual review with no changes to criteria.



Negative Pressure Wound Therapy Pumps

Type of Policy: DME

Prior Approval Date: 03/04/2024

Approval Date: 10/07/2024

Effective Date: 12/01/2024

Related Polices: Hyperbaric Oxygen Therapy (HBO)

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

CPT Code:	Description:
E2402	Negative pressure wound therapy electrical pump, stationary or portable

Experimental/Investigational Codes Requiring Retrospective Review

N/A

Common Procedure Codes

CPT Codes: 97597, 97598, 97602, 97605, 97606, 97607, 97608, A6550, A7000

Common Diagnosis Codes

ICD-10- CM Diagnosis Codes:

E10.1, E10.5, E10.62, I73.0, I73.00, I73.01, I73.1, I73.8, I73.81, I73.89, I73.9, I87.01, I87.011, I87.012, I87.013, I87.019, I87.031, I87.031, I87.032, I87.033, I87.039, I87.2, I87.3, I87.301, I87.302, I87.303, I87.309, I87.311, I87.311, I87.312, I87.313, I87.319, L97.10, L97.11, L97.12, L97.20, L97.211, L97.301, L97.311, L97.321, L97.401, L97.411, L97.421, L97.501, L97.511, L97.521, L97.801, L97.811, L97.821

Common Diagnosis Codes associated with this policy have been provided for informational purposes only. The list of codes may not be all-inclusive and may be updated to reflect any applicable revisions to the ICD-10 code set and/or medical necessity guidelines applied in this policy.

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring priorauthorization for some products may require retrospective review for plans that do not require priorauthorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

A wound that does not heal over time and is unresponsive to appropriate care is defined as a chronic wound. Chronic wounds are complex by nature and can result from vascular disease, diabetes, traumatic injury, or post-surgery complications.

Negative pressure wound therapy may be beneficial to those patients who have chronic Stage III or IV pressure ulcers as a result of venous stasis ulcers, diabetic neuropathy, or as a complication of surgically created wounds.

The staging of pressure ulcers used in this policy is as follows:

<u>Stage I</u> - Observable pressure related alteration of intact skin whose indicators, as compared to the adjacent or opposite area on the body, may include changes in one or more of the following: skin temperature (warmth or coolness), tissue consistency (firm or boggy feel), and/or sensation (pain, itching). The ulcer appears as a defined area of persistent redness in lightly pigmented skin whereas, in darker skin tones, the ulcer may appear with persistent red, blue, or purple hues.

<u>Stage II</u> - Partial thickness skin loss involving epidermis, dermis, or both. The ulcer is superficial and presents clinically as an abrasion, blister, or shallow crater.

<u>Stage III</u> - Full thickness skin loss involving damage to, or necrosis of, subcutaneous tissue that may extend down to, but not through, underlying fascia. The ulcer presents clinically as a deep crater with or without undermining of adjacent tissue.

<u>Stage IV</u> - Full thickness skin loss with extensive destruction, tissue necrosis, or damage to muscle, bone, or supporting structures (e.g., tendon, joint capsule). Undermining and sinus tracts also may be associated with Stage IV pressure ulcers.

Smaller disposable nondurable medical equipment negative pressure wound therapy devices have been proposed for the treatment of wounds. These smaller, disposable battery powered NPWT devices are intended to maintain a closed environment of surgical incisions that continue to drain following sutured or stapled closure by removing exudate via the NPWT. Examples of disposable single-use devices include, but may not be limited to, the following: The Smart Negative Pressure (SNaP) Wound Care Device, PICO Single Use Negative Pressure Wound Therapy System and the V.A.C. Via Therapy System.

Indications/Criteria

Documentation Requirements

Documentation must include the history, previous treatment regimens (if applicable), and current wound management for which a negative pressure wound therapy (NPWT) pump is being requested.

Documentation must include such elements as length of sessions of use, dressing types and frequency of change, and changes in wound conditions, including precise measurements, quantity of exudates, presence of granulation and necrotic tissue and concurrent measures being addressed relevant to wound therapy (debridement, nutritional concerns, support surfaces in use, positioning, incontinence control, etc.).

Documentation of quantitative measurements of wound characteristics including wound length and width (surface area), and depth, and amount of wound exudate (drainage), indicating progress of healing must be entered at least monthly.

Initial Coverage

A negative pressure wound therapy (NPWT) pump [E2402] and supplies (A6550, A7000) are covered when the following criteria have been met:

A. <u>Ulcers and Wounds in the Home Setting</u>

- *Please refer to section B for NPWT coverage when treatment ordered to continue beyond inpatient setting discharge to the home setting
- The customer has a chronic Stage III or IV pressure ulcer, neuropathic (for example, diabetic) ulcer, venous or arterial insufficiency ulcer, or a chronic (being present for at least 30 days) ulcer of mixed etiology.
- A complete wound therapy program described below, as applicable depending on the type of wound, must have been tried or considered and ruled out prior to application of NPWT.
- 1. All ulcers or wounds, the following components of a wound therapy program must include a minimum of all of the following general measures, which should either be addressed, applied, or considered and ruled out prior to application of NPWT:
 - a. Documentation in the medical record of evaluation, care, and wound measurements such as by a licensed medical professional; and
 - b. application of dressings to maintain a moist wound environment; and
 - c. debridement of necrotic tissue, if applicable; and
 - d. evaluation of, and provision for, adequate nutritional status.

2. Stage III or IV pressure ulcers:

- a. The customer has been appropriately turned and positioned, and
- b. The customer has used a group 2 or 3 support surface for pressure ulcers on the posterior trunk or pelvis, and

- c. The customer's moisture and incontinence have been appropriately managed
- 3. Neuropathic (for example, diabetic) ulcers:
 - a. The customer has been on a comprehensive diabetes management program, and
 - b. Reduction in pressure on a foot ulcer has been accomplished with appropriate modalities
- 4. Venous insufficiency ulcers:
 - a. Compression bandages and/or garments have been consistently applied, and
 - b. Leg elevation and ambulation have been encouraged
- B. <u>Ulcers and Wounds Encountered in an Inpatient Setting</u>
 - 1. An ulcer or wound (described under A above) is encountered in the inpatient setting and, after wound treatments described under A-1 through A-4 have been tried or considered and ruled out, NPWT is initiated because it is considered in the judgment of the treating practitioner, the best available treatment option.
 - 2. The customer has complications of a surgically created wound (for example, dehiscence) or a traumatic wound (for example, pre-operative flap or graft) where there is documentation of the medical necessity for accelerated formation of granulation tissue which cannot be achieved by other available topical wound treatments (for example, other conditions of the beneficiary that will not allow for healing times achievable with other topical wound treatments).
- *NPWT will be covered when treatment is ordered to continue beyond discharge to the home setting.
- A licensed health care professional, for the purposes of this policy, may be a physician, physician's assistant (PA), registered nurse (RN), licensed practical nurse (LPN), or physical therapist (PT). The treating practitioner should be licensed to assess wounds and/or administer wound care within the state where the beneficiary is receiving NPWT.

C. Continued Coverage

1. For wounds and ulcers described under A or B above, once placed on an NPWT pump and supplies, in order for coverage to continue, a licensed medical professional must do the following:

On a regular basis,

- a. Directly assess the wound(s) being treated with the NPWT pump, and
- b. Supervise or directly perform the NPWT dressing changes, and
- 2. On at least a monthly basis, document changes in the ulcer's dimensions and characteristics.

End of Coverage

For wounds and ulcers described under A or B above, an NPWT pump and supplies will be denied as not reasonable and necessary with any of the following, whichever occurs earliest:

- 1. Criteria C1-C2 cease to occur,
- 2. In the judgment of the treating practitioner, adequate wound healing has occurred to the degree that NPWT may be discontinued,
- 3. Any measurable degree of wound healing has failed to occur over the prior month. Wound healing is defined as improvement occurring in either surface area (length times width) or depth of the wound
- 4. Four (4) months (including the time NPWT was applied in an inpatient setting prior to discharge to the home) have elapsed using an NPWT pump in the treatment of the most recent wound
- 5. Once equipment or supplies are no longer being used for the customer, whether or not by the practitioner's order.

Exclusions

- Requests for wound care not meeting the above criteria.
- An NPWT pump and supplies will be denied at any time as not medically necessary if one or more of the following are present:
 - o the presence in the wound of necrotic tissue with eschar if debridement is not attempted;
 - o osteomyelitis within the vicinity of the wound that is not concurrently being treated with intent to cure;
 - o cancer present in the wound; or
 - o the presence of a fistula to an organ or body cavity within the vicinity of the wound.
- NPWT pumps (E2402) must be capable of accommodating more than one wound dressing set for multiple wounds on a beneficiary. Therefore, more than one E2402 billed per beneficiary for the same time period will be denied as not reasonable and necessary.

Medicare Variation

MVP follows the Medicare criteria. For a complete description of the indications and limitations of coverage for Negative Pressure Wound Therapy for Medicare customers, please refer to the Local Coverage Determination (LCD) (L33821). Available: https://med.noridianmedicare.com/web/jddme/policies/lcd/active

There is a Local Coverage Article for Negative Pressure Wound Therapy. Please refer to the Local Coverage Article (A52511) for Negative Pressure Wound Therapy. Available: https://med.noridianmedicare.com/web/jddme/policies/lcd/active

Disposable Negative Pressure Wound Therapy (NPWT) devices (97607, 97608) are covered for a Medicare Advantage plan customer under a home health care benefit. The procedure is covered in the home when provided by a home health care agency. The coverage includes both performing the wound care service and the disposable negative pressure wound therapy device.

The disposable negative pressure wound therapy device is not covered as durable medical equipment because they are disposable and do not meet the durability requirement.

Medicaid Managed Care (MMC) Variation

A negative pressure wound therapy (NPWT) pump (E2402) are covered according to the following criteria:

- Coverage will be considered when the customer has a chronic Stage IV pressure ulcer, neuropathic (for example, diabetic) ulcer, venous or arterial insufficiency ulcer, a non-healing surgically created or traumatic wound, or a chronic (being present for at least 30 days) ulcer of mixed etiology. See below for diagnosis specific coverage criteria.
- A complete wound therapy program described below, as applicable depending on the type of wound, should have been tried prior to application of NPWT.
 NPWT should be attempted first in a hospital or another health care facility prior to discharge to the home setting. In these continuing cases, documentation should reflect customer compliance and pain management during application of NPWT.
- Documentation of the availability of licensed medical professionals to perform dressing changes and cleaning of the devices should be maintained and/or submitted for all cases.

Diagnosis Specific Coverage Criteria:

- All ulcers or wounds:
 - 1. Documentation in the customer's medical record of evaluation, care, and wound measurements by the treating physician, and
 - 2. Application of dressings to maintain a moist wound environment, and
 - 3. Debridement of necrotic tissue if present, and
 - 4. Evaluation of and provision for adequate nutritional status
- Stage IV pressure ulcers:

- 1. The customer has been appropriately turned and positioned, and
- 2. The customer has used a support surface for pressure ulcers and the posterior trunk or pelvis (not required if the ulcer is not on the trunk or pelvis) and
- 3. The customer's moisture and incontinence have been appropriately managed.
- Neuropathic (for example, diabetic) ulcers:
 - 1. The customer has been on a comprehensive diabetic management program, and
 - 2. Reduction in pressure on a foot ulcer has been accomplished with appropriate modalities.
- Venous insufficiency ulcers:
 - 1. Compression bandages and/or garments have been consistently applied, and
 - 2. Leg elevation and ambulation have been encouraged.
- Non-healing surgically created or traumatic wounds:
 - 1. Documentation of medical necessity for accelerated formation of granulated tissue which cannot be achieved by other topical wound treatments.

Non-covered conditions:

- The presence in the wound of necrotic tissue with eschar, if debridement is not attempted;
- Untreated osteomyelitis within the vicinity of the wound;
- Cancer present in the wound,
- The presence of a fistula to an organ or body cavity within the vicinity of the wound.

Documentation requirements (for continuation of services)

- Documentation of wound evaluation and treatment, recorded in the customer's medical record, must indicate regular evaluation and treatment of the customer's wounds and must be available upon request.
- Documentation of quantitative measurements of wound characteristics including wound length and width (surface area), and depth and amount of wound exudate (drainage), indicating progress of healing must be entered at least weekly.
- If treatment beyond the initial approved period of service is indicated by the treating physician upon review of the clinical progress, this documentation must be submitted with the new prior approval request. Lack of improvement of a wound is defined as a lack of progress in quantitative measurements of wound

- characteristics including wound length and width (surface area), or depth measured serially and documented, over the approved period of service.
- Wound healing is defined as improvement occurring in either surface area or depth of the wound. If detailed documentation is insufficient or if any measurable degree of wound healing has failed to occur, prior approval beyond the initial approved period of service will not be granted.

This coverage is according to the New York State Department of Health eMedNY Provider Manuals Durable Medical Equipment, Prosthetics, Orthotics, and Supplies. Procedure Codes and Coverage Guidelines. Copyright ©2021 DOH.

References (Updated 2024)

- 1. Noridian Healthcare Solutions, LLC LCD Negative Pressure Wound Therapy Pumps (L33821). Effective Date 10/01/2015. Revision Effective Date: 05/01/2021. Available: https://med.noridianmedicare.com/web/jddme/policies/lcd/active
- 2. HAYES Health Technology Assessment. Negative pressure wound therapy for wounds Other than Sternal Wounds and Skin Grafts. Hayes, Inc. July 17, 2012. ARCHIVED August 17, 2017. Available: www.hayesinc.com
- 3. Abbade, L.P., Lastória, S. Venous ulcer: epidemiology, physiopathology, diagnosis and treatment. Int J Dermatol. 2005;44(6):449-56.
- 4. The National Pressure Ulcer Advisory Panel (NPUAP). Pressure injury stages revised. (Jan 2017). Available: https://npiap.com/page/PressureInjuryStages
- 5. Fleming CA, Kuteva M, O'Hanlon K, O'Brien G, McGreal G Routine use of PICO dressings may reduce overall groin wound complication rates following peripheral vascular surgery. J Hosp Infect. 2018;May;99(1):75-80.
- 6. Galiano RD, Hudson D, Shin J, van der Hulst R, Tanaydin V, Djohan R, Duteille F, Cockwill J, Megginson S, Huddleston E Incisional negative pressure wound therapy for prevention of wound healing complications following reduction mammoplasty. Plast Reconstr Surg Glob Open. 2018;Jan;6(1):e1560.
- 7. Tanaydin V, Beugels J, Andriessen A, Sawor JH, van der Hulst R Randomized controlled study comparing disposable negative-pressure wound therapy with standard care in bilateral breast reduction mammoplasty evaluating surgical site complications and scar quality. Aesthetic Plast Surg. 2018;Feb 13.
- 8. Gillespie BM, Rickard CM, Thalib L, Kang E, Finigan T, Homer A, Lonie G, Pitchford D, Chaboyer W Use of negative-pressure wound dressings to prevent surgical site complications after primary hip arthroplasty: a pilot RCT. Surg Innov. 2015; Oct;22(5):488-495.

- 9. Hayes Health Technology Assessment: Negative Pressure Wound Therapy For Chronic Wounds: Home Use. Hayes, Inc. December 15, 2016. Annual Review: April 17, 2020. Archived January 15, 2022.
- 10. Hayes, Inc. Hayes Medical Technology Directory Report. Negative Pressure Wound Therapy (NPWT) in the Adjunct Treatment of Skin Grafts. Lansdale, PA: Hayes, Inc.; published Jun 25, 2015. Reviewed Jun 2017; Jun 2018; Jul 2019; Archived Jul 25, 2020.
- 11. Hayes, Inc. Hayes Medical Technology Directory Report. SNaP Wound Care System (Spiracur Inc.) For Treatment Of Lower Extremity Ulcers. Lansdale, PA: Hayes, Inc.; published Dec. 27, 2012. Reviewed Dec. 30, 2014.
- 12. New York State Department of Health eMedNY Provider Manuals Durable Medical Equipment, Prosthetics, Orthotics, and Supplies. Procedure Codes and Coverage Guidelines. Copyright ©2021 DOH.

Customer Product	Medical Management Requirements*
New York Products	
HMO	Prior Auth
PPO In Plan	Prior Auth
PPO OOP	Prior Auth
POS In Plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Prior Auth
MVP Child Health Plus	Prior Auth
MVP Harmonious Health Care Plan	Prior Auth
MVP Medicare Complete Wellness	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure HMP POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP Medicare WellSelect PPO	Prior Auth
MVP Medicare WellSelect Plus PPO	Prior Auth
MVP Patriot Plan PPO	Prior Auth
MVP DualAccess D-SNP HMO	Prior Auth
MVP DualAccess Complete D-SNP HMO	Prior Auth
MVP DualAccess Plus D-SNP HMO	Prior Auth
UVM Health Advantage Select PPO	Prior Auth
USA Care	Potential for Retrospective Review
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	300 31 D
POS In Plan	Prior Auth
POS OOP	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP VT HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
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[♦] Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

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Revision History:

08/01/2020 – Updated format. Revised: "treating physician" to "treating practitioner," added definition of practitioner, no changes to the indications or criteria for Commercial/Medicare plans. Added Medicaid Managed Care Plan coverage criteria that is consistent with NYS Medicaid criteria.

08/1/2023 – Annual review completed, no changes to the indications or criteria.

06/01/2024 – Removed disposable negative pressure wound therapy (CPT Codes: 97607 and 97608) from medical review.

12/01/2024 – Removed language referencing disposable negative pressure wound therapy pumps.



Neuropsychological Testing

Type of Policy: Medical/Behavioral

Health

Prior Approval Date: 01/08/2025

Approval Date: 03/28/2025

Effective Date: 06/01/2025

Related Polices: N/A

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

N/A

Experimental/Investigational Codes Requiring Retrospective Review

CPT Code:	Description:
96146	Psychological or neuropsychological test administration, with single automated, standardized instrument via electronic platform, with automated result only

Common Diagnosis Codes

N/A

Common Procedure Codes

CPT Codes: 96116, 96121, 96132, 96133, 96136, 96137, 96138, 96139

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

Neuropsychological testing is a standardized, clinically established procedure developed to assess an individual's cognitive level of functioning and, when deficits are present, to quantify the severity and scope of existing cognitive impairment.

There are two types of neuropsychological testing; fixed (standardized) and flexible (non-standardized) neuropsychological test batteries. In the fixed battery approach, patients are given the same pre-set group of tests, such as the Halsted-Reitan battery. In the flexible battery approach, the neuropsychologist tailors the battery for the particular problem a given individual is suspected of having.

There is a wide variety of neuropsychological tests which may be administered in different contexts such as paper and pencil, computer, and visual aids.

Computerized neuropsychological testing is also known as automated or computer-based testing. The features of computerized testing, not part of traditional neuropsychological testing, include timing of response latencies, automated analysis of response patterns, and transfer of results to a database for further analysis. Many computer-based tests do not require a professional to interpret or to complete the report.

Additional computerized neuropsychological test batteries are used in management of concussions to facilitate decisions about safe return to play, work or school. These tests generally take about 15-25 minutes to complete. An example of computerized testing used in evaluation of concussion include is the ImPACT (Immediate Post-Concussion Assessment and Cognitive Testing) (ImPACT Applications, Inc., Pittsburgh, PA). According to the vendor website the test can be administered by an athletic trainer, school nurse, athletic director, team coach, team doctor, or anyone trained to administer baseline testing. It takes approximately 20 minutes and a clinical report is provided by the program.

Indications/Criteria

Neuropsychological testing is indicated when there has been significant mental status change, cognitive function change, memory loss or behavior change as a result of suspected organic brain dysfunction resulting from illness or injury.

Examples of neurologic disorders in which neuropsychological testing may be indicated are:

- hydrocephalus;
- intracranial neoplasm;
- seizure disorders;

- traumatic brain injury (TBI): TBI is defined as a bump, blow, or jolt to the head or a penetrating head injury that disrupts the normal function of the brain. ^[14] This must be characterized by:
 - o significant mental status change
 - o significant behavioral change or memory loss
 - o abnormality on cranial imaging
- vascular or hereditary disorders;
- demyelinating disorders (i.e., Multiple Sclerosis); or
- extrapyramidal disorders (i.e., Parkinson's Disease)
- stroke or cerebral vascular injury (e.g., brain aneurysm, subdural hematoma
- Attention-deficit/hyperactivity disorder (ADHD) or autism spectrum disorders (ASD) when all of the following are present:
 - Specific neurocognitive behavioral deficits need to be evaluated related to ASD and ADHD; and
 - Testing has been recommended by a physician and may be related or secondary to a known or suspected neurologically complicating condition resulting from brain injury or disease process (e.g., concussion, intractable seizure disorder, cancer treatment effects, genetic disorders, inborn errors of metabolism)
 - Testing for the diagnosis of attention-deficit/hyperactivity disorder or autism spectrum disorders (ASD) can be made through a comprehensive evaluation, including developmental history and administration of rating scales, using the diagnostic criteria of the most recent version of the Diagnostic and Statistical Manual of Mental Disorders (DSM). Testing may be approved if the appropriate assessments have been conducted as described above and the member is not responding to standard treatment with no clear explanation for treatment failure.

Examples of psychiatric disorders in which neuropsychological testing may be indicated are:

- dementia of various etiologies (i.e., primary neurodegenerative, infectious, etc.);
- delirium/confusional state;
- depression and other psychiatric disorders presenting with neurologic symptomatology making differential diagnosis difficult but imperative to formulating a treatment plan; or
- amnestic disorders.

Each neuropsychological test administered must be medically necessary. A standard battery of tests is only medically necessary if each individual test in the battery is

medically necessary. Neuropsychological testing is intended to describe and diagnose the neurocognitive effects of medical disorders that impinge directly or indirectly on the functional integrity of the brain. Indications for neuropsychological testing include: [1, 3]

- detection of neurologic disorders based on quantitative assessment of neurocognitive abilities (e.g., mild head injury, anoxic injuries, AIDS, dementia);
- differential diagnosis between psychogenic and neurogenic syndromes (e.g., depression vs. dementia); or
- assessment of neurocognitive functions for the formulation of rehabilitation and/or management strategies among individuals with neurologic disorders.
- Subsequent testing may be approved on a limited basis when testing is required to:
 - o determine a significant treatment change; or
 - o confirm a diagnosis; or
 - o evaluate a reasonable suspicion of another problem; or
 - o a comprehensive battery of neuropsychological tests is available through licensed practitioners and technicians.

To be covered, neuropsychological testing must be indicated for the purpose of providing information about the member's condition which is necessary to assist in determining a diagnosis and/or plan of care that can reasonably be expected to improve the member's outcome. Neuropsychological testing is an ancillary procedure to general clinical and/or neurologic evaluations. Prior to neuropsychological testing, a thorough behavioral health assessment and neurological evaluation should be completed and documented in the medical record. If neuropsychological testing is being requested to differentiate depression from organic brain dysfunction, a behavioral health specialist consult should be considered prior to testing.

Exclusions

Neuropsychological testing is not medically necessary for the following:

- the routine monitoring of chronic disorders such as cerebrovascular disease, HIV infection, etc. unless significant clinical change is documented;
- Baseline neuropsychological testing in asymptomatic individuals at risk for sportrelated concussions;
- periodic re-testing of stable members;
- routine testing of nursing home patients;
- members who have had surgery for epilepsy within the last 12 months;
- standard or routine use of neuropsychological testing for individuals with attention deficit/hyperactivity disorder (ADHD) and autism spectrum disorder (ASD) is not

medically necessary because there is insufficient peer-reviewed literature to support use without a specific or suspected medical condition (brain injury or disease process, i.e., intractable seizure disorder, genetic disorder).

- when the member has a history of substance abuse, and the member continues to use mood altering substances and/or when the member is <10 days postdetoxification;
- for pre-procedure work-up (e.g., deep brain stimulation) unless neuropsychological testing is required to determine if the member is cognitively able to benefit from the procedure and is able to cooperate with all aspects of the treatment plan and the member meets all other criteria for the proposed procedure;
- screening tests are non-covered services, i.e., screening tests of cognitive function such as the Folstein Mini Mental Status Examinations (MMSE), Beck Depression Scale, and the 7-Minute Screen are considered included in the associated consultation evaluation or clinical interview;
- use of computer-based neuropsychological testing (e.g., ImPACT™, CogState Sport®, HeadMinder) (CPT: 96146) is considered investigational and not medically necessary. There is a lack of evidence in the peer-reviewed literature to support computer-based neuropsychological testing improves outcomes. Computer-based or computerized neuropsychological testing for any indication does not require a physician, psychologist, or licensed mental health professional to provide interpretation and preparation of report.

Neuropsychological testing is not a covered benefit when testing is primarily for educational, vocational or legal purposes.

New York Variation

Effective 1/1/2025, comprehensive neuropsychological examinations for dyslexia are covered for New York Commercial plans upon referral of a physician and when performed by a health care professional licensed, certified, or authorized pursuant to title eight of the education law and acting within their scope of practice.

MVP Medicare Products

There is a Medicare National Government Services Local Determination for Psychiatry and Psychology Services (L33632). Revision Effective Date:01/01/2024. For full coverage indications and exclusion details for computerized neuropsychological testing refer to the following link: https://www.cms.gov/medicare-coverage-database/search.aspx

Neuropsychological Testing including Neuro-Cognitive, Mental Status, Speech Testing: Medical Record Documentation

Typically, neuropsychological testing will require from four (4) to six (6) hours to perform, including administration, scoring and interpretation. Supporting documentation in the medical record must be present to justify greater than 8 hours per patient per evaluation. If the testing is done over several days, the testing time should be combined and reported all on the last date of service. If the testing time exceeds eight (8) hours, medical necessity for extended time should be documented.

Indications/Criteria

Testing intended to diagnose and characterize the neurocognitive effects of medical disorders that impinge directly or indirectly on the brain. Examples of problems that might lead to neuropsychological testing are:

- Detection of neurologic diseases based on quantitative assessment of neurocognitive abilities (e.g., mild head injury, anoxic injuries, AIDS dementia);
- Differential diagnosis between psychogenic and neurogenic syndromes;
- Delineation of the neurocognitive effects of central nervous system disorders;
- Neurocognitive monitoring of recovery or progression of central nervous system disorders; or
- Assessment of neurocognitive functions for the formulation of rehabilitation and/or management strategies among individuals with neuropsychiatric disorders.

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Psychological testing is limited to physicians, clinical psychologists, and on a limited basis, to qualified non-physician practitioners (e.g., speech language pathologists for aphasia evaluation).

Vermont Variation

Neuropsychological Testing

Vermont law mandates that neuropsychological testing is considered medically necessary when it is required to aid in the assessment and diagnosis of early childhood developmental disorders for children beginning at birth and continuing until the child reaches age 21.

Services that are considered primarily educational or training in nature to improve academic or work performance or to correct a learning disability are considered to be not medically necessary.

References (Updated 2025)

1. American Academy of Child and Adolescent Psychiatry (AACAP). Practice Parameter for the Assessment and Treatment of Children and Adolescents with Attention-

- Deficit/Hyperactivity Disorder. (ARCHIVED) J Am Acad Child Adolesc Psychiatry. 2007;46(7):894-921.
- American Academy of Clinical Neuropsychology (AACN). American Academy of Clinical Neuropsychology (AACN) practice guidelines for neuropsychological assessment and consultation. Clinical Neuropsychology. 2007 March; 21(2):2009-31. Available: https://www.tandfonline.com/doi/abs/10.1080/13825580601025932
- 3. American Academy of Pediatrics (AAP). Clinical Practice Guideline. Clinical practice guideline for the diagnosis, evaluation and treatment of attention deficit/hyperactivity disorder in children and adolescents. https://www.aap.org. Published October 2019.
- 4. American Psychiatric Association (APA). Attention-deficit/hyperactivity disorder. Diagnostic and Statistical Manual of Mental Disorders, (5th ed. Text Revision; DSM–5-TR; American Psychiatric Association [APA], 2022)
- 5. American Psychological Association (APA). Psychological and Neuropsychological Testing Billing and Coding Guide. 2019. Available at: https://www.apaservices.org/practice/reimbursement/health-codes/testing/billing-coding.
- 6. Bechtel N, Kobel M, Penner IK, et al. Attention-deficit/hyperactivity disorder in childhood epilepsy: a neuropsychological and functional imaging study. Epilepsia. 2012 Feb;53(2):325-33.
- 7. Broglio SP, Katz BP, Zhao S, et al.; CARE Consortium Investigators. Test-Retest reliability and interpretation of common concussion assessment tools: findings from the NCAA-DoD CARE Consortium. Sports Med. 2017 Nov 14.
- 8. Children and Adults with Attention-Deficit/Hyperactivity Disorder (CHADD)

 Comprehensive Evaluation for ADHD. Available: <a href="https://chandbox.org/chandbo
- 9. Department of Health and Human Services. Centers for Medicare and Medicaid Services. Medicare Learning Network. Mental Health Services. ICN 903195 March 2012.
- 10. Frazier TW, Demaree HA, Youngstrom EA. Meta-analysis of intellectual and neuropsychological test performance in attention-deficit/hyperactivity disorder. Neuropsychology. 2004;18(3):543-555.
- 11. Gaudet CE, Weyandt LL. Immediate Post-Concussion and Cognitive Testing (ImPACT): a systematic review of the prevalence and assessment of invalid performance. Clin Neuropsychol. 2017 Jan;31(1):43-58.
- 12. Halstead ME, Walter KD; Council on Sports Medicine and Fitness. American Academy of Pediatrics. Clinical report-sport-related concussion in children and adolescents. Pediatrics. 2010 Sep;126(3):597-615. Reaffirmed August 2014.

- 13. Hang B, Babcock L, Hornung R, Ho M, Pomerantz WJ. Can Computerized Neuropsychological Testing in the Emergency Department Predict Recovery for Young Athletes With Concussions? Pediatr Emerg Care. 2015 Oct;31(10):688-93.
- 14. Haran FJ, Dretsch MN, Slaboda JC, et al. Comparison of baseline-referenced versus norm-referenced analytical approaches for in-theatre assessment of mild traumatic brain injury neurocognitive impairment. Brain Inj. 2016;30(3):280-6.
- 15. Hayes, Inc. Evolving Evidence Review. EndeavorRx (Akili Interactive Labs Inc.) for treatment of attention-deficit/hyperactivity disorder in children. https://evidence.hayesinc.com. Published January 18, 2023.
- 16. Johnson CP, Myers SM; American Academy of Pediatrics, Council on Children with Disabilities. Identification and evaluation of children with autism spectrum disorders. *Pediatrics*. 2007; 120:1183–1215.
- 17. Krull KR. Attention deficit hyperactivity disorder in children and adolescents: Clinical features and diagnosis. UpToDate [online serial]. Waltham, MA: UpToDate; updated May 2021.
- 18. MacDonald J, Duerson D. Reliability of a Computerized Neurocognitive Test in Baseline Concussion Testing of High School Athletes. Clin J Sport Med. 2015 Jul;25(4):367-72.
- 19. MacDonald J, Duerson D. Reliability of a Computerized Neurocognitive Test in Baseline Concussion Testing of High School Athletes. Clin J Sport Med. 2015 Jul;25(4):367-72.
- 20. National Government Services Local Determination for Psychiatry and Psychology Services (L33632). Revision Date:11/28/2019. Available: https://www.cms.gov
- 21. Nelson LD, Pfaller AY, Rein LE, et al. Rates and Predictors of Invalid Baseline Test Performance in High School and Collegiate Athletes for 3 Computerized Neurocognitive Tests: ANAM, Axon Sports, and ImPACT. Am J Sports Med. 2015 Aug;43(8):2018-26.
- 22. Pelham WE, et al. Evidence-based assessment of Attention Deficit Hyperactivity Disorder in children and adolescents. J Clin Child Adolesc Psychol 2005;34(3):449-76.
- 23. Pineda DA, et al. The role of neuropsychologic tests in the diagnosis of attention deficit hyperactivity disorder. Pediatr Neurol 2007 Jun;36(6):373-81.
- 24. Pliszka S; AACAP Work Group on Quality Issues. Practice parameter for the assessment and treatment of children and adolescents with attention-deficit/hyperactivity disorder. J Am Acad Child Adolesc Psychiatry. 2007 Jul;46(7):894-921. Accessed March 23, 2022. Available at URL address:

 https://www.aacap.org/aacap/Resources for Primary Care/Practice Parameters and Resource Centers/Practice Parameters.aspx

- 25. Scott M. Myers, MD, Chris Plauche´ Johnson, MD, MEd, the Council on Children with Disabilities. Management of Children with Autism Spectrum Disorders. American Academy of Pediatrics. *Pediatrics* Volume 120, Number 5, November 2007, 1165.
- 26. The Vermont Statutes Online. Title 8: Banking and Insurance, Chapter 107: HEALTH INSURANCE 8 V.S.A. § 4088i. Coverage for diagnosis and treatment of autism spectrum disorders.
- 27. UpToDate, Inc. Attention deficit hyperactivity disorder in children and adolescents: clinical features and diagnosis. https://www.uptodate.com. Updated April 2022.
- 28. UpToDate, Inc. Attention deficit hyperactivity disorder in children and adolescents: overview of treatment and prognosis. https://www.uptodate.com. Updated April 2022.
- 29. Volkmar F, Siegel M, Woodbury-Smith M, King B, McCracken J, American Academy of Child and Adolescent Psychiatry (AACAP) Committee on Quality Issues (CQI). Practice Parameter for the assessment and treatment of children and adolescents with autism spectrum disorder. J Am Acad Child Adolesc Psychiatry. 2014 Feb;53(2):237-57.

Member Product	Medical Management Requirements*
New York Products	
HMO	Retrospective Review
PPO in Plan	Retrospective Review
PPO OOP	Retrospective Review
POS in Plan	Retrospective Review
POS OOP	Retrospective Review
Essential Plan	Retrospective Review
MVP Medicaid Managed Care	Retrospective Review
MVP Child Health Plus	Retrospective Review
MVP Harmonious Health Care Plan	Retrospective Review
MVP Medicare Complete Wellness	Retrospective Review
MVP Medicare Preferred Gold HMO POS	Retrospective Review
MVP Medicare Secure HMO POS	Retrospective Review
MVP Medicare Secure Plus HMO POS	Retrospective Review
MVP Medicare WellSelect PPO	Retrospective Review
MVP Medicare WellSelect Plus PPO	Retrospective Review
MVP Medicare Patriot Plan PPO	Retrospective Review
MVP DualAccess D-SNP HMO	Retrospective Review
MVP DualAccess Complete D-SNP HMO	Retrospective Review
MVP DualAccess Plus D-SNP HMO	Retrospective Review
UVM Health Advantage Select PPO	Retrospective Review
USA Care PPO	Potential for Retrospective Review
Healthy NY	Retrospective Review
MVP Premier	Retrospective Review
MVP Premier Plus	Retrospective Review
MVP Premier Plus HDHP	Retrospective Review
MVP Secure	Retrospective Review
MVP EPO	Retrospective Review
MVP EPO HDHP	Retrospective Review
MVP PPO	Retrospective Review
MVP PPO HDHP	Retrospective Review
Student Health Plans	Retrospective Review
ASO	See SPD
	See SPD
Vermont Products	Detroes
POS in Plan	Retrospective Review
POS OOP	Retrospective Review
MVP Medicare Preferred Gold HMO POS	Retrospective Review
MVP Medicare Secure Plus HMO POS	Retrospective Review
MVP VT HMO	Retrospective Review
MVP VT Plus HMO	Retrospective Review
MVP VT HDHP HMO	Retrospective Review
MVP VT Plus HDHP HMO	Retrospective Review
MVP Secure	Retrospective Review
ASO	See SPD

[♦] Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro ReviewRetrospective Review RequiredNot CoveredService is not a covered benefit.See SPDSee Specific Plan Design

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Revision History:

06/01/2021 – format updated, Annual review with no changes to the indications or criteria. Updates made to Medicare variation based on Medicare LCD.

02/01/2022 – Eliminated the requirement for specialists or specific practitioners to provide testing.

04/01/2023 – Annual Review; added criteria and indications for testing ADHD and ASD, exclusions for testing in asymptomatic individuals, educational and vocational use, and routine use for ADHD and ASD. Updated references.

01/01/2025 – added coverage for comprehensive neuropsychological examinations for dyslexia according to NYS regulation. Revised Medicare variation with approved providers of service. References reviewed and updated.

06/01/2025 –Completed formal review of changes effective 01/01/2025.



Non-Invasive Liver Fibrosis Testing

Type of Policy: Medical

Prior Approval Date: 02/06/2023

Approval Date: 06/03/2024

Effective Date: 08/01/2024

Related Polices: Hepatitis C Treatment

Serum Testing for Hepatic Fibrosis in the Evaluation and Monitoring of Chronic Liver Disease Payment Policy

Codes Requiring Prior Authorization:

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

N/A

Experimental/Investigational Codes Requiring Retrospective Review:

CPT Codes	Code Description
76981	Ultrasound, elastography; parenchyma (eg, organ) (sonoelastography)
76982	Ultrasound, elastography; first target lesion
76983	Ultrasound, elastography; each additional target lesion
81599	Unlisted multianalyte assay with algorithmic analysis
81517	Liver disease, analysis of 3 biomarkers (hyaluronic acid [HA], procollagen III amino terminal peptide [PIIINP], tissue inhibitor of metalloproteinase 1
	[TIMP-1]), using immunoassays, utilizing serum, prognostic algorithm
	reported as a risk score and risk of liver fibrosis and liver-related clinical
	events within 5 years

Common Procedure Codes:

83520	Immunoassay for analyte other than infectious agent antibody or
	infectious agent antigen; quantitative, not otherwise specified

83883	Nephelometry, each analyte not elsewhere specified	
91200	Liver elastography, mechanically induced shear wave (eg, vibration),	
	without imaging, with interpretation and report (FibroScan)	

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

Hepatic fibrosis is a broad term used to describe the excessive accumulation of fibrotic connective tissue resulting from prolonged inflammation and progressive scarring of the liver due to a sustained wound-healing response to liver injury. The increased fibrosis and liver stiffness reduces blood flow through the liver, which leads to hardening and death of liver cells. Chronic liver diseases that may lead to hepatic fibrosis include such diseases as alcoholic liver disease, chronic viral hepatitis B, chronic viral hepatitis C, non-alcoholic hepatosteatosis (NASH), non-alcoholic fatty liver disease (NAFLD), and autoimmune hepatitis.

Liver biopsy is considered the gold standard test for diagnosis and staging of hepatic fibrosis. Staging of fibrosis is often indicated to determine treatment decisions and risk for progression to cirrhosis. Liver biopsy is an invasive procedure that may result in complications. For that reason, non-invasive hepatic fibrosis tests are being introduced.

Examples of these tests include serum biomarkers of hepatic fibrosis (Fibrotest ® patented formula combining α -2-macroglobulin, γ -GT, apolipoprotein A1, haptoglobin, total bilirubin, age, and gender) and transient elastography (FibroScan ®, 1-dimensional ultrasound measuring the velocity of a low-frequency elastic shear wave propagating through the liver. This velocity is directly related to tissue stiffness).

According to the American Association for the Study of Liver Diseases (AASLD) and the Infectious Disease Society of America (IDSA) *Recommendations for testing, managing, and treating hepatitis C*, evaluation for advanced fibrosis using liver biopsy, imaging, and/or noninvasive markers is recommended for all persons with HCV infection to facilitate an appropriate decision regarding HCV treatment strategy, and to determine the need for initiating additional measures for cirrhosis management (eg, hepatocellular carcinoma screening) (Level of evidence I,A).

The MVP Policy on Hepatitis C Treatment states, "The following information must be provided for all drugs: Test results identifying HC antibody, quantitative HCV PCR level, HCV genotype, and fibrosis score must be provided."

Indications/Criteria

-Transient elastography

Transient elastography (e.g., FibroScan) (91200) is considered medically necessary for distinguishing hepatic cirrhosis from non-cirrhosis in persons with chronic liver disease caused by hepatitis C. Performance of this test is only indicated once per customer lifetime except for the following conditions:

- If the customer is status post successful treatment for hepatitis C; and
- If the customer is experiencing a new/re-infection hepatitis C diagnosis for which they are indicated for non-invasive transient elastography for assessment of fibrosis; and
- No previous tests (e.g. liver biopsy, FibroTest-ActiTest/HCV-FibroSure, FibroScan) that have shown liver fibrosis.

Performance of this test should not be done for monitoring interval change in liver fibrosis. Performance of transient elastography within 6 months following a liver biopsy or HCV-Fibrosure is considered not medically necessary. Transient elastography is considered experimental and investigational for all other indications.

Exclusions

Performance of HCV-FibroSure or FibroScan for serial monitoring/interval change of liver fibrosis is excluded.

As there is little evidence to support the accuracy and specificity of non-invasive fibrosis testing in chronic liver diseases that are not viral hepatitis C, this testing is excluded for chronic liver disease diagnoses of other causes, including, but not limited to, viral hepatitis B, NASH, NAFLD, autoimmune hepatitis, and alcoholic liver disease.

If a patient already has a positive liver biopsy on record, there is no evidence to support performance of either HCV-FibroSure or FibroScan.

The following serum marker tests are considered experimental and investigational for detecting and monitoring hepatic fibrosis in persons with hepatitis C or other chronic liver diseases because their effectiveness for these indications has not been established:

FibroMAX

FibroSpect

HepaScore

Micro-fibrillar associated glycoprotein 4 (MFAP4)

MicroRNA-21

Plasma cytokeratin-18

Signal-induced proliferation-associated 1 like 1 (SIPA1L1)

All other noninvasive imaging (76391, 76981, 76982, 76983) that maps the elastic properties of soft tissue to evaluate and/or monitor individuals with chronic liver disease are considered *investigational*. These technologies include, but are not limited to, the following:

- Shear wave ultrasound elastography of the liver without imaging
- Ultrasound elastography of the liver
- Magnetic resonance elastography (CPT: 76391)
- Acoustic radiation force impulse imaging (ARFI)(e.g., Acuson S2000™)
- Real-time tissue elastography (e.g., HI VISION Preirus™)

References (Reviewed 2024)

- 1. European Association for the Study of the Liver (EASL), Associacion Latinoamericana para el Estudio del Higado (ALEH). EASL-ALEH Clinical Practice Guidelines: Non-invasive tests for evaluation of liver disease severity and prognosis. Journal of Hepatology.2015;63:237–264.
- 2. AASLD-IDSA recommendations for testing, managing, and treating adults infected with hepatitis C virus. Hepatology. 2015;(62):932-954.
- 3. AASLD-IDSA. Recommendations for testing, managing, and treating hepatitis C [Internet]. 2018. http://hcvguidelines.org/
- 4. Castera L, Winnock M, Pambrun E, et al. Comparison of transient elastography (Fibroscan), Fibrotest, APRI and two algorithms combining these non-invasive tests for liver fibrosis staging in HIV/HCV coinfected patients: ANRS CO13 HEPAVIH and FIBROSTIC collaboration. HIV Med. 2014;15(1):30-9.
- 5. Castera L. Noninvasive methods to assess liver disease in patients with hepatitis B or C. Gastroenterology. 2012;142(6):1293-1302.
- 6. Castera L, Sebastiani G, LeBail B, et al. Prospective comparison of two algorithms combining non-invasive methods for staging liver fibrosis in chronic hepatitis C. Journal of Hepatology. 2010; 52: 191-198.
- 7. Hayes, Inc. Health Technology Assessment. HCV FibroSure (LabCorp) for assessment of liver fibrosis in patients with hepatitis C. https://evidence.hayesinc.com. Published February 2, 2021. Annual Review: January 2022
- 8. Hayes, Inc. Health Technology Assessment. Magnetic resonance elastography for detecting and staging liver fibrosis. https://evidence.hayesinc.com. Published June 19, 2020. Updated July 13, 2021.

- 9. Hayes, Inc. Medical Technology Directory. Ultrasound transient elastography for detecting hepatic fibrosis in patients with hepatitis C. https://evidence.hayesinc.com. Published March 27, 2019. Updated May 5, 2021.
- 10. Lv S, Jiang S, Liu S, et al. Noninvasive quantitative detection methods of liver fat content in nonalcoholic fatty liver disease. J Clin Transl Hepatol 2018; 6(2):217-221.
- 11. Kaswala DH, Lai M, and Afdhal NH. Fibrosis assessment in nonalcoholic fatty liver disease in 2016. Dig Dis Sci. 2016; 61:1356-1364.
- 12. Lim JK, Flamm SL, Singh S, et al. American Gastroenterological Association Institute guideline on the role of elastography in the evaluation of liver fibrosis. Gastroenterology. 2017; 152:1536-1543.
- 13. Afdhal NH, Bacon BR, Patel K, Lawitz EJ, Gordon SC, Nelson DR, et al. Accuracy of fibroscan, compared with histology, in analysis of liver fibrosis in patients with hepatitis B or C: a United States multicenter study. Clin. Gastroenterol. Hepatol. 2015;13(4):772-779.
- 14. Ultrasound Transient Elastography for Detecting Hepatic Fibrosis in patients with Hepatitis C. Medical Technology Directory. Hayesinc.com/login [via subscription only]. Published December 9, 2014. Updated November 20, 2017. Accessed August 29, 2018.

Customer Product	Medical Management Requirements*
New York Products	Retrospective Review
HMO	Retrospective Review
PPO In Plan	Retrospective Review
PPO OOP	Retrospective Review
POS In Plan	Retrospective Review
POS OOP	Retrospective Review
Essential Plan	Retrospective Review
MVP Medicaid Managed Care	Retrospective Review
MVP Child Health Plus	Retrospective Review
MVP Harmonious Health Care Plan	Retrospective Review
MVP Medicare Complete Wellness	Retrospective Review
MVP Medicare Preferred Gold HMO POS	Retrospective Review
MVP Medicare Secure HMO POS	Retrospective Review
MVP Medicare Secure Plus HMO POS	Retrospective Review
MVP Medicare WellSelect PPO	Retrospective Review
MVP Medicare WellSelect Plus PPO	Retrospective Review
MVP Medicare Patriot Plan PPO	Retrospective Review
MVP DualAccess D-SNP HMO	Retrospective Review
MVP DualAccess Complete D-SNP HMO	Retrospective Review
MVP DualAccess Plus D-SNP HMO	Retrospective Review
UVM Health Advantage Select PPO	Retrospective Review
USA Care PPO	Potential for Retrospective Review
MVP SmartFund MSA	Retrospective Review
Healthy NY	Retrospective Review
MVP Premier	Retrospective Review
MVP Premier Plus	Retrospective Review
MVP Premier Plus HDHP	Retrospective Review
MVP Secure	Retrospective Review
MVP EPO	Retrospective Review
MVP EPO HDHP	Retrospective Review
Student Health Plans	Retrospective Review
ASO	See SPD
Vermont Products	300 31 2
POS In Plan	Retrospective Review
POS OOP	Retrospective Review
MVP Medicare Preferred Gold HMO POS	Retrospective Review
MVP Medicare Secure Plus HMO POS	Retrospective Review
MVP VT HMO	Retrospective Review
MVP VT HDHP HMO	Retrospective Review
MVP VT Plus HMO	Retrospective Review Retrospective Review
MVP VT Plus HMO MVP VT Plus HDHP HMO	Retrospective Review Retrospective Review
MVP Secure	Retrospective Review Retrospective Review
ASO ASO	·
ASU	See SPD

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Auth
Prior Authorization Required
Potential for Retrospective Review
No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Revision History:

04/01/2020: Moved 0002M and 0003M to investigational section as they have required retrospective review. Expanded the definition of noninvasive imaging that are considered investigational.

04/01/2023: Removed ASH FibroSure (0002M) and NASH FibroSure (0003M) from the indications section. Added ASH FibroSure to the exclusions, updated references.

01/01/2024 - 81517 added as experimental.

08/01/2024 – Removed HCV FibroSure (CPT Code: 81596), ASH FibroSure (Code: 0002M) and NASH FibroSure (Code: 0003M) because they are managed through the Serum Testing for Hepatic Fibrosis in the Evaluation and Monitoring of Chronic Liver Disease Payment Policy.



Obstructive Sleep Apnea: Devices

Type of Policy: Medical

Prior Approval Date: 10/03/2022

Approval Date: 10/07/2024

Effective Date: 12/01/2024

Related Polices: Durable Medical Equipment Medical Policy

Durable Medical Equipment Payment Policy

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

E0485- Oral device/appliance used to reduce upper airway collapsibility, adjustable or nonadjustable, prefabricated, includes fitting and adjustment

E0486- Oral device/appliance used to reduce upper airway collapsibility, adjustable or nonadjustable, custom fabricated, includes fitting and adjustment

E0530 - Electronic positional obstructive sleep apnea treatment, with sensor, includes all components and accessories, any type

Codes Subject to Retrospective Review

None

Experimental/Investigational

E0530 - Electronic positional obstructive sleep apnea treatment, with sensor, includes all components and accessories, any type

Common Diagnosis Codes

ICD-10 Diagnoses Codes: E67.2, E67.8, E68, Q75.0, Q75.1, Q75.3, Q75.4, Q75.8, Q75.9, Q87.0, G47.14, G47.30

Common Procedure Codes

CPT Code: 94660, A4604, A7027, A7028, A7029, A7030, A7031, A7032, A7033, A7034, A7035, A7036, A7037, A7038, A7039, A7044, A7045, A7046, A7047, E0470, E0471, E0472, E0561, E0562, E0601

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy.

Overview

For the purpose of this policy, the following definitions apply:

- apnea is defined as the cessation of airflow for at least 10 seconds;
- hypopnea is defined as an abnormal respiratory event lasting at least 10 seconds associated with at least a 30% reduction in thoracoabdominal movement or airflow as compared to baseline and with at least a 4% decrease in oxygen saturation;
- The apnea-hypopnea index (AHI) is defined as the average number of episodes of apnea and hypopnea per hour of sleep without the use of a positive airway pressure device.
- The respiratory disturbance index (RDI) is defined as the average number of apneas plus hypopneas per hour of recording without the use of a positive airway pressure device.
- The terms apnea-hypopnea index (AHI) and respiratory disturbance index (RDI) are used interchangeably in this policy;
- positive airway pressure (PAP) is a general term for devices that deliver positive airway pressure. Types of PAP devices include auto-titrating positive airway pressure (APAP), continuous positive airway pressure (CPAP), and bi-level positive airway pressure (BPAP); and
- oral appliances used to treat obstructive sleep apnea are devices placed in the mouth during sleep to prevent the collapse of the upper airway thus maintaining patency to allow adequate ventilation and prevent sleep apneic episodes.

Documentation Requirements

Documentation in the customer's medical record must indicate the medical necessity for the treatment requested and must include a face-to-face clinical evaluation including all of the following:

- signs and symptoms of sleep-disordered breathing including snoring, daytime sleepiness, observed apneas, choking or gasping during sleep, morning headaches; and
- duration of symptoms; and
- validated sleep hygiene inventory such as the Epworth Sleepiness Scale; and
- focused cardiopulmonary and upper airway system evaluation; and
- body mass index (BMI).

For continued coverage of CPAP, BPAP, or APAP the following must also be documented in the customer's record:

 documentation of adherence to PAP therapy shall be accomplished through direct download or visual inspection of usage data with documentation provided in a written report format to be reviewed by the treating physician and included in the customer's medical record.

Indications/Criteria

Customers must undergo auto-titration positive pressure (APAP) titration unless APAP titration is not appropriate. (Refer to MVP Obstructive Sleep Apnea: Diagnosis medical policy).

PAP for Adults (CPAP or APAP) (E0601)

A positive airway pressure (PAP) device is covered for the treatment of obstructive sleep apnea (OSA) if all of the following criteria are met:

- the patient has a face-to-face clinical evaluation by the treating physician prior to the sleep test to assess the patient for obstructive sleep apnea; and
- the patient has a sleep test that meets either of the following criteria:
 - the Apnea-hypopnea Index (AHI) or Respiratory Disturbance Index (RDI) is greater than or equal to 15 events per hour with a minimum of 30 events; or
 - the AHI or RDI is greater than or equal to 5 and less than or equal to 14 events per hour with a minimum of 10 events throughout the sleep test and documentation of:
 - excessive daytime sleepiness, impaired cognition, mood disorders, or insomnia; or
 - hypertension, ischemic heart disease, or history of stroke; and
- the patient and/or their caregiver have received instruction from the supplier of the PAP device and accessories in the proper use and care of the equipment; and

If a request for a PAP device is submitted and all of the criteria above have not been met, it will be denied as not medically necessary.

PAP for Children (E0601)

A positive airway pressure (PAP) device is covered for children one to 18 years of age for the treatment of obstructive sleep apnea (OSA) if all of the following criteria are met:

- documentation must include a complete medical history and physical examination;
 and
- children must be evaluated by an Ear Nose and Throat (ENT) specialist; and
- sleep study/polysomnogram must be ordered by an Ear, Nose, and Throat (ENT) specialist or a pediatric pulmonologist; and
- diagnosis of OSA must be confirmed by a sleep study/polysomnogram indicating one of the following:
 - one obstructive apneic event of any length per hour (e.g., an apnea hypopnea index greater than 1 event per hour); or
 - o any central apnea of any length associated with desaturation below 90%; and
- surgical correction with adenotonsillectomy is contraindicated, inappropriate, or has failed.

BPAP (E0470)

A BPAP without back-up rate is covered for those patients who qualify for CPAP (E0601) and, in addition, meet the following:

- a CPAP device has been tried and proven ineffective based on a therapeutic trial
 conducted in either a facility or in a home setting. If a CPAP device is tried and found
 ineffective during the initial three (3) month home trial, substitution of a BPAP device
 does not require a new initial face-to-face clinical evaluation or a new sleep test. If a
 CPAP device has been used for more than three months, and the patient is switched
 to a BPAP device, a new initial face-to-face clinical evaluation is required but a new
 sleep test is not required. A new three-month trial would begin for use of the BPAP
 device; or
- an APAP device has been tried and proven ineffective based on a therapeutic trial conducted in either facility or in a home setting.

Refer to Noridian, Corp LCD Respiratory Assist Devices (L33800) Document (Available: https://med.noridianmedicare.com/web/jadme/policies/lcd/active) for the qualifying coverage criteria of BiPAP and BIPAP ST (E0470, E0471) for the following diagnoses:

 Restrictive Thoracic Disorders (i.e., neuromuscular diseases or severe thoracic cage abnormalities)

- Severe chronic obstructive airway disease (COPD)
- Central Sleep Apnea (CSA or CompSA)
- Hypoventilation Syndrome

Sleep Tests

Coverage of CPAP, BPAP, or APAP devices for the treatment of OSA is limited to those customers with a diagnosis of OSA. The sleep test must be ordered by the customer's treating physician and conducted by an entity that qualifies as a provider of sleep tests and is in compliance with all applicable state regulatory requirements. Sleep studies done in a place of service other than the home require prior authorization. Refer to the MVP Obstructive Sleep Apnea-Diagnosis medical policy.

Continued Coverage Beyond the First Three Months of Therapy

Continued coverage of a PAP (E0601) device or <u>BPAP (E0470)</u> and/or a heated humidifier (E0562) or a non-heated (E0561) beyond the first three months of therapy requires documentation that the customer is benefiting from PAP therapy. Clinical benefit is demonstrated by:

- documentation that symptoms of obstructive sleep apnea are improved; and
- objective evidence of adherence to use of the PAP or BPAP device reviewed by the
 treating physician. Adherence to therapy is defined as use of PAP > 4 hours per night on
 70% of nights during a consecutive thirty (30) day period anytime during the first three (3)
 months of initial usage. If the above criteria are not met, continued coverage of a PAP
 device and related accessories will be denied as not medically necessary.

If the physician evaluation demonstrates that the patient is benefiting from PAP therapy as defined in the above criteria, coverage of the PAP device will continue. If a CPAP device is tried and found ineffective during the initial three-month home trial, substitution of a BPAP device does not change the length of the trial unless there is less than 30 days remaining in the trial period.

Adherence to therapy during the three-month trial with BPAP must be documented. If there is discontinuation of usage of a PAP device at any time, the supplier is expected to ascertain this and stop billing for the equipment and related accessories and supplies.

Oral Appliances (E0486)

All of the following criteria must be met for approval of an oral appliance:

- Face-to-face clinical evaluation by the treating physician prior to sleep test to assess for obstructive sleep apnea testing;
- Mild (AHI or RDI is 5 -14 events per hour) to moderate OSA (AHI or RDI is 15 30 events per hour) as confirmed by appropriate sleep testing;
- Device is ordered by the physician specializing in sleep medicine;

- Physician specializing in sleep medicine documents a failure of PAP therapy after a reasonable trial period, or documents that customer did not respond to PAP therapy, or customer cannot tolerate PAP therapy and reasons for intolerance, or PAP therapy is not appropriate treatment for the customer;
- Have no specific contraindications to the use of an oral appliance

Oral appliances are eligible for replacement at the end of their five-year reasonable useful lifetime. These items may be replaced prior to the end of the five-year reasonable useful lifetime in cases of loss, theft, or irreparable damage. Irreparable damage refers to a specific accident to a natural disaster (e.g., fire, flood). Replacement due to wear–and-tear as the result of everyday use will be denied as statutorily non-covered prior to expiration of the five-year reasonable useful lifetime.

Exclusions

- Positive airway pressure devices for the treatment of snoring without OSA are considered to be not medically necessary.
- Positive airway pressure devices for the treatment of upper airway resistance syndrome (UARS) are considered to be investigational.
- Use of oral appliances for customers with a diagnosis of OSA who are under eighteen (18) years of age.
- Abbreviated cardio-respiratory sleep study to acclimate an individual to PAP (e.g. PAP-Nap study, CPT Code 95807-52) is not covered as there is limited published medical literature that PAP-Nap studies improve adherence to therapy, therefore, it is considered experimental/investigational.
- Oral pressure therapy (Winx® Sleep Therapy System, HCPCS Code A7047 [mask], E0600 [pump console], A7002 [tubing]) is not covered as there is limited published medical literature that this system is effective for the treatment of obstructive sleep apnea.
- Positional sleep therapy devices (e.g., NightBalance Lunoa System) (HCPCS Code E0530) are considered investigational because there is insufficient evidence to demonstrate the safety and efficacy of this device in the treatment of obstructive sleep apnea.
- The monitoring feature/device, stand-alone or integrated, any type, including all accessories, components and electronics, not otherwise classified (HCPCS: A9279) is considered inclusive to the positive airway pressure device.
- Devices used to clean or sanitize the CPAP or BPAP devices are considered a convenience item and are ineligible for coverage (e.g., SoClean, SoClean 2 Go).

Medicare Variation

Oral Appliances

A custom fabricated mandibular advancement oral appliance (E0486) used to treat obstructive sleep apnea is covered when the following criteria are met:

- the customer has an in-person clinical evaluation by the treating physician prior to the sleep test to assess the customer for obstructive sleep apnea testing;
- the customer has a sleep test that meets one of the following criteria:
 - the apnea-hypopnea Index (AHI) or Respiratory Disturbance Index (RDI) is greater than or equal to 15 events per hour with a minimum of 30 events; or
 - the AHI or RDI is greater than or equal to 5 and less than or equal to 14 events per hour with a minimum of 10 events throughout the sleep tests and documentation of:
 - excessive daytime sleepiness, impaired cognition, mood disorders, or insomnia; or
 - hypertension, ischemic heart disease, or history of stroke; or
 - o if the AHI is greater than 30 or the RDI is greater than 30 and meets one (1) of the following criteria:
 - the customer is not able to tolerate a positive airway pressure (PAP) device; or
 - the treating physician determines that the use of a PAP device is contraindicated.
 - The device is ordered by the treating practitioner following a review of the report of the sleep test. (The practitioner who provides the order for the oral appliance could be different from the one who performed the clinical evaluation in criterion A.)
 - o The device is provided and billed for by a licensed dentist (DDS or DMD).

For full Medicare coverage details for oral appliances refer to the following LCD for Medicare Customers: Noridian Healthcare Solutions, LLC Local Coverage Determination (LCD) Oral Appliances for Obstructive Sleep Apnea (L33611). Revision effective date: 08/08/2021.

For full Medicare coverage details for positive airway pressure (PAP) Devices for the treatment of Obstructive Sleep Apnea refer to the following LCD for Medicare customers: Noridian Healthcare Solutions, LLC Local Coverage Determination (LCD) Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea (L33718).

References (Updated 2024)

- 1. American Academy of Pediatrics. Clinical practice guideline: Diagnosis and management of childhood obstructive sleep apnea syndrome. Pediatrics 2002;109(4):704-712.
- 2. American Academy of Sleep Medicine. Practice parameters for the use of autotitrating continuous positive airway pressure devices for titrating pressures and treating adult patients with obstructive sleep apnea. Sleep 2002;25(2):143-147.
- 3. Barone, D.A. Alternative devices for obstructive sleep apnea. Neurology: Clinical Practice. 2013 Feb; 3(1): 67-70.
- 4. Centers for Medicare & Medicaid Services (CMS). Medicare Coverage Database. NCD for Continuous Positive Airway Pressure (CPAP) Therapy for Obstructive Sleep Apnea (OSA). (240.4) Mar 13, 2008. Available: Medicare Coverage Database Search
- 5. Collop, N.A., Anderson, W.M., Boehlecke, B., et al. Clinical guidelines for the use of unattended monitors in the diagnosis of obstructive sleep apnea in adult patients. Portable Monitoring Task Force of the American Academy of Sleep Medicine. *JCSM Journal of Clinical Sleep Medicine*, Vol. 3 No 7, 2007.
- 6. Colrain IM, Black J, Siegel LC, Bogan RK, Becker PM, Farid-Moayer M, et al. A multicenter evaluation of oral pressure therapy for the treatment of obstructive sleep apnea. Sleep Med. 2013 Sep; 14(9):830-7.
- 7. DiFeo N, et al. Predictors of positive airway pressure therapy adherence in children: a prospective study. J Clin Sleep Med 2012 Jun 15;8(3):279-286.
- 8. Farid-Moayer, M., et al. A feasibility evaluation of oral pressure therapy for the treatment of obstructive sleep apnea. Ther Adv Respir Dis. 2013 Feb; 7(1):3-12.
- 9. Farid-Moayer, M., et al. Oral pressure therapy for the treatment of obstructive sleep apnea: clinical feasibility. Nature & Science Sleep. 2013 5:53-9.
- 10. Ferguson, K.A., Cartwright, R., Rogers, R., et al. Oral appliances for snoring and obstructive sleep apnea: A review. *Sleep*, Vol. 29, No.2, 2006.
- 11. Gao, W. et al. Is automatic CPAP titration as effective as manual CPAP titration in OSAHS patients? A meta-analysis. Sleep Breath. 2012 Jun; 16 (2):329-40.
- 12. Hayes Health Technology Assessment. NightBalance (Philips) for the Treatment of Positional Obstructive Sleep Apnea. HAYES, Inc.; © 2021 Hayes, a symplr company.. December 6, 2021. Available: https://www.hayesinc.com/
- 13. HAYES Health Technology Assessment. Comparative Effectiveness Review Of Mandibular Advancement Devices For Sleep Apnea: A Review Of Reviews. HAYES, Inc.; © 2021 Hayes, a symplr company. September 20, 2018. Annual Review October 25, 2021.

- 14. InterQual® Clinical Decision Support Criteria. McKesson Health Solutions LLC, Copyright © 2021 McKesson Corporation.
- 15. Krakow B, Ulibarri V, Melendex D, Kikta S, Togami L, Haynes P. A daytime, abbreviated cardio-respiratory sleep study (CPT 95807-52) to acclimate insomnia patients with sleep disordered breathing to positive airway pressure (PAP-NAP). J Clin Sleep Med. 2008 Jun 15; 4(3):212-22.
- 16. Kushida, C.A., Chediak, A., Berry, R.B., et al. Clinical guidelines for the manual titration of positive airway pressure in patients with obstructive sleep apnea. Positive Airway Pressure Titration Task Force of the American Academy of Sleep Medicine. JCSM Journal of Clinical Sleep Medicine, Vol. 4. No.2, 2008.
- 17. Marcus, CL., et al. Diagnosis and management of childhood obstructive sleep apnea syndrome. Pediatrics. 2012; 130:576-584.
- 18. Morgenthaler, T.I., et al. Practice Parameters for the Use of Auto titrating Continuous Positive Airway Pressure Devices for Titrating Pressures and Treating Adult Patients with Obstructive Sleep Apnea Syndrome. An American Academy of Sleep Medicine Report (AASM). Sleep; 2008; 31(1): 141-147.
- 19. NHIC, Corp. LCD for Oral Appliances for Obstructive Sleep Apnea (L33611). Revision Effective Date 08/08/2021. Available: Medicare Coverage Database Search
- 20. NHIC, Corp. LCD for Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea (L33718). Original Effective Date: 10/01/2015. Available: Medicare Coverage Database Search
- 21. Noridian Healthcare Solutions, LLC. Article for Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea Policy Article (A52467). Updated January 2020. Available: Medicare Coverage Database Search
- 22. Noridian Healthcare Solutions, LLC. Local Coverage Article for Respiratory Assist Devices (A52517). Revision Effective Date 01/01/2020. Available: Medicare Coverage Database Search
- 23. Nussbaumer, Y., et al. Equivalence of auto adjusted and constant continuous positive airway pressure in home treatment of sleep apnea. Chest. 2006. Mar; 129(3):638-43.
- 24. Patil SP, et al. Treatment of adult obstructive sleep apnea with positive airway pressure: An American Academy of Sleep Medicine Clinical Practice Guideline. J Clin Sleep Med 2019 Feb 15;15(2):335-343.

Customer Product	Medical Management Requirements*
New York Products	-
HMO	Prior Auth
PPO in Plan	Prior Auth
PPO OOP	Prior Auth
POS In plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Prior Auth
MVP Child Health Plus	Prior Auth
MVP Harmonious Health Care Plan	Prior Auth
MVP Medicare Complete Wellness	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP Medicare WellSelect PPO	Prior Auth
MVP Medicare WellSelect Plus PPO	Prior Auth
MVP Medicare Patriot Plan PPO	Prior Auth
MVP DualAccess D-SNP HMO	Prior Auth
MVP DualAccess Complete D-SNP HMO	Prior Auth
MVP DualAccess Plus D-SNP HMO	Prior Auth
UVM Health Advantage Select PPO	Prior Auth
USA Care PPO	Potential for Retrospective Review
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	
POS in Plan	Prior Auth
POS OOP	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP VT HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD

[♦] Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Revision History:

12/01/2022 – Annual review; prior authorization removed from E0470, E0471, E0472, E0562, E0601. References updated. Provent exclusion removed as technology has been discontinued.

01/01/2024 - K1001 replaced with E0530.

12/01/2024 – Annual review for policy. Added exclusions for monitoring devices and cleaning devices, updated Medicare section to match Medicare criteria, updated references.



Obstructive Sleep Apnea: Diagnosis and Other Sleep Disorders

Type of Policy: Medical

Prior Approval Date: 10/04/2024

Approval Date: 12/02/2024

Effective Date: 04/01/2025

Related Polices: Obstructive Sleep Apnea: Devices

Obstructive Sleep Apnea: Surgical

Treatment

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

CPT Codes: None

Codes Subject to Retrospective Review

CPT Codes:

95803 - Actigraphy testing, recording, analysis, interpretation, and report (minimum of 72 hours to 14 consecutive days of recording)

Experimental/Investigational

CPT Codes:

95803 - Actigraphy testing, recording, analysis, interpretation, and report (minimum of 72 hours to 14 consecutive days of recording)

95807 -Sleep study, simultaneous recording of ventilation, respiratory effort, ECG or heart rate, and oxygen saturation, attended by a technologist

Common Diagnosis Codes

ICD-10 Diagnosis Codes: F51.3, F51.4, F51.5, F51.8, F51.8, G47.10, G47.11, G47.12, G47.30, G47.31, G47.33, G47.34, G47.35, G47.36, G47.37, G47.39, G47.50, G47.51, G47.52,

G47.61, G47.411, G47.429, G47.421, G47.30, G47.14, G47.30, G47.10, G47.8, G47.30, R06.3

Common Procedure Codes

CPT Codes: 95782, 95783, 95800, 95801, 95805, 95806, 95808, 95810, 95811

HCPCS Code: G0398, G0399, G0400 (Home Sleep Tests)

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy.

Overview

Home sleep studies may be used for patients with increased risk of moderate to severe obstructive sleep apnea. Studies on home sleep tests have shown that home sleep studies may underestimate the severity of sleep disordered breathing in patients with a low risk of moderate to severe obstructive sleep apnea and, therefore, facility testing could be indicated. Multiple Sleep Latency Test requests will require comprehensive review.

Sleep studies use technology to monitor the course of the sleep cycle and aid in determining the following:

- to identify patients with sleep apnea syndrome;
- to establish the precise factors responsible for the apnea;
- to determine the most appropriate treatment strategy; and
- to identify patients with narcolepsy.

Standard overnight polysomnography involves continuous monitoring and recording of physiologic and neurologic data during sleep to diagnose sleep disorders.

A split-night sleep study utilizes the first two or three hours for evaluating the presence of sleep apnea and the second half to titrate and adjust positive airway pressure (PAP). The same monitoring modalities used in the full-night PSG are used in the split-night study.

A Multiple Sleep Latency Test (MSLT) measures the speed of falling asleep under conditions that favor sleep in a series of 20-minute trials during the patient's habitual periods of wakefulness. MSLT is the method of establishing the presence of true physiologic sleepiness but must follow strict protocols. MSLT is used in patients with complaints of irresistible daytime sleepiness suggestive of narcolepsy.

A Maintenance of Wakefulness Test (MWT) measures the patient's ability to stay awake and alert during a defined period of time.

This policy addresses sleep studies for the diagnosis of obstructive sleep apnea and narcolepsy. Refer to the MVP Obstructive Sleep Apnea Devices medical policy for autotitrating positive airway pressure (APAP), continuous positive airway pressure (CPAP), and bi-level positive airway pressure (BPAP).

Indications/Criteria

Home/Portable Sleep Study and Sleep Lab-based Polysomnography (PSG) for adults are indicated when any of the following are met:

- evidence of sleepiness based on excessive daytime sleepiness, and
- evidence suggestive of sleep disordered breathing based on 2 out of 3 of the following:
 - loud disruptive snoring, or
 - o witnessed apnea events, choking or gasping during sleep, or
 - diagnosed hypertension

A consultation for a sleep study by a sleep medicine specialist (Boarded Sleep Specialist) may be appropriate but is not required for a home sleep test (HST).

Only a specifically contracted vendor or provider for home polysomnography will be allowed to perform home sleep tests.

A home sleep test is the preferred first line test, even in a population for moderate to severe sleep apnea. In the event that a home sleep test is negative or equivocal, an in-lab study would be approved.

The presence of any one of the following co-morbid conditions or complicating factors supports the necessity of lab-based sleep testing:

- documented unexplained pulmonary hypertension; or
- heart failure; or
- cardiac arrhythmia such as atrial fibrillation or ventricular dysrhythmias; or
- symptomatic lung disease not controlled by medical therapy; or
- evidence of chronic respiratory failure with either elevated levels of CO₂, or O₂ requirements; or
- history of prior stroke or
- previous diagnosis of central or complex sleep apnea; or
- BMI ≥ 40 (candidates for bariatric surgery); or

- suspicion of nocturnal seizures; or
- neurogenic disorder resulting in neuromuscular weakness or cognitive impairment restricting activities of daily living such that a home sleep study is unable to be performed; or
- sustained complex disruptive sleep behaviors, not recalled by the member, that are suspicious of REM behavior sleep disorder (parasomnia, severe insomnia); or
- chronic opiate medication use; or
- less than 18 years of age; or
- suspected narcolepsy or idiopathic hypersomnolence, or other suspected sleep disorders not indicative of obstructive sleep apnea (for initial diagnostic study only: CPT codes 95808, 95810); or
- environmental or personal factors that preclude the adequate data acquisition (homelessness, psychiatric disorder, alcohol abuse, etc.)
- follow-up testing for home sleep study with negative results.

All patients undergoing standard sleep lab-based overnight polysomnography for the purpose of diagnosing obstructive sleep apnea should be considered potential candidates for "Split-Night Polysomnography" which is utilized for the diagnosis and treatment of patients with severe Obstructive Sleep Apnea as a means of expediting treatment in this subset of patients while optimizing resources. Patients who demonstrate 40 apneas within the first two hours of sleep are candidates for CPAP/Bi-Level titration. PAP Titration must be done for a minimum of 3 hours.

<u>Polysomnography (PSG)/Sleep Studies for Children</u> are indicated when one of the following criteria for sleep or daytime symptoms is met:

- sleep symptoms including snoring, difficulty breathing, choking sounds, heavy sweating, abnormal motor activity, and possible bed wetting at an inappropriate age; or
- children with clinical with clinical evidence of adenoid or tonsil hypertrophy and daytime symptoms including sleepiness, irritability, hyperactivity, disciplinary problems, learning problems, and headaches; or
- one apparent life-threatening event (ALTE) characterized by cyanosis, pallor, limpness and/or stiffness, cessation of breathing resulting in vigorous shaking or mouth to mouth resuscitation, a pediatric sleep study would be indicated without need for other criteria.

Polysomnogram/sleep studies for children must be ordered by an otolaryngologist, sleep specialist, pediatric neurologist or pediatric pulmonologist.

Multiple Sleep Latency Test (MSLT) is indicated in patients with any of the following:

- suspected narcolepsy≥8 weeks; or
- excessive daytime sleepiness with involuntary daytime sleep episodes (i.e., falling asleep while driving, eating, amnesic episodes) ≥8 weeks; or
- cataplexy; or
- other REM phenomena (i.e., sleep paralysis and hypnagogic hallucinations).

Maintenance of Wakefulness Testing (MWT) is indicated in patients with the following:

- an individual who is unable to stay awake, resulting in a safety issue; or
- assessing response to treatment in individuals with narcolepsy or idiopathic hypersomnia

The diagnosis of narcolepsy is confirmed by an overnight polysomnogram followed immediately by a MSLT.

The MSLT or MWT always follows a facility-based PSG (95810) or full night titration (95811) during which the individual's sleep adequacy is objectively measured.

Auto-titration Positive Airway Pressure (APAP) Titration and Therapy Initiation

Members must undergo auto-titration positive pressure titration (APAP) unless APAP titration is not appropriate or contraindicated.

APAP titration is indicated when all the following criteria are met:

- the patient has a face-to-face clinical evaluation by the requesting or treating physician prior to the sleep test to assess the patient for suspected obstructive sleep apnea; and
- the patient has a sleep test that yields either of the following diagnostic results:
 - the Apnea-hypopnea Index (AHI) or Respiratory Disturbance Index (RDI) is greater than or equal to 15 events per hour with a minimum of 30 events; or
 - the AHI or RDI is greater than or equal to five and less than or equal to 14 events per hour with a minimum of 10 events throughout the sleep test and documentation of one of the following:
 - excessive daytime sleepiness, impaired cognition, mood disorders, insomnia;
 or

hypertension, ischemic heart disease, or history of stroke.

APAP titration is not appropriate for members with any of the following:

- member presents with any one of the co-morbid conditions or complicating factors listed in the Indication/Criteria section above; or
- during the sleep study (home sleep study or sleep lab-based polysomnography) it is identified that the member has central apnea; or

 during the sleep study (home sleep study or sleep lab-based polysomnography) it is identified that the member has a decrease in O2 saturations and supplemental oxygen is required.

Exclusions

- Sleep lab-based polysomnography unless the member has a co-morbidity or complicating factor listed in the Indications/Criteria section.
- Home sleep studies are not indicated for children under 18 years old.
- Actigraphy, (CPT 95803) a method of monitoring motor activity during an in-lab polysomnograph, is considered to be investigational for all indications.
- Peer reviewed evidence does not support that polysomnography for the diagnosis of chronic insomnia provides definitive diagnostic data or that such information is useful in-patient treatment or is associated with improved clinical outcome. The use of polysomnography for the diagnosis of patients with chronic insomnia is not covered because it is not medically necessary.
- Abbreviated cardio-respiratory sleep study to acclimate an individual to PAP (e.g., PAP-Nap study, CPT Code 95807) is considered experimental/investigational as there is limited published medical literature that PAP-Nap studies improve adherence to therapy.
- Multiple Sleep Latency Test (MSLT) or Maintenance of Wakefulness Testing (MWT) for the diagnosis of Obstructive Sleep Apnea (OSA) is considered not medically necessary.
- Use of the Home Pulse Oximetry for the detection of sleep apnea.
- Use of the Eccovision Acoustic Pharyngometer.
- Use of Type IV home sleep study (measuring less than 3 channels).

Medicare Variation

For the diagnosis of obstructive sleep apnea, Medicare covers a home/portable sleep study or sleep lab-based polysomnography (PSG).

Sleep testing devices measuring three or more channels that include actigraphy (95803) is covered.

Nationally Non-Covered Indications:

Other diagnostic sleep tests for the diagnosis of OSA, other than those noted above for prescribing CPAP, are not sufficient for the coverage of CPAP and are not covered.

For details and full National Coverage Determination (NCD) go to:

Centers for Medicare & Medicaid Services (CMS). Medicare Coverage Database. NCD for Sleep Testing for Obstructive Sleep Apnea (OSA) (240.4.1) Mar 3, 2009. Available: https://www.cms.gov/

Medicaid Variation

For the diagnosis of obstructive sleep apnea, Medicaid covers a home/portable sleep study or sleep lab-based polysomnography (PSG).

References (Updated 2024)

- 1. Kapur VK, et al. Clinical practice guideline for diagnostic testing for adult obstructive sleep apnea: an American Academy of Sleep Medicine clinical practice guideline. J Clin Sleep Med. 2017;13(3):479-504.
- 2. Schectner, M., et al. American Academy of Pediatrics. Technical report: Diagnosis and management of obstructive sleep apnea syndrome. Pediatrics. 2002 Apr; 109(4): 1-41.
- 3. Morgenthaler, T.I., et al. Practice Parameters for the Treatment of Narcolepsy and other Hypersomnia of Central Origin. An American Academy of Sleep Medicine Report. Sleep Vol.30 No 12, 2007.
- 4. Collop, N.A., Anderson, W.M., Boehlecke, B., et al. Clinical guidelines for the use of unattended monitors in the diagnosis of obstructive sleep apnea in adult patients. Portable Monitoring Task Force of the American Academy of Sleep Medicine. JCSM Journal of Clinical Sleep Medicine, Vol. 3 No 7, 2007.
- 5. Agency for Healthcare and Research Quality, Technology Assessment. Home diagnosis of Obstructive Sleep Apnea-Hypopnea Syndrome. Tufts-New England Medical Center EPC, 2007. Technology Assessment Program.
- Flemons, W.W., et al. Home diagnosis of sleep apnea: a systematic review of the literature. An evidence review co-sponsored by the American Academy of Sleep Medicine, the American College of Chest Physicians, and the American Thoracic Society. Chest. 2003 Oct; 124(4); 1543-79.
- Centers for Medicare & Medicaid Services (CMS). Medicare Coverage Database. NCD for Sleep Testing for Obstructive Sleep Apnea (OSA) (240.4.1) Mar 3, 2009. Available: https://www.cms.gov/.
- 8. Centers for Medicare & Medicaid Services (CMS): Medicare Coverage Database: LCD for Polysomnography and Sleep Studies Medical Policy Article (A53019) Effective: 10/01/2015 Revision: 10/31/2019 Available: https://www.cms.gov/.
- 9. NHIC, Corp. Local Coverage Determination (LCD) for Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea (L11528). Revision Effective Date: August 2, 2011.

- 10. Morgenthaler, T.I., et al. Practice Parameters for the Use of Auto titrating Continuous Positive Airway Pressure Devices for Titrating Pressures and Treating Adult Patients with Obstructive Sleep Apnea Syndrome. An American Academy of Sleep Medicine Report (AASM). Sleep; 2008; 31(1): 141-147.
- 11. Epstein, LJ., et al. Clinical Guideline for the Evaluation, Management and Long Term Care of Obstructive Sleep Apnea in Adults. Adult Obstructive Sleep Apnea Task Force of the American Academy of Sleep Medicine Journal of Clinical Sleep Medicine, Vol 5, No. 3 2009: 263-276.
- 12. Aurora, RN., et al. Practice Parameters for the Respiratory Indications for Polysomnography in Children. An American Academy of Sleep Medicine Report (AASM). Sleep; 2011; 34(3): 379-388.
- 13. Beck, SE. and Marcus, CL. Pediatric Polysomnography. Sleep Med Clinic. 2009. September; (3): 393-406.
- 14. Marcus, CL., et al. Diagnosis and management of childhood obstructive sleep apnea syndrome. Pediatrics. 2012; 130:576-584.
- 15. Mokhlesi, B., Obesity Hypoventilation Syndrome: A state of the art review. Respir Care. 2010; 55(10) 1347-1362.
- 16. Casey, K., et al. Sleep-related hypoventilation/hypoxemia syndromes. Chest 2007; 131:1936-1948.
- 17. Morgenthaler T, Alessi C, Friedman L, Owens J, Kapur V, Boehlecke B, et al. Standards of Practice Committee, American Academy of Sleep Medicine. Practice parameters for the use of actigraphy in the assessment of sleep and sleep disorders: an update for 2007. Sleep. 2007 Apr 1; 30(4):519-29.
- 18. Sadeh A. The role and validity of actigraphy in sleep medicine: an update. Sleep Med Rev 2011 Aug; 15(4):259-67.
- 19. HAYES Health Technology Assessment. Actigraphy For Diagnosis Of Obstructive Sleep Apnea Syndrome In Adults. HAYES, Inc.; © 2021 Hayes, a symplr company. August 17, 2008. ARCHIVED: May 17, 2013 Available: www.hayesinc.com.
- 20. Littner M, Hirshkowitz M, Kramer M, Kapen S, Anderson WM, Bailery D, et al. Practice parameters for using polysomnography to evaluate insomnia: an update. Sleep. 2003 Sep; 26(6):754-60.
- 21. Liesching T, Carlisle C, Marte A, Millman R. Evaluation of the accuracy of SNAP technology sleep sonography in detecting obstructive sleep apnea in adults compared to standard polysomnography. Chest. 2004 Mar; 125(3):7-11.
- 22. Collop NA, Tracy SL, Kapur V, et al. Obstructive Sleep Apnea Devices for Out-Of-Center (OOC) Testing: Technology Evaluation. J Clin Sleep Med. 2011 Oct 15; 7(5):531-48.

- 23. Hall, L., et al. Evaluation and management of apparent Life Threatening events in children. American Family Physician. 2005. June 15:71(12): 2301-2308.
- 24. Chihorek AM, Abou-Khalil B, Malow BA. Obstructive sleep apnea is associated with seizure occurrence in older adults with epilepsy. Neurology. 2007;69(19):1823-1827.
- 25. Choi, JB., et al. Does obstructive sleep apnea increase hematocrit? Sleep Breath. 2006 Sep; 10(3):155-60.
- 26. Beutler, E. Chapter 61 Polycythemia. Hematology. December 2011. Available: http://medtextfree.wordpress.com/2011/12/30/chapter-61-polycythemia/.
- 27. Kuna ST, Gurubhagavatula I, Maislin G, Hin S, Hartwig KC, McCloskey S, Hachadoorian R, et al. Non-inferiority of functional outcome in ambulatory management of obstructive sleep apnea. Am J Respir Crit Care Med. 2011 May 1; 183(9):1238-44. Epub 2011 Jan 21.
- 28. Krakow B, Ulibarri V, Melendex D, Kikta S, Togami L, Haynes P. A daytime, abbreviated cardio-respiratory sleep study (CPT 95807-52) to acclimate insomnia patients with sleep disordered breathing to positive airway pressure (PAP-NAP). J Clin Sleep Med. 2008 Jun 15; 4(3):212-22.
- 29. Berry RB, Hill G, Thompson L, Mclaurin V. Portable monitoring and autotitration versus polysomnography for the diagnosis and treatment of sleep apnea. Sleep. 2008;31(10):1423-1431.
- 30. Rosen CL, Auckley D, Benca R, et al. A multisite randomized trial of portable sleep studies and positive airway pressure autotitration versus laboratory based polysomnography for the diagnosis and treatment of obstructive sleep apnea: the HomePAP study. Sleep. 2012;35(6):757-767.
- 31. Skomro RP, Gjevre J, Reid J, et al. Outcomes of home-based diagnosis and treatment of obstructive sleep apnea. Chest. 2010;138(2):257-263.
- 32. HAYES Health Technology Assessment. Actigraphy For Diagnosis Of Circadian Rhythm Sleep Disorders. HAYES, Inc.; © 2021 Hayes, a symplr company. November 17, 2010. ARCHIVED: December 17, 2015. Available: www.hayesinc.com.
- 33. HAYES Health Technology Assessment. Home Sleep Studies For Diagnosis Of Obstructive Sleep Apnea Syndrome In Patients Younger Than 18 Years Of Age. HAYES, Inc.; © 2021 Hayes, a symplr company. October 5, 2012. Annual Review September 12, 2016. Archived November 5, 2017.

Member Product	Medical Management Requirements*
New York Products	
HMO	Retrospective Review
PPO In Plan	Retrospective Review
PPO OOP	Retrospective Review
POS In Plan	Retrospective Review
POS OOP	Retrospective Review
Essential Plan	Retrospective Review
MVP Medicaid Managed Care	Retrospective Review
MVP Child Health Plus	Retrospective Review
MVP Harmonious Health Care Plan	Retrospective Review
MVP Medicare Complete Wellness	Retrospective Review
MVP Medicare Preferred Gold HMO POS	Retrospective Review
MVP Medicare Secure HMO POS	Retrospective Review
MVP Medicare WellSelect PPO	Retrospective Review
MVP Medicare WellSelect Plus PPO	Retrospective Review
MVP Medicare Patriot Plan	Retrospective Review
MVP SmartFund MSA	Retrospective Review
USACare PPO	Retrospective Review
MVP DualAccess D-SNP HMO	Retrospective Review
MVP DualAccess Complete D-SNP HMO	Retrospective Review
MVP DualAccess Plus D-SNP HMO	Retrospective Review
UVM Health Advantage Select PPO	Retrospective Review
Healthy NY	Retrospective Review
MVP Secure	Retrospective Review
MVP EPO	Retrospective Review
MVP EPO HDHP	Retrospective Review
MVP PPO	Retrospective Review
MVP PPO HDHP	Retrospective Review
Student Health Plan	Retrospective Review
ASO	See SPD
Vermont Products	
POS In Plan	Retrospective Review
POS OOP	Retrospective Review
MVP Medicare Preferred Gold HMO POS	Retrospective Review
MVP Medicare Secure Plus HMO POS	Retrospective Review
MVP Medicare WellSelect PPO	Retrospective Review
MVP SmartFund MSA	Retrospective Review
MVP VT HMO	Retrospective Review
MVP VT HDHP HMO	Retrospective Review
MVP VT Plus HMO	Retrospective Review
MVP Secure	Retrospective Review
ASO	See SPD
AND	366 31 D

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Auth Potential for Retrospective Review Retro Review Not Covered See SPD Prior Authorization Required
No Prior Authorization Required. May be subject to Retrospective Review
Retrospective Review Required
Service is not a covered benefit
See Specific Plan Design

Revision History:

10/1/2022 – Annual review, references updated.

04/01/2023- Prior Auth removed from 95805.

04/01/2024 – Remove facility-based sleep studies (CPT Codes: 95808, 95810, 95811, 95807) from prior authorization for all lines of business.

10/01/2024 – Removed exclusion for Medicaid for home sleep studies.

04/01/2025 - Completed formal review of changes effective 10/01/2024.



Obstructive Sleep Apnea: Surgical Treatment

Type of Policy: Surgical

Prior Approval Date: 01/20/2025

Approval Date: 03/28/2025

Effective Date: 06/01/2025

Related Policies: Obstructive Sleep Apnea: Diagnosis

Obstructive Sleep Apnea: Devices

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

CPT Codes:

42145 - Palatopharyngoplasty (eg, uvulopalatopharyngoplasty, uvulopharyngoplasty).

Codes Subject to Retrospective Review as Experimental and Investigational

CPT Codes:

33276 – Insertion of phrenic nerve stimulator system [pulse generator and stimulating lead(s)], including vessel catheterization, all imaging guidance, and pulse generator initial analysis with diagnostic mode activation, when performed

33277 – Insertion of phrenic nerve stimulator transvenous sensing lead

33278 – Removal of phrenic nerve stimulator, including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; system, including pulse generator and lead(s)

33279 – Removal of phrenic nerve stimulator, including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; transvenous stimulation or sensing lead(s) only

33280 – Removal of phrenic nerve stimulator, including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; pulse generator only

Obstructive Sleep Apnea: Surgical Treatment

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33281 – Repositioning of phrenic nerve stimulator transvenous lead(s)

33287 – Removal and replacement of phrenic nerve stimulator, including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; pulse generator

33288 – Removal and replacement of phrenic nerve stimulator, including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; transvenous stimulation or sensing lead(s)

41512 - Tongue base suspension, permanent suture technique

41530 – Submucosal ablation of the tongue base, radiofrequency, 1 or more sites, per session

93150 - Therapy activation of implanted phrenic nerve stimulator system, including all interrogation and programming

93151 - Interrogation and programming (minimum one parameter) of implanted phrenic nerve stimulator system

93152 - Interrogation and programming of implanted phrenic nerve stimulator system during polysomnography

93153 - Interrogation without programming of implanted phrenic nerve stimulator system

HCPCS Codes:

C9727 – Insertion of implants into the soft palate; minimum of three implants

S2080 - Laser-assisted uvulopalatoplasty (LAUP)

Common Diagnosis Codes

N/A

Common Procedure Codes

CPT Codes:

64582- Open implantation of hypoglossal nerve neurostimulator array, pulse generator, and distal respiratory sensor electrode or electrode array

64583 - Revision or replacement of hypoglossal nerve neurostimulator array and distal respiratory sensor electrode or electrode array

64584 - Removal of hypoglossal nerve neurostimulator array, pulse generator, and distal respiratory sensor electrode or electrode array

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are

Obstructive Sleep Apnea: Surgical Treatment

Overview

When patients with obstructive sleep apnea are not able to achieve benefit with non-invasive positive pressure therapy (PAP) or fail the standard treatment in the form of continuous positive airway pressure (CPAP) a second-line treatment may be a surgical option. This policy is addressing some surgical treatment options for obstructive sleep apnea including emerging procedures.

Uvulopalatopharyngoplasty (UPPP) is performed as an outpatient procedure under general anesthesia. It is used to treat obstructive sleep apnea (OSA) by enlarging the oropharynx. It may be done with or without a laser assist for enlarging the upper airway, specifically the oropharyngeal region by removal of the tonsils and partial removal/resectioning of the soft palate, uvula and pharyngeal arches for the treatment of snoring and obstructive sleep apnea.

Mandibular Maxillary Osteotomy (MMO) and Advancement is a procedure that modifies the airway space by advancing the maxilla, the mandible, and therefore, the tongue. The procedure is used to correct retrolingual or hypopharyngeal obstruction and is usually performed after no response to CPAP and a failed uvulopalatopharyngoplasty. Mandibular maxillary osteotomy is not generally considered as initial therapy.

Phrenic Nerve Stimulator (PNS), also known as diaphragm pacing, is the electrical stimulation of the phrenic nerve using a surgically implanted device. The remedē System (Zoll Medical Corporation) is a fully implanted neurostimulator intended for treatment of moderate-to-severe Central Sleep Apnea in adults.

Indications/Criteria

<u>Uvulopalatopharyngoplasty</u>

Requests for uvulopalatopharyngoplasty surgical treatment require **all** the following documentation:

- a diagnosis of obstructive sleep apnea/hypopnea confirmed by sleep studies/polysomnogram; and
 - o the apneic/hypopneic (AHI/AI) events must be 10 seconds or greater with \geq 15 episodes per hour of sleep; or
 - o apneic/hypopneic events > 5 and < 14 episodes occurring per hour of sleep with documented symptoms of **one** of the following:
 - excessive daytime sleepiness;
 - impaired cognition;
 - mood disorder;
 - insomnia:

Obstructive Sleep Apnea: Surgical Treatment

- documented hypertension;
- ischemic heart disease; or
- history of stroke; and
- documentation of failure of a trial of alternative medical therapy with CPAP or BPAP under the direction of a sleep lab director, pulmonary, neurological, or otolaryngological physician; and
- documentation of failure to demonstrate significant improvement of sleep apnea syndrome with medical therapy (weight loss, medications, etc.); and
- evidence or retropalatal or combination retropalatal/retrolingual obstruction as the cause of obstructive sleep apnea.

Mandibular Maxillary Osteotomy and Advancement

Mandibular maxillary osteotomy and advancement is covered when all the criteria for uvulopalatopharyngoplasty are met and:

 evidence of retrolingual obstruction as the cause of the obstructive sleep apnea, or previous failure of uvulopalatopharyngoplasty to correct the obstructive sleep apnea.

Hypoglossal Nerve Stimulation

Hypoglossal nerve stimulation using a U.S. Food and Drug Administration (FDA) approved hypoglossal nerve stimulator may be considered medically necessary in adults with OSA under the following conditions:

- Hypoglossal Nerve Stimulation is covered for members according to the following coverage indications:
- FDA-approved hypoglossal nerve neurostimulation is considered medically reasonable and necessary for the treatment of moderate to severe obstructive sleep apnea when all of the following criteria are met:
- Beneficiary is 22 years of age or older; and
- Body mass index (BMI) is less than 35 kg/m2; and
- A polysomnography (PSG) is performed within 24 months of first consultation for HGNS implant; and
- Beneficiary has predominantly obstructive events (defined as central and mixed apneas less than 25% of the total AHI); and
- AHI is 15 to 65 events per hour; and
- Beneficiary has documentation that demonstrates CPAP failure (defined as AHI greater than 15 despite CPAP usage) or CPAP intolerance (defined as less than 4 hours per night, 5 nights per week or the CPAP has been returned) including

- shared decision making that the patient was intolerant of CPAP despite consultation with a sleep expert; and
- Absence of complete concentric collapse at the soft palate level as seen on a drug-induced sleep endoscopy (DISE) procedure (31575); and
- No other anatomical findings that would compromise performance of device (e.g., tonsil size 3 or 4 per standardized tonsillar hypertrophy grading scale).

Exclusions

- Treatment for Upper Airway Resistance Syndrome/Snoring for the treatment of Obstructive Sleep Apnea is considered investigational as the peer-reviewed medical literature has not been proven to improve health outcomes, and therefore not covered.
- Laser assisted uvulo-palatoplasty (S2080) for the treatment of Obstructive Sleep Apnea is considered investigational as the peer-reviewed medical literature has not been proven to improve health outcomes, and therefore not covered.
- Submucosal Radiofrequency Tissue Volume Reduction/Somnoplasty (41530) for the treatment of Obstructive Sleep Apnea is considered investigational as the peerreviewed medical literature has not been proven to improve health outcomes, and therefore not covered.
- Cautery-assisted Palatal Stiffing Operation (CAPSO) for the treatment of Obstructive Sleep Apnea is considered investigational as the peer-reviewed medical literature has not been proven to improve health outcomes, and therefore not covered.
- Pillar™ Palatal Implant System (C9727) for the treatment of Obstructive Sleep Apnea is considered investigational as the peer-reviewed medical literature has not been proven to improve health outcomes, and therefore not covered.
- The AIRVance System (41512) for the treatment of Obstructive Sleep Apnea is considered investigational as the peer-reviewed medical literature has not been proven to improve health outcomes, and therefore not covered.
- Central Sleep Apnea (CSA) surgical treatments including, but may not be limited to, phrenic nerve stimulation (e.g., remede System) are considered investigational as the peer-reviewed medical literature has not been proven to improve health outcomes, and, therefore, are not covered. (CPT Codes: 33276, 33277, 33278, 33279, 33280, 33281, 33287, 33288, 93150, 93151, 93152, 93153)

Medicare Variation

For full CMS/Medicare coverage and limitation details refer to the following Medicare Local Coverage Determination (LCD): Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea (L38387) Original Effective Date: 04/01/2020

Medicaid Variation

Obstructive Sleep Apnea: Surgical Treatment

Hypoglossal Nerve Stimulation is covered for the following conditions:

- Individuals 13 years of age through 17 years of age with Down Syndrome and a diagnosis of moderate to severe OSA with inability to tolerate PAP therapy or has failed PAP therapy.
- Individuals 18 years of age and over with a diagnosis of moderate to severe OSA and inability to tolerate PAP therapy or has failed PAP therapy.

References (Updated 2025)

- Caples SM, Rowley JA, Prinsell JR, Pallanch JF, Elamin MB, Katz SG, Harwick JD.
 Surgical modifications of the upper airway for obstructive sleep apnea in adults: a
 systematic review and meta-analysis. Sleep 2010 Oct; 33(10):1396-407. Available:
 http://www.aasmnet.org/Resources/PracticeParameters/Review SurgicalModificationsOSA.pdf.
- 2. Won, C, et al., Surgical treatment of obstructive sleep apnea. Proceedings of the American Thoracic Society. 2008. Vol 5: 193-1999.
- 3. Epstein, LJ, et al. Obstructive Sleep Apnea Task Force of the American Academy of Sleep Medicine. Clinical guideline for the evaluation, management, and long-term care of obstructive sleep apnea in adults. Journal of Clinical Sleep Medicine. 2009; 5(3):263-76.
- Sundaram, S. Surgery for obstructive sleep apnea. Cochrane Database Systematic Review. 2005. Oct. 19; (4): CD001004. This version published 2013; Review content assessed as up-to-date: July 01, 2008. Available: https://www.ncbi.nlm.nih.gov/pubmed/16235277.
- 5. Aurora, RN, et al. Practice parameters for the surgical modifications of the upper airway for obstructive sleep apnea in adults. Sleep. 2010. Oct 1; 33 (10): 1408-13.
- Centers for Medicare & Medicaid Services (CMS). National Government Services LCD for Category III CPT® Code Coverage-Related to LCD L33392. Effective: Oct. 01, 2015. Revised: Jan. 01, 2019. Available: https://www.cms.gov/.
- 7. Balk EM, Moorthy D, Obadan NO, Patel K, Ip S, Chung M, Bannuru RR et al. Diagnosis and Treatment of Obstructive Sleep Apnea in Adults. Comparative Effectiveness Review No. 32. (Prepared by Tufts Evidence-based Practice Center under Contract No. 290-2007-10055-1). AHRQ Publication No. 11-EHC052-EF. Rockville, MD: Agency for Healthcare Research and Quality. July 2011. Available: https://www.ncbi.nlm.nih.gov/pubmed/21977519.
- 8. Franklin KA, Anttila H, Axelsson S, Gislason T, Maasilta P, Myhre KI, Rehnqvist N. Effects and side-effects of surgery for snoring and obstructive sleep apnea—a systematic review. Sleep. 2009 Jan 1; 32(1):27-36.
- 9. Littner M, Kushida CA, Hartse K, et al. Practice parameters for the use of laser-assisted uvulopalatoplasty: An update for 2000. Sleep. 2001; 24(5):603-619.

- 10. Woodson BT, Steward DL, Weaver EM, et al. A randomized trial of temperature-controlled radiofrequency, continuous positive airway pressure, and placebo for obstructive sleep apnea syndrome. Otolaryngol Head Neck Surg. 2003; 128(6):848-861.
- 11. Wassmuth Z, Mair E, Loube D, Leonard D. Cautery-assisted palatal stiffening operation for the treatment of obstructive sleep apnea syndrome. Otolaryngol Head Neck Surg. 2000 Jul; 123(1 Pt 1):55-60.
- 12. Medtronic Inc. Pillar Procedure for Snoring and Sleep Apnea. Overview. Updated Feb. 2019. Available: https://www.medtronic.com/it-it/operatori-sanitari/products/ear-nose-throat/sleep-disordered-breathing/pillar-procedure-system-snoring-sleep-apnea.html.
- 13. Choi JH, Kim SN, Cho JH. Efficacy of the Pillar implant in the treatment of snoring and mild-to-moderate obstructive sleep apnea: a meta-analysis. Laryngoscope. 2013 Jan; 123(1):269-76. doi: 10.1002/lary.23470.
- 14. Nordgard S, Stene BK, Skjostad KW. Soft palate implants for the treatment of mild to moderate obstructive sleep apnea. Otolaryngol Head Neck Surg. 2006 Apr; 134(4):565-70.
- 15. Friedman M, Vidyasagar R, Bliznikas D, Joseph NJ. Patient selection and efficacy of pillar implant technique for treatment of snoring and obstructive sleep apnea/hypopnea syndrome. *Otolaryngol Head Neck Surg.* 2006; 134(2):187-196.
- 16. Walker RP, Levine HL, Hopp ML, Greene D, Pang K. Palatal implants: a new approach for the treatment of obstructive sleep apnea. *Otolaryngol Head Neck Surg.* 2006; 135(4):549-554.
- 17. Friedman M, Schalch P, Lin HC, Kakodkar KA, Joseph NJ, Mazloom N. Palatal implants for the treatment of snoring and obstructive sleep apnea/hypopnea syndrome. *Otolaryngol Head Neck Surg.* 2008; 138(2):209-216.
- 18. Steward DL, Huntley TC, Woodson BT, Surdulescu V. Palate implants for obstructive sleep apnea: multi-institution, randomized, placebo-controlled study. *Otolaryngol Head Neck Surg.* 2008; 139(4):506-510.
- 19. Thomas AJ, Chavoya M, Terris DJ. Preliminary findings from a prospective, randomized trial of two tongue base surgeries for sleep-disordered breathing. *Otolaryngol Head Neck Surg.* 2003; 129(5):539-546.
- 20. Fibbi A, Ameli F, Brocchetti F, Mignosi S, Cabano ME, Semino L. Tongue base suspension and radiofrequency volume reduction: a comparison between 2 techniques for the treatment of sleep-disordered breathing. Am J Otolaryngol. 2009; 30(6):401-406.

- 21. Miller FR, et al. Role of the tongue base suspension suture with the Repose System bone screw in the multilevel surgical management of obstructive sleep apnea.

 Otolaryngol Head Neck Surg 2002 Apr; 126(4):392-8.
- 22. Kuhnel T; Schurr C; Wagner B, Geisler P. Morphological Changes of the Posterior Airway Space After Tongue Base Suspension. Laryngoscope. 2005 Mar; 115(3):475-80.
- 23. American Sleep Apnea Association (ASAA). Varieties of OSA surgery. 2015. Available: https://www.sleepapnea.org/treat/sleep-apnea-treatment-options/sleep-apnea-surgery/.
- 24. Medtronic AlRvance website. Available: https://www.medtronic.com/us-en/healthcare-professionals/products/ear-nose-throat/sleep-disordered-breathing/airvance-system-obstructive-sleep-apnea.html.
- 25. Food and Drug Administration. AlRvance™ Tongue Suspension system. Available: http://www.accessdata.fda.gov/cdrh docs/pdf/K981677.pdf.
- 26. Food and Drug Administration. Pillar® System. Available: http://www.accessdata.fda.gov/cdrh docs/pdf4/K040417.pdf.
- 27. HAYES Medical Technology Directory: Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea. HAYES, Inc.; © 2021 Hayes, a symplr company. October 30, 2018. Annual Review December 17, 2021.
- 28. HAYES Medical Technology Directory: Phrenic Nerve Stimulation (remede System) for Central Sleep Apnea. HAYES, Inc.; © 2023 Hayes, a symplr company. Published April 22, 2022. Annual Review May 26, 2023.
- 29. Inspire Upper Airway Stimulation website. Available: https://www.inspiresleep.com/.
- 30. Heiser C, Maurer JT, Steffen A. Functional outcome of tongue motions with selective hypoglossal nerve stimulation in patients with obstructive sleep apnea. *Sleep Breath*. 2016;20(2):553-560.
- 31. Hofauer B, Steffen A, Knopf A, Hasselbacher K, Heiser C. Patient experience with upper airway stimulation in the treatment of obstructive sleep apnea. *Sleep Breath*. 2018. June 28, 2018. Available: https://link.springer.com/article/10.1007%2Fs11325-018-1689-4.
- 32. Philip P, Heiser C, Bioulac S, et al. Hypoglossal nerve stimulation on sleep and level of alertness in OSA: a preliminary study. *Neurology*. 201891(7):e615-e619.
- 33. Medicare Local Coverage Determination National Government Services Inc. (LCD): Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea (L38387) Effective: 04/01/2020. Available: https://www.cms.gov/.
- 34. New York State Department of Health. New York State Medicaid Update November 2024 Volume 40 Number 12

Member Product	Medical Management Requirements*
New York Products	
HMO	Prior Auth
PPO In Plan	Prior Auth
PPO OOP	Prior Auth
POS In Plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Prior Auth
MVP Harmonious Health Care Plan	Prior Auth
MVP Medicaid Managed Care	Prior Auth
MVP Child Health Plus	Prior Auth
MVP Medicare Complete Wellness	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare WellSelect PPO	Prior Auth
MVP Medicare WellSelect Plus PPO	Prior Auth
MVP Medicare Secure HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP Medicare Patriot Plan PPO	Potential for Retrospective Review
MVP DualAccess D-SNP HMO	Prior Auth
MVP DualAccess Complete D-SNP HMO	Prior Auth
MVP DualAccess Plus D-SNP HMO	Prior Auth
UVM Health Advantage Select PPO	Prior Auth
USACare PPO	Potential for Retrospective Review
Healthy NY	Prior Auth
MVP Premier	Potential for Retrospective Review
MVP Premier Plus	Potential for Retrospective Review
MVP Premier Plus HDHP	Potential for Retrospective Review
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	
POS in Plan	Prior Auth
POS OOP	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP VT HMO	Prior Auth
-	
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

*Medical Management Requirements

Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

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MVP Health Care Medical Policy Revision History:

08/01/2021 – Hypoglossal Nerve Stimulator (0466T, 0467T, 0468T) added as a covered benefit for Commercial and Medicaid Plans according to criteria in policy.

10/1/2022 – Annual review completed; references updated; Medicare variation deleted.

10/01/2024 – Updated policy to reflect phrenic nerve stimulation and CPT Codes: 33276, 33277, 33278, 33279, 33280, 33281, 33287, 33288, 93150, 93151, 93152, 93153 are experimental investigational.

03/01/2025 - Added criteria for coverage of Medicaid Managed Care plans for hypoglossal nerve stimulation.

06/01/2025 - Completed formal review of changes effective 03/01/2025.



OncotypeDX™ and other Cancer Gene Expression Tests

Type of Policy: Medical

Prior Approval Date: 07/01/2024

Provisional Approval 06/20/2025

Date:

Provisional Effective

07/01/2025

Date:

Related Polices: Genetic and Molecular

Diagnostic Testing

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

81313, 81520, 81522, 81525, 81551, 0005U, 0045U, 0047U

Codes Subject to Retrospective Review

81529, 81539, 81479, 81541, 81542, 81552, 81599, 0089U, 0090U, 0220U, 0295U, 0306U, 0315U, 0364U

Experimental/Investigational Codes

81313, 81479, 81520, 81522, 81525, 81529, 81539, 81551, 81552, 81599, 0005U, 0045U, 0089U, 0090U, 0220U, 0295U, 0306U, 0315U, 0364U

Common Diagnosis Codes

ICD-10 Diagnosis Codes: C50.011, C50.012, C50.019, C50.111, C50.112, C50.119, C50.211, C50.212, C50.219, C50.311, C50.312, C50.319, C50.411, C50.412, C50.419, C50.511, C50.512, C50.519, C50.611, C50.612, C50.619, C50.811, C50.812, C50.819, C50.911, C50.912, C50.919, C50.021, C50.022, C50.029, C50.121, C50.122, C50.219, C50.221, C50.222, C50.229, C50.321, C50.322, C50.329, C50.421, C50.422, C50.429, C50.521, C50.529, C50.621, C50.622, C50.629, C50.821, C50.822, C50.829, C50.921, C50.922, C50.929, D05.00, D05.01, D05.02, D05.10, D05.11, D05.12, D05.80, D05.81, D05.82, D05.90, D05.91, D05.92, Z17.0

Common Procedure Codes

CPT Codes: 81518, 81519, 81521

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy.

Overview

Genetic expression assays, gene expression analysis, or gene-expression profiling have been proposed as an adjuvant tool to assist in determining overall survival, recurrence probability, appropriate treatment options and responsiveness to chemotherapy for cancer treatment.

Examples of tumor-based cancer gene expression tests for breast cancer include, but are not limited to:

- OncotypeDX™ Breast Recurrence Score is a patented 21-gene panel test developed for node-negative or node-positive, hormone receptor positive breast cancer. The assay can be conducted on routine paraffin-embedded breast cancer tissue. Algorithmic weighting of gene expression yields a Recurrence Score (RS) which is strongly correlated with the recurrence of breast cancer.
- EndoPredict, a multi gene test, has been proposed to detect the likelihood of late metastasis (i.e., metastasis formation after more than five years) and guide treatment decisions for chemotherapy as well as extended anti-hormonal therapy.
- MammaPrint breast cancer recurrence signature
- Breast cancer index (BCI)
- OncotypeDX™ Breast DCIS Score
- Prosigna Breast Cancer Prognostic Gene Signature Assay
- BluePrint 80-gene molecular subtyping assay
- DCISionRT®

Examples of tumor-based cancer gene expression tests for prostate cancer include, but are not limited to:

- OncotypeDX™ Genomic Prostate Score
- Decipher® Prostate Cancer Classifier Assay
- Prolaris® Prostate Cancer Test

Genetic testing is also used as a screening tool to determine the presence of prostate cancer. The tumor marker or biomarker for prostate cancer screening is focused on the prostate specific antigen (PSA). Various approaches to improve the performance of PSA in early cancer detection have been tested, which include the measurement of prostate biomarkers. Examples of prostate biomarker tests include:

- 4K Score
- percent free PSA (%fPSA)
- Prostate Health Index (PHI)
- ConfirmMDx
- Progensa PCA3
- SelectMDx
- ExosomeDx (ExoDx) Prostate (AKA Intelliscore)

Circulating Tumor Cells Testing (or liquid biopsy testing) is the testing of blood in individuals with various forms of metastatic cancer. These tests are proposed to detect tumor cells in blood for the monitoring of progression or response to treatment of cancer. One example of this is the OncotypeDX™ AR-V7 Nucleus Detect test. This test is a liquid biopsy that proposes to identify if a prostate cancer patient is likely to benefit from the selection of certain second line therapies for treatment.

Other proposed cancer indications addressed in this policy include, but may not be limited to:

 OncotypeDX™ Colon Recurrence Score quantifies the expression of seven recurrence-risk genes and five reference genes. It has been proposed as a predictor of the likelihood of disease recurrence in individuals with colon cancer.

Indications/Criteria

Coverage of the OncotypeDX™ Breast Recurrence Score (81519) test and Mammaprint® 70-gene panel (81521) is allowable when all the following criteria are met:

- Ordered within 6 months after diagnosed stage 1 or stage 2 breast cancer; and
- the breast tumor is:
 - hormone-receptor positive (estrogen positive (ER+) or progesterone positive (PR+)); and
 - o human epidermal growth factor receptor- negative disease (HER2-); and
 - node negative axillary lymph nodes or 1-3 positive nodes no greater than 2 mm;
 and
 - o tumor size is > 0.5 cm; and

- o adjuvant chemotherapy is not precluded due to any other factor (e.g., advanced age and/or significant co-morbidities); **and**
- o customer and physician (prior to testing) have discussed the potential results of the test and agree to use the results to guide therapy (i.e., customer will forgo adjuvant chemotherapy if Oncotype DX™ Breast Cancer Assay score is low).

Coverage for Breast Cancer Index (BCI) (CPT 81518) is allowable when the following criteria are met:

- To assess necessity of adjuvant endocrine therapy; and
 - Breast tumor is HER2 negative; and
 - Breast tumor is hormone receptor (HR) positive (Estrogen Receptor (ER) and/or progesterone receptor (PR) positive; and
 - Breast tumor size greater than 0.5 cm; and
 - Member will be treated with chemotherapy and/or adjuvant endocrine therapy (e.g., tamoxifen, aromatase inhibitors).
- To guide decisions about extended endocrine therapy when the individual to be tested meets the above criteria and has received 5 years of endocrine therapy without recurrence.
- this test will be covered once per patient lifetime.

Coverage for Prolaris® Biopsy Test (81541), Decipher® Prostate Cancer Classifier (81542), or Oncotype DX® Genomic Prostate Score (0047U) are considered medically necessary when the following criteria are met:

- PSA persistence after radical prostatectomy (i.e., failure of PSA to fall to undetectable levels or subsequent detectable PSA that increases on two or more determinations);
 and
- Post-prostate biopsy; and
- Life expectancy is at least 10 years.

Exclusions

Based upon our criteria and review of the peer reviewed literature, all other breast cancer gene expression profiling assays other than OncotypeDX[™], Breast Cancer Index (BCI)[™], and Mammaprint® 70-gene panel have not been proven to improve health outcomes and are considered investigational. These assays include but are not limited to:

- EndoPredict (81522), a gene expression profiling assay, have not been proven to improve health outcomes and are considered experimental and investigational to select individuals with early stage breast cancer for adjuvant chemotherapy.
- The OncotypeDX™ Breast DCIS Score (0045U) for determining risks in individuals with DCIS of the breast has not been proven to improve outcomes, therefore it is considered experimental and investigational.

- Prosigna Breast Cancer Prognostic Gene Signature Assay (81520) for the assessment of risk recurrence in individuals with breast cancer has not been proven to improve outcomes, therefore it is considered experimental and investigational.
- BluePrint (or "80-gene profile") has not been proven to improve outcomes, therefore it is considered experimental and investigational.
- OncotypeDX™ Breast Recurrence Score testing is not covered for any indication not listed in the Indications/Criteria section.
 - o There is no data on the relevance of the test for male breast cancer.
 - There is no clinical indication for OncotypeDX™ Breast Recurrence Score testing for recurrent or metastatic breast cancer.
- PreciseDX™ Breast Cancer Test (0220U)
- DCISionRT® by PreludeDx (0295U, 81599)

The following prostate cancer screening and prognostic tests are considered investigational and therefore not covered as there is insufficient evidence to determine the test improves clinical outcomes. These tests include, but may not be limited to:

- 4K score (hK2) test (81539)
- ExosomeDx (ExoDx) Prostate IntellisScore (EPI), Exosome Diagnostics, Inc. (CPT code 0005U)
- ConfirmMDx® for Prostate Cancer (81551)
- PROGENSA® PCA3 Assay (Prostate Cancer Antigen 3 (81313)
- SelectMDx
- Percent free PSA (%fPSA)
- Prostate Health Index (PHI)™

Based upon our criteria and review of the peer reviewed literature, the following tumorbased cancer gene expression profiling assays have not been proven to improve health outcomes and are considered investigational:

- Circulating tumor cell testing or liquid biopsy testing using OncotypeDX AR-V7 Nucleus Detect (81479) is investigational.
- OncotypeDX[™] Colon Recurrence Score (81525) test for the assessment of risk recurrence in individuals with colon cancer has not been proven to improve outcomes, therefore it is considered experimental and investigational.
- clonoSEQ next generation sequencing profile test (0364U) proposed to detect or quantify minimal residual disease (MRD) on bone marrow specimens for lymphoblastic leukemia or multiple myeloma is experimental and investigational

- because there is insufficient published evidence assess the safety and/or impact on health outcomes or patient management.
- Cutaneous Melanoma Based upon our criteria and review of the peer review literature, the following cancer gene expression profiling assays for cutaneous melanoma have not been proven to improve health outcomes and are considered investigational. These assays include but are not limited to:
 - DecisionDX Melanoma (Castle Biosciences, Phoenix, AZ) (81552, 81529) is gene expression profile technique that is proposed to determine the molecular signature of a patient's melanoma. DecisionDX Melanoma has been determined to be considered investigational and therefore not covered as there is insufficient evidence that the test results provide accurate, clinically actionable information resulting in improved patient outcomes.
 - Pigmented Lesion Assay (0089U) proposed to rule out melanoma in atypical, pigmented lesions.
 - myPath Melanoma proposed to distinguish malignant melanoma from a benign birthmark or mole.
 - Uveal Melanoma DecisionDX UM (Uveal Melanoma) (Castle Biosciences, Phoenix, AZ) (81552) is gene expression profile technique that is proposed to determine the risk of metastasis of uveal melanoma within 5 years. DecisionDX-UM has been determined to be considered investigational and therefore not covered as there is insufficient evidence that the test results provide accurate, clinically actionable information resulting in improved patient outcomes.
 - Squamous Cell Carcinoma DecisionDX SCC (Castle Biosciences, Phoenix, AZ) (0315U, 81529) is gene expression profile technique that is proposed to determine the molecular signature of a patient's cutaneous squamous cell carcinoma and risk of metastasis within 5 years. DecisionDX-SCC has been determined to be considered investigational and therefore not covered as there is insufficient evidence that the test results provide accurate, clinically actionable information resulting in improved patient outcomes.
 - PancraGEN Oncogene Panel (Interpace Diagnostics) Topographic genotyping
 with tests such as the PancraGEN test is experimental, investigational, or
 unproven. There is limited published evidence of clinical validity and clinical utility
 to support its use in conjunction with testing individuals with unclassified
 pancreatic cysts.
 - Percepta Genomic Sequencing Classifier (GSC) is a gene classifying test that uses RNA sequencing of transcripts from 1232 genes to determine risk of lung cancer among current and former smokers. Percepta GSC has been determined

- to be considered investigational and therefore not covered as there is insufficient evidence that the test results provide accurate, clinically actionable information resulting in improved patient outcomes.
- Upper Gastrointestinal Metaplasia, Dysplasia, and Neoplasia with Barrett's esophagus Molecular tests for detection of upper gastrointestinal metaplasia, dysplasia, and neoplasia with Barrett's esophagus (EsoGuard (0114U), Esophageal String Test (0095U), Esopredict (0398U), TissueCypher (0108U) have been determined to be considered investigational and therefore not covered as there is insufficient evidence that the test results provide accurate, clinically actionable information resulting in improved patient outcomes.

Medicare Variation

Breast Cancer Assay:

The Breast Cancer Index™ (BCI) (81518) is covered for Medicare customers who are postmenopausal individuals with invasive breast cancer when the following criteria are met:

- Pathology reveals invasive carcinoma of the breast that is estrogen positive (ER+) or progesterone positive (PR+) and human epidermal growth factor receptor- negative disease (HER2-); and
- Patient has early-stage disease (T1-3, pNO, M0); and
- Patient has no evidence of distant breast cancer metastasis; and
- Test results will be used in determining treatment management of the patient for chemotherapy and/or endocrine therapy.

For full CMS/Medicare coverage and limitation details refer to the following Medicare Local Decision; Noridian Healthcare Solutions, LLC. Local Coverage Decision, MolDx: Breast Cancer Index™ (BCI) Gene Expression Test (L37824) Revision Effective date: 10/28/2021. Available: https://www.cms.gov/

Oncotype DX® Breast Cancer Assay (81519) is covered for Medicare customers with the following clinical findings:

- estrogen-receptor positive, node-negative carcinoma of the breast
- estrogen-receptor positive micrometastases of carcinoma of the breast, and
- estrogen-receptor positive breast carcinoma with 1-3 positive nodes

For full CMS/Medicare coverage and limitation details refer to the following Medicare Local Coverage Article; Noridian Healthcare Solutions, LLC. Local Coverage Article, MolDx: Oncotype DX® Breast Cancer Assay Coding Billing Guidelines (A54480) Revision Effective date:11/01/2019. Available: https://www.cms.gov/

The Oncotype DX DCIS assay (CPT Code 0045U) is covered only when the following clinical conditions are met:

- Pathology (excisional or core biopsy) reveals ductal carcinoma in situ of the breast (no pathological evidence of invasive disease), and
- FFPE specimen with at least 0.5 mm of DCIS length, and
- Patient is a candidate for and is considering breast conserving surgery alone as well as breast conserving surgery combined with adjuvant radiation therapy, and
- Test results will be used to determine treatment choice between surgery alone vs. surgery with radiation therapy, and
- Patient has not received and is not planning on receiving a mastectomy.

For full CMS/Medicare coverage and limitation details refer to the following Medicare Local Coverage Decision; Noridian Healthcare Solutions, LLC. Local Coverage Determination (LCD), MoIDX - CDD: Oncotype DX® Breast Cancer for DCIS (Genomic Health ™) (L36941) Effective Date 03/27/2017. Revision Effective Date: 11/25/2021 Available: https://www.cms.gov/

EndoPredict® Breast Cancer Gene Expression Test (81522)

The EndoPredict® is covered for Medicare Customers only with post-menopausal breast cancer when the following criteria are met:

- Diagnosed with early state (TNM stage T1 -3) estrogen-receptor (ER+) positive, HER2 negative breast cancer
- who have lymph node negative; or
- who have 1-3 positive nodes; and
- who has no evidence of distant metastasis, and
- Test result will be used to determine treatment choice between endocrine therapy alone vs. endocrine therapy plus chemotherapy.

For full CMS/Medicare coverage and limitation details refer to the following Medicare Local Coverage Determination: MoIDX: ENDOPREDICT Noridian® Breast Cancer Gene Expression Test (LCD L37295) Revision Effective Date: 07/11/2021. Available: https://www.cms.gov/

Prosigna® Breast Cancer Gene Expression Test (81520)

Prosigna® is covered for Medicare customers that meet the following criteria:

- Post-menopausal female either
 - Estrogen-receptor (ER+), lymph node-negative, stage I or II breast cancer;
 or

 Estrogen-receptor (ER+), lymph node-positive (1-3 positive nodes), stage II breast cancer

For full CMS/Medicare coverage and limitation details refer to the following Medicare Local Coverage Determination: MoIDX: Breast Cancer Assay: Prosigna® (L36386)
Original Effective Date For services performed on or after 04/22/2021. Available: MCD Search (cms.gov)

MammaPrint™ (CPT 81521, 81523) is covered for Medicare customers for early-stage breast cancer, <5cm up to 3 positive lymph nodes and independent of receptor status. The test may be performed upon occasion twice per patient lifetime for bilateral disease.

For full CMS/Medicare coverage and limitation details refer to the following Medicare Local Coverage Article: MoIDX: MammaPrint (A53104). Revision Effective Date: 01/01/2022. Available: MCD Search (cms.gov)

BluePrint®, a molecular subtyping assay, is excluded from coverage for Medicare customers because there is insufficient evidence to support the required clinical utility for the established Medicare benefit category.

For full CMS/Medicare coverage and limitation details refer to the following Medicare Local Coverage Article: MoIDX: BluePrint® (A53484) Original Effective Date For services performed on or after 10/24/2019. Available: MCD Search (cms.gov)

Prostate Cancer Assays:

The Oncotype DX® Prostate Cancer Assay or Oncotype DX® Genomic Prostate Score (CPT Code 0047U) is covered for Medicare customers for use in very low risk, low risk, and favorable intermediate risk prostate cancer.

For full CMS/Medicare coverage and limitation details refer to the following Medicare Local Coverage Article (LCA) Billing and Coding: Billing and Coding: MolDX: Prostate Cancer Genomic Classifier Assay for Men with Localized Disease (L38339 & A57372) Original Effective Date: 12/06/2021. Revision Effective Date: 01/01/2021

Available: MCD Search (cms.gov)

ConfirmMDx is covered when all the following criteria are met:

- Individuals aged 40 to 85 years old that have undergone a previous cancer-negative prostate biopsy within 24 months and are being considered for a repeat biopsy due to persistent or elevated cancer-risk factors, and
- The previous negative prostate biopsy must have collected a minimum of 8 tissue cores (but not have received a saturation biopsy of > 24 tissue cores) and remaining FFPE tissue from all cores is available for testing, and
- Minimum tissue volume criteria of 20 microns of prostate biopsy core tissue is available (40 microns preferable), and

- Previous biopsy histology does not include a prior diagnosis of prostate cancer or cellular atypia suspicious for cancer (but may include the presence of high-grade prostatic intraepithelial neoplasia (HGPIN), proliferative inflammatory atrophy (PIA), or glandular inflammation), and
- Patient is not being managed by active surveillance for low stage prostate cancer, and
- Tissue was extracted using standard patterned biopsy core extraction [and not transurethral resection of the prostate (TURP), and
- Patient has not been previously tested by ConfirmMDx from the same biopsy samples or similar molecular test, and

For Medicare billing and coding please refer to the following article for Medicare Customers: National Government Services, Inc. Billing and Coding: Biomarker Testing for Prostate Cancer Diagnosis (A56609). Available: MCD Search (cms.gov)

The Decipher® Prostate Cancer Classifier Assay (81542) and Prolaris™ Prostate Cancer Genomic Assay (81541) are considered reasonable and necessary to help identify individuals with localized Prostate Cancer and a life expectancy of at least 10 years who are good candidates for active surveillance.

The tests are covered for individuals with prostate cancer with localized or biochemically recurrent adenocarcinoma of the prostate (i.e., no clinical evidence of metastasis) who have a life expectancy of greater than or equal to 10 years if they are a candidate and are considering (or being considered for) at least 1 of the following:

- Conservative management and yet would be eligible for definitive therapy (radical prostatectomy (RP), radiation or brachytherapy), or;
- Radiation therapy and yet would be eligible for the addition of a brachytherapy boost, or;
- Radiation therapy and yet would be eligible for the addition of short-term androgen deprivation therapy (ADT), or;
- Radiation therapy with short-term ADT yet would be eligible for the use of longterm ADT, or;
- Radiation with standard ADT yet would be eligible for systemic therapy intensification using next generation androgen signaling inhibitors or chemotherapy, or;
- Observation post-prostatectomy yet would be eligible for the addition of postoperative adjuvant radiotherapy, or;
- Salvage radiotherapy post-prostatectomy yet would be eligible for the addition of ADT.

The following criteria must also be met for coverage:

- The assay is performed on formalin-fixed paraffin embedded (FFPE) prostate biopsy tissue with at least 0.5 mm of linear tumor diameter or FFPE tissue from a prostate resection specimen, and;
- Result will be used to determine treatment according to established practice guidelines, and;
- Patient has not received pelvic radiation or ADT prior to the biopsy or prostate resection specimen, and;
- Patient is monitored for disease progression according to established standards of care.

For full Medicare coverage details please refer to the following LCD website for Medicare Customers: Noridian Healthcare Solutions. Local Coverage Determination (LCD): MolDX: Prostate Cancer Genomic Classifier Assay for Men with Localized Disease (L38339). Revision Effective Date:02/03/2022. Available: MCD Search (cms.gov)

Biomarker test [%fPSA, PHI, 4Kscore or EPI (ExomeDx)] for Prostate Cancer Diagnosis (81539, 0005U):

The Percent Free prostate-specific antigen ratio (%fPSA), the Prostate Health Index (PHI) or 4Kscore test are blood tests that Medicare allows for assessing the risk of prostate cancer development. Medicare customers must meet the following criteria to be eligible for this testing:

One biomarker test (%fPSA, PHI, 4Kscore or EPI) is covered **Once** in individuals \geq 45 years old (\geq 50 years old for EPI), prior to initial biopsy, with confirmed* moderately elevated prostate-specific antigen (PSA) (>3 and <10 ng/mL; \geq 4 and <10 ng/mL in individuals >75 years old) with **Both** the following:

- 1. No other relative indication for prostate biopsy including **Any** of the following:
 - a. Digital rectal exam (DRE) suspicious for cancer
 - b. Persistently elevated prostate-specific antigen (PSA)
 - c. Positive multiparametric magnetic resonance imaging (MRI) (if done)
 - d. Other major risk factor for prostate cancer including:
 - i. Ethnicity at higher risk for prostate cancer*
 - ii. First-degree relative with prostate cancer*
 - iii. High-penetrance prostate cancer risk gene(s) per NCCN (if known)
- 2. No other relative contraindication for prostate biopsy including **Any** of the following:

- a. <10 year life expectancy
- b. Benign disease not ruled out

*Limitation does not apply to EPI

81479 is not considered medically necessary when used for SelectMDx, MiPS

For Medicare billing and coding please refer to the following article for Medicare Customers: National Government Services, Inc. Billing and Coding: Biomarker Testing for Prostate Cancer Diagnosis (A56609) Available: MCD Search (cms.gov).

For full CMS/Medicare coverage and limitation details of 4Kscore Test, refer to the following Medicare Local Coverage Decision (LCD): 4Kscore Test Algorithm (L37792). Revision Effective Date: 03/21/2019. Available: MCD Search (cms.gov).

The Oncotype DX AR-V7 Nucleus Detect (81479) has limited coverage for assays that detect biomarkers from circulating tumor cells (CTCs):

Assays that detect biomarkers from CTCs are covered when ALL of the following are met:

- The patient has been diagnosed with cancer
- The specific cancer type has an associated biomarker
- The associated biomarker has already established clinical utility (CU) in the peer-reviewed published literature for the intended cancer type and for the specific indication in the intended patient population; as recommended by national or society guidelines (i.e., American Society of Clinical Oncology (ASCO), National Comprehensive Cancer Network (NCCN))
- At least 1 of the following criteria are met AND there is clear documentation of at least 1 of these in the medical record:
 - The patient's cancer has not previously been tested for the specific biomarker, OR
 - The patient has newly metastatic cancer, and a metastatic lesion has not been tested for the specific biomarker, OR
 - The patient demonstrates signs of clinical, radiological or pathologic disease progression, OR
 - There is concern for resistance to treatment based on specific and wellestablished clinical indication
- Testing for the biomarker can be performed using CTCs
- Tissue-based testing for the specific biomarker is infeasible (e.g., quantity not sufficient or invasive biopsy is medically contraindicated) OR will not provide

- sufficient information for subsequent medical management. There is clear documentation of at least 1 of these reasons for testing in the medical record.
- For a given patient encounter, only 1 test for assessing the biomarker may be performed UNLESS a second test, meeting all the criteria established herein, is reasonable and necessary as an adjunct to the first test.
- Duplicate testing of the same biomarker (from the same sample type and for the same clinical indication) using different methodologies is not covered.

For full CMS/Medicare coverage and limitation details refer to the following Medicare Local Coverage Determination: MoIDX: Phenotypic Biomarker Detection from Circulating Tumor Cells (L38645). Available: MCD Search (cms.gov)

The Oncotype DX® Colon Cancer Assay (CPT 81525)

The Oncotype DX® Colon Cancer Assay is covered for Medicare customers only with Stage II colon cancer.

For full CMS/Medicare coverage and limitation details refer to the following Medicare Local Coverage Article: Noridian Healthcare Solutions, LLC. Local Coverage Article, MoIDX Oncotype DX® Colon Cancer Coding and Billing Guidelines (A54486) Revision Effective Date11/01/2019. Available: MCD Search (cms.gov)

clonoSEQ (Adaptive Biotechnologies) – Medicare has determined that clonoSEQ Assay testing is reasonable and necessary when performed on bone marrow specimens in patients with B-Cell acute lymphoblastic leukemia (ALL) or multiple myeloma.

For full CMS/Medicare coverage and limitation details refer to the following Medicare Local Coverage Article: Palmetto GBA Local Coverage Determination: MoIDX: Minimal Residual Disease Testing for Cancer (L38779) Original Effective Date: 12/26/2021. Available: MCD Search (cms.gov)

Cutaneous Melanoma:

Pigmented Lesion Assay (PLA) (0089U): The PLA is indicated only for use on pigmented skin lesions, for which a diagnosis of melanoma is being considered. The test may only be ordered by clinicians who evaluate pigmented skin lesions and perform biopsies. The test is covered for use as a source of information on whether or not to perform a biopsy.

For full CMS/Medicare coverage and limitations details refer to the following Medicare Local Coverage Determination (LCD): MoIDX: Pigmented Lesion Assay (L38151) Effective 06/07/2020. Available: MCD Search (cms.gov)

DecisionDX (CPT Code: 81529) – Melanoma: Molecular diagnostic tests used to assist in risk stratification of melanoma patients are covered when:

- 1. The patient has a personal history of melanoma AND:
 - a. Either:

- i. Has Stage T1b and above OR
- ii. Has T1a with documented concern about adequacy of microstaging
- b. Is undergoing workup or being evaluated for treatment, AND
- c. Does not have metastatic disease AND
- d. Presumed risk for a positive Sentinel Lymph Node Biopsy (SLNB) based on clinical, histological, or other information is >5% AND
- e. Has a disease stage, grade, and Breslow thickness (or other qualifying conditions) within the intended use of the test

For full CMS/Medicare coverage and limitations details refer to the following Medicare Local Coverage Determination (LCD): MolDX: Melanoma Risk Stratification Molecular Testing (L37748) Revision Effective Date:06/20/2024. Available: MCD Search (cms.gov) myPath® Melanoma Assay

myPath® Melanoma Assay (0090U) has limited coverage for the diagnosis or exclusion of melanoma from a biopsy.

For full CMS/Medicare coverage and limitations details refer to the following Medicare Local Coverage Determination (LCD): MoIDX: Molecular Assays for the Diagnosis of Cutaneous Melanoma. Noridian Healthcare Solutions, LLC (L39373 & A59179)

Available: MCD Search (cms.gov)

Uveal Melanoma

DecisionDX-UM (Uveal Melanoma) (CPT code: 81552)

Medicare plans have limited coverage for the DecisionDx-UM (Castle Bioscience, Inc.) test for the management of newly diagnosed uveal melanoma. This test is intended for the determination of metastatic risk, and to guide surveillance and referral to medical oncology (preferably an oncologist with expertise in melanoma) in patients who have a confirmed diagnosis of uveal melanoma (UM) and no evidence of metastatic disease.

For full CMS/Medicare coverage and limitations details refer to the following Medicare Local Coverage Determination (LCD): MolDX: Decision Dx-UM (Uveal Melanoma) (L37210) Revision Effective Date: 6/27/2024. Available: MCD Search (cms.gov)

Squamous Cell Carcinoma

Decision DX – Squamous Cell Carcinoma (SCC) (Castle Biosciences) (Codes 0315U)

Current molecular biomarker tests that risk stratify individuals with cutaneous squamous cell carcinoma (cSCC) are non-covered. For full CMS/Medicare coverage and limitations details refer to the following Medicare Local Coverage Determination (LCD): MolDX: Molecular Biomarker Testing for Risk Stratification of Cutaneous Squamous Cell Carcinoma Noridian Healthcare Solutions, LLC (L39614 & A59429)

Detection of Upper Gastrointestinal Metaplasia, Dysplasia, and Neoplasia with Barrett's esophagus

Molecular testing for detection of upper gastrointestinal metaplasia, dysplasia, and neoplasia with Barrett's esophagus (EsoGuard (0114U), Esophageal String Test (0095U), Esopredict (0398U), TissueCypher (0108U)

Current molecular diagnostic tests that identify individuals with upper gastrointestinal metaplasia, dysplasia, and neoplasia are non-covered. There is limited coverage for tests that complete a Technical Assessment for Medicare to show clinical validity. The related Article A59015 indicates that only the PLA code 0114U for EsoGuard has demonstrated validity.

For full CMS/Medicare coverage and limitations details refer to the following Medicare Local Coverage Determination (LCD): MoIDX: Molecular Testing for Detection of Upper Gastrointestinal Metaplasia, Dysplasia, and Neoplasia (L39256) Noridian Healthcare Solutions, LLC (L39256 & A59015).

Medicaid Variation:

The MVP Managed Medicaid program provides coverage for the OncotypeDX™ Breast Recurrence Score, EndoPredict,® Prosigna,® Breast Cancer Index® (BCI), and MammaPrint® for breast cancer for use of chemotherapy in customers regardless of gender. Only one prognostic breast cancer assay is reimbursable per histologically distinct tumor. They must be recently diagnosed breast tumors that meet the following criteria:

- The test results will aid the patient and practitioner in making the decision regarding chemotherapy (i.e., when chemotherapy is a therapeutic option and is not precluded due to any other factor); and
- The tumor is estrogen receptor positive (ER+), progesterone receptor positive (PR+), or both; and
- The tumor is human epidermal growth factor receptor 2 (HER2) negative; and
- The tumor is T1 or T2; and
- The tumor is node-negative or one to three positive nodes.

The MVP Managed Medicaid program provides coverage for clonoSEQ® - clonoSEQ®, an FDA-cleared in vitro diagnostic (IVD) test (must be billed using CPT 81479). The test is covered for the following conditions:

- detect measurable residual disease (MRD) in bone marrow from patients with multiple myeloma or B-cell acute lymphoblastic leukemia (B-ALL)
- blood or bone marrow from patients with chronic lymphocytic leukemia (CLL).

References (Reviewed 2024)

- 1. National Comprehensive Cancer Network. NCCN® Practice Guidelines in Oncology-v4.2020. May 08, 2020. Breast Cancer. Available: www.nccn.org.
- 2. Noridian Healthcare Solutions, LLC. Local Coverage Determination, MolDx-CDD: Genomic Health™: Oncotype DX® Prostate Cancer Assay (L36364). Original Effective date: 07/05/2016. Retired 06/30/2021. Available: www.cms.gov/.
- 3. Habel, L.A., Shak, S., Jacobs, M.K., et al. A population-based study of tumor gene expression and risk of breast cancer death among lymph node-negative patients. Breast Cancer Res. 2006; 8(3):R25.
- 4. Lyman, H.Gary, Edge, Stephen., Theriault, Richard;. NCCN Clinical Practice Guidelines in Oncology Symposium: Breast Cancer (Slides with Transcript) NCCN Available: https://www.medscape.org/viewarticle/584536.
- 5. Paik, S., Shak, S., Tang, G., et al. A multigene assay to predict recurrence of tamoxifentreated, node-negative breast cancer. N Engl J Med. 2004; 351(27):2817-2826.
- 6. Paik, S., Tang, G., Shak, S., et al. Gene expression and benefit of chemotherapy in women with node-negative, estrogen receptor-positive breast cancer. J Clin Oncol. 2006; 24(23):3726-3734.
- 7. Van De Vijver, et al. A gene expression signature as a predictor of survival in breast cancer. New England Journal of Medicine. 2002 Dec; 347 (25): 1999-2009.
- 8. Genomic Health. Oncotype DX Breast Cancer Assay for DCIS FAQS. Available: https://www.oncotypeiq.com/en-US/breast-cancer/healthcare-professionals/oncotype-dx-breast-dcis-score/about-the-test.
- 9. American Society of Clinical Oncology. Practice and Guidelines. Use of Biomarkers to Guide Decisions on Adjuvant Systemic Therapy for Women With Early-Stage Invasive Breast Cancer J Clin Oncol. Updated May 31, 2019. Available: <a href="https://www.asco.org/research-guidelines/quality-guidelines/quidelines/guideline
- 10. BlueCross/BlueShield Association. Technology Evaluation Center (TEC). Gene expression profiling of breast cancer to select women for adjuvant chemotherapy. 2008; 22 (13) 1-49.
- 11. Albain, KS, et al. Prognostic and predictive value of the 21-gene recurrence score assay in postmenopausal women with node-positive, estrogen-receptor-positive breast cancer on chemotherapy; a retrospective analysis of a randomized trial. Lancet Oncol 2010; 11:55-65.
- 12. Crawford ED, Scholz MC, Kar AJ, et al. Cell cycle progression score and treatment decisions in prostate cancer: results from an ongoing registry. Curr Med Res Opin. 2014; 30(6):1025-1031.
- 13. National Comprehensive Cancer Network. NCCN® Practice Guidelines in Oncology Colon Cancer. Version 3.2020 May 6, 2020. Available: www.nccn.org.

- 14. National Comprehensive Cancer Network. NCCN® Practice Guidelines in Oncology Prostate Cancer. Version 2.2020. May 21, 2020. Available: www.nccn.org.
- 15. O'Connell, MJ, et al. Relationship between tumor gene expression and recurrence in four independent studies of patients with stage II/III colon cancer treated with surgery alone or surgery plus adjuvant fluorouracil plus leucovorin. J Clin Oncol 2010; 28:3937-3944.
- 16. Gray, RG, et al. Validation study of a quantitative multigene reverse transriptase-polymerase chain reaction assay for assessment recurrence risk in patients with stage II colon cancer. J Clin Oncol 2011; 29:4611-4619.
- 17. O'Connell, M., et al. Validation of the 12-gene colon cancer recurrence score (RS) in NSABP C07 as a predictor of recurrence in stage II and III colon cancer patients treated with 5FU/LV(FU) and 5FU/LV+oxaiplatin (FU+Ox) [abstract]. ASCO Meeting abstracts. Available: https://ascopubs.org/doi/pdf/10.1200/JCO.2012.47.3116.
- 18. Knezevic D, Goddard AD, Natraj N, Cherbavaz DB, Clark-Langone KM, Snable J, Watson D, Falzarano SM, Magi-Galluzzi C, Klein EA, Quale C. Analytical validation of the Oncotype DX prostate cancer assay -- a clinical RT-PCR assay optimized for prostate needle biopsies. BMC Genomics. 2013 Oct 8; 14(1):690.
- 20. National Cancer Institute (NCI). (b) Male breast cancer treatment (PDQ®). January 23, 2020. Available: http://www.cancer.gov/cancertopics/pdq/treatment/malebreast/healthprofessional/allpages.
- 21. New York State Department of Health. Medicaid Program. Medicaid Update. Volume 31, Number 1. January 2015. Available: http://www.health.ny.gov/health_care/medicaid/program/update/2015/jan15_mu.pdf
- 22. Dowsett M, Sestak I, Lopez-Knowles E, et al. Comparison of PAM50 risk of recurrence score with oncotype DX and IHC4 for predicting risk of distant recurrence after endocrine therapy. J Clin Oncol. 2013; 31(22):2783-2790.
- 23. Gnant M, Sestak I, Filipits M, et al. Identifying clinically relevant prognostic subgroups of postmenopausal women with node-positive hormone receptor-positive early-stage breast cancer treated with endocrine therapy: a combined analysis of ABCSG-8 and ATAC using the PAM50 risk of recurrence score and intrinsic subtype. Ann Oncol. 2015; 26(8):1685-1691.

- 24. Sestak I, Cuzick J, Dowsett M, et al. Prediction of late distant recurrence after 5 years of endocrine treatment: a combined analysis of patients from the Austrian breast and colorectal cancer study group 8 and arimidex, tamoxifen alone or in combination randomized trials using the PAM50 risk of recurrence score. J Clin Oncol. 2015; 33(8):916-922.
- 25. Sestak I, Dowsett M, Zabaglo L, et al. Factors predicting late recurrence for estrogen receptor-positive breast cancer. J Natl Cancer Inst. 2013; 105(19):1504-1511.
- 26. Fitzal F, Filipits M, Rudas M, et al.The genomic expression test EndoPredict is a prognostic tool for identifying risk of local recurrence in postmenopausal endocrine receptor-positive, her2neu-negative breast cancer patients randomised within the prospective ABCSG 8 trial. Br J Cancer. 2015; 112(8):1405-1410.
- 27. Harris LN, Ismaila N, McShane LM, Hayes DF. Use of biomarkers to guide decisions on adjuvant systemic therapy for women with early-stage invasive breast cancer: American Society of Clinical Oncology Clinical Practice Guideline. J Clin Oncol. 2016; 34(10):1134-1150.
- 28. Buus R, et al. Comparison of EndoPredict and EPclin with Oncotype Dx recurrence score for prediction of risk of distant recurrence after endocrine therapy. Natl Cancer Inst 2016;9108):djw149.
- 29. Myriad ®. Enopredict ®. Available: http://myriadgenetics.eu/products/endopredict/.
- 30. Albain, KS, Barlow, WE, et al. Adjuvant chemotherapy and timing of tamoxifen in postmenopausal patients with endocrine responsive, node-positive breast cancer: a phase 3, open-label, randomised control trial. Lancet. 2009 Dec. 19; 374: 2055-2063. Available: https://www.ncbi.nlm.nih.gov/pubmed/20004966.
- 31. New York State Department of Health Medicaid Laboratory Manual Procedure Codes. Available: https://www.emedny.org/ProviderManuals/Laboratory/index.aspx.
- 32. HAYES Healthcare and Evidence Genetic Testing Evaluation Report: EndoPredict (Myriad Genetics). Lansdale, PA: HAYES, Inc.; ©2018 Winifred S. Hayes, Inc. July 20, 2017, Annual Review: September 15, 2018.
- 33. HAYES Healthcare and Evidence Genetic Testing Evaluation Report: Breast Cancer Index (BioTheranostics Inc.). Lansdale, PA: HAYES, Inc.; ©2020 TractManager. October 13, 2016, Annual Review: July 25, 2018. ARCHIVED January 11, 2020.
- 34. Medicare Local Coverage Decision: Noridian Healthcare Solutions, LLC. Local Coverage Decision, MolDx: Breast Cancer Index™ (BCI) Gene Expression Test (L37824) Revision Effective date: 01/01/2020. Available: https://www.cms.gov/.
- 35. Myriad ®. Prolaris ® 2016. Available: https://www.myriad.com/products-services/prostate-cancer/prolaris/.

- 36. Noridian Healthcare Solutions. Local Coverage Determination (LCD): MoIDX: Prostate Cancer Genomic Classifier Assay for Men with Localized Disease (L38339). Available: MCD Search (cms.gov).
- 37. HAYES Genetic Test Evaluation Overview[™]. ConfirmMDx for Prostate Cancer. Lansdale, PA: HAYES, Inc.; ©2016 Winifred S. Hayes, Inc. Reviewed October 15, 2015. Available: https://www.hayesinc.com/.
- 38. The National Comprehensive Cancer Network. NCCN. Prostate Cancer Early Detection. Clinical Practice Guidelines in Oncology, Version 2.2020. Available: https://www.nccn.org/.
- 39. Boström PJ, Bjartell AS, Catto JW, et al. Genomic Predictors of Outcome in Prostate Cancer. Eur Urol. 2015 Apr 23. Abstract available: http://www.ncbi.nlm.nih.gov/pubmed/25913390
- 40. MDxHealth. ConfrmMDx. 2015. Available: https://mdxhealth.com/tests/#confirmMdx.
- 41. Noridian Healthcare Solutions, LLC. Local Coverage Determination (LCD) MolDX-: Prolaris™ Prostate Cancer Genomic Assay (L36348) Revised 01/01/2019. Available: https://med.noridianmedicare.com/web/jeb/policies/lcd/active.
- 42. HAYES Healthcare and Evidence Genetic Testing Evaluation Report: BluePrint Molecular Subtyping Profile For Breast Cancer. Lansdale, PA: HAYES, Inc.; ©2020 TractManager. December 18, 2014. Annual Review: December 7, 2016. ARCHIVED November 15, 2017.
- 43. HAYES Healthcare and Evidence Genetic Testing Evaluation Report: MammaPrint 70-Gene Breast Cancer Recurrence Assay (Agendia). Lansdale, PA: HAYES, Inc.; ©2020 TractManager. May 12, 2016. Annual Review: March 16, 2018. ARCHIVED November 29, 2018.
- 44. HAYES Healthcare and Evidence Genetic Testing Evaluation Report: Prosigna Breast Cancer Prognostic Gene Signature Assay. Lansdale, PA: HAYES, Inc.; ©2020 TractManager. December 17, 2015. Annual Review: September 25, 2019. ARCHIVED May 13, 2020.
- 45. HAYES Healthcare and Evidence Genetic Testing Evaluation Report: Decipher Prostate RP (Decipher Biosciences). Lansdale, PA: HAYES, Inc.; ©2020 TractManager. May 21, 2019. Annual Review: April 25, 2020.
- 46. National Government Services. Local Coverage Determination (LCD) Biomarker Testing (Prior to Initial Biopsy) for Prostate Cancer Diagnosis (L37733) Original Effective Date: 12/01/18. Revision Effective Date: 12/01/2019 Available: https://www.ngsmedicare.com/. RETIRED 03/01/2024
- 47. Alvarado MD, Prasad C, Rothney M, Cherbavaz DB, Sing AP, Baehner FL, Svedman C, Markopoulos CJ. A Prospective Comparison of the 21-Gene Recurrence Score and

- the PAM50-Based Prosigna in Estrogen Receptor-Positive Early-Stage Breast Cancer. Adv Ther. 2015 Dec;32(12):1237-47.
- 48. American Cancer Society. 2019. Accessed Sep 9, 2019. Available: http://www.cancer.org/.
- 49. American Society of Clinical Oncology (ASCO). Clinical practice guideline. Uses of serum tumor markers in adult males with germ cell tumors. Jul, 2010. Accessed Sep 9, 2019. Available: http://www.asco.org/guidelines/Genitourinary-Cancer.
- 50. American Society of Clinical Oncology (ASCO). Circulating Tumor DNA Analysis in Patients With Cancer: American Society of Clinical Oncology and College of American Pathologists Joint Review. Accessed Sep 9, 2019. Available: http://ascopubs.org/doi/pdf/10.1200/JCO.2017.76.8671.
- 51. Badani K, Thompson DJ, Buerki C, et al. Impact of a genomic classifier of metastatic risk on postoperative treatment recommendations for prostate cancer patients: a report from the DECIDE study group. Oncotarget. 2013 Apr;4(4):600-9.
- 52. Bishoff JT, Freedland SJ, Gerber L, et al. Prognostic utility of the cell cycle progression score generated from biopsy in men treated with prostatectomy. J Urol. 2014; 192(2):409-414.
- 53. Erho N, Crisan A, Vergara IA, Mitra AP, Ghadessi M, Buerki C, et al. Discovery and validation of a prostate cancer genomic classifier that predicts early metastasis following radical prostatectomy. PLoS One. 2013 Jun 24;8(6):e66855.
- 54. Hendriks RJ, van Oort IM, Schalken JA. Blood-based and urinary prostate cancer biomarkers: a review and comparison of novel biomarkers for detection and treatment decisions. *Prostate Cancer Prostatic Dis.* 2017a;20(1):12-19.
- 55. National Comprehensive Cancer Network® (NCCN). NCCN GUIDELINES™ Clinical Practice Guidelines in Oncology. National Comprehensive Cancer Network. Accessed Sep 12, 2019. Available: http://www.nccn.org/.
- 56. Van Poznak C, Harris LN, Somerfield MR. Use of Biomarkers to Guide Decisions on Systemic Therapy for Women With Metastatic Breast Cancer: American Society of Clinical Oncology Clinical Practice Guideline. J Oncol Pract. 2015 Nov;11(6):514-6.
- 57. Wojno KJ, Costa FJ, Cornell RJ, Small JD, Pasin E, Van Criekinge W, et al. Reduced rate of repeated prostate biopsies observed in ConfirmMDx clinical utility field study. Am Health Drug Benefits. 2014 May;7(3):129-34.
- 58. Badani K, Thompson DJ, Buerki C, et al. Impact of a genomic classifier of metastatic risk on postoperative treatment recommendations for prostate cancer patients: a report from the DECIDE study group. Oncotarget. 2013 Apr;4(4):600-9.

- 59. Michalopoulos SN, Kella N, Payne R, et al. Influence of a genomic classifier on post-operative treatment decisions in high-risk prostate cancer patients: results from the PRO-ACT study. Curr Med Res Opin. 2014 Aug;30(8):1547-56.
- 60. Punnen, S., Pavan, N., & Parekh, D. (2015). Finding the wolf in sheep's clothing: the 4Kscore is a novel blood test that can accurately identify the risk of aggressive prostate cancer. Reviews in Urology, 17 (1), 3-13.
- 61. Parekh DJ, Punnen S, Sjoberg DD, et al. A Multi-institutional Prospective Trial in the USA Confirms that the 4Kscore Accurately Identifies Men with High-grade Prostate Cancer. Eur Urol. Oct 27 2014. PMID 25454615.
- 62. Centers for Medicare & Medicaid Services, Decision Memo for Screening Colorectal Cancer Stool DNA Testing (CAG 00440N). October 9, 2014. Available: https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=277.
- 63. MDxHealth. SelectMDx for Prostate Cancer. 2019a. Available: https://mdxhealth.com/selectmdx-prostate-cancer.
- 64. HAYES Healthcare and Evidence Genetic Testing Evaluation Report: SelectMDx for Prostate Cancer (MDxHealth Inc.). Lansdale, PA: HAYES, Inc.; ©2020 TractManager. May 21, 2019. Annual Review: February 23, 2020.
- 65. HAYES Precision Medicine Research Brief: DCISionRT (PreludeDx). ©2022 Hayes, a sympire company. August 27, 2021.
- 66. HAYES Molecular Test Assessment. Percepta Genomic Sequencing Classifier (GSC). HAYES, Inc.; © 2022 Hayes, a symplr company July 21, 2020. Annual review March 30, 2022.
- 67. HAYES Molecular Test Assessment. DecisionDx-UM (Castle Biosciences Inc.). HAYES, Inc.; © 2022 Hayes, a symplr company. June 17, 2020. Annual review May 11, 2022.
- 68. New York State Department of Health Medicaid Expansion of Prognostic Tests for Breast Cancer Treatment. December 2023 Volume 39 Number 17. Available: New York State Medicaid Update December 2023 Volume 39 Number 17 (ny.gov)

Customer Product	Medical Management Requirements*
New York Products	
HMO	Prior Auth
PPO In Plan	Prior Auth
PPO OOP	Prior Auth
POS In Plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Prior Auth
MVP Child Health Plus	Prior Auth
MVP Harmonious Health Care Plan	Prior Auth
MVP Medicare Complete Wellness	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP Medicare WellSelect PPO	Prior Auth
MVP Medicare WellSelect Plus PPO	Prior Auth
MVP Medicare Patriot Plan PPO	Prior Auth
MVP DualAccess D-SNP HMO	Prior Auth
MVP DualAccess Complete D-SNP HMO	Prior Auth
MVP DualAccess Plus D-SNP HMO	Prior Auth
UVM Health Advantage Select PPO	Prior Auth
USA Care	Potential for Retrospective Review
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	Sec 51 D
POS In Plan	Prior Auth
POS OOP	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Fleiered Gold FIMO FOS MVP Medicare Secure Plus HMO POS	Prior Auth
MVP VT HMO	Prior Auth
MVP VT HIMO	Prior Auth
MVP VT Plus HMO	Prior Auth Prior Auth
MVP VT Plus HIMO MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD

[♦] Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Revision History:

06/01/2021 – Removed prior authorization from 81599 and moved to retrospective review for experimental/investigational review.

10/01/2021 - Under the Medicare variations; all the Medicare variations were updated to be in line with current Medicare coverage. This included updating the Medicare variation for the Decipher prostate. For Medicare plans; the Decipher prostate test is considered reasonable and necessary to help identify men with localized Prostate Cancer and a life expectancy of at least 10 years who are good candidates for active surveillance according to the most recent National Comprehensive Cancer Network (NCCN) guidelines.

02/01/2022 - Exclusions added for clonoSEQ and cutaneous melanoma tumor testing (DecisionDX – Melanoma, Pigmented Lesion Assay and myPath Melanoma as investigational. Medicare variations added for clonoSEQ, DecisionDX – Melanoma and Pigmented Lesion Assay.

05/20/2022 - DCISionRT added to exclusions; Medicare variations updated.

12/1/2022- Percepta, DecisionDX -SCC and UM added to Exclusions. DecisionDX-Melenoma and PanGen Oncogene Panel moved to OncotypeDX and Cancer Gene Expression Policy from Genetic and Molecular Diagnostic Testing Policy.

10/01/2023 – Added coverage to Breast Cancer Index (CPT 81518) and removed prior authorization.

12/01/2023 – Added Medicaid Managed Care (MMC) coverage to Breast Cancer Index® (BCI)(CPT 81518) and MammaPrint® (CPT 81521).

07/01/2024 - Added Medicaid Managed Care (MMC) coverage to clonoSEQ®.

08/01/2024 – CPT Codes 84153, 84154, 86316 for %fPSA, PHI prostate diagnostic tests now managed in the Prostate Specific Antigen (PSA) Testing Payment Policy.

10/01/2024 – Added coverage criteria to Decipher (CPT 81542), Prolaris (CPT 81541), and Oncotype DX Prostate (0047U).

07/01/2025 –updated the Medicare variations for cutaneous melanoma, uveal melanoma, squamous cell carcinoma, and for detection of upper GI with Barrett's esophagus LCDs for reference when performing medical necessity reviews.



Orthognathic Surgery

Type of Policy: Surgical

Prior Approval Date: 11/17/2023

Approval Date: 02/05/2024

Effective Date: 04/01/2024

Related Polices: TMJ Joint Dysfunction NY

TMJ Joint Dysfunction Vermont

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

CPT/HCPCS Codes:	Description:	
21110	Application of interdental fixation device for conditions other than	
21110	fracture or dislocation	
21120	Genioplasty; augmentation (autograft, allograft, prosthetic material)	
21121	Genioplasty; sliding osteotomy, single piece	
21122	Genioplasty; sliding osteotomies, 2 or more osteotomies (eg, wedge	
21122	excision or bone wedge reversal for asymmetrical chin)	
Genioplasty; sliding, augmentation with interpositional bone graf		
21123	(includes obtaining autografts)	
21141	Reconstruction midface, LeFort I; single piece, segment movement in	
21141	any direction (eg, for Long Face Syndrome), without bone graft	
21142	Reconstruction midface, LeFort I; 2 pieces, segment movement in any	
21142	direction, without bone graft	
21143	Reconstruction midface, LeFort I; 3 or more pieces, segment movement	
21145	in any direction, without bone graft	
21145	Reconstruction midface, LeFort I; single piece, segment movement in	
21143	any direction, requiring bone grafts (includes obtaining autografts)	

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21146	Reconstruction midface, LeFort I; 2 pieces, segment movement in any direction, requiring bone grafts (includes obtaining autografts) (eg, ungrafted unilateral alveolar cleft)		
21147	Reconstruction midface, LeFort I; 3 or more pieces, segment movement in any direction, requiring bone grafts (includes obtaining autografts)		
21150	Reconstruction midface, LeFort II; anterior intrusion (eg, Treacher-Collins Syndrome)		
21154	Reconstruction midface, LeFort III (extracranial), any type, requiring bone grafts (includes obtaining autografts); without LeFort I		
21155	Reconstruction midface, LeFort III (extracranial), any type, requiring bone grafts (includes obtaining autografts); with LeFort I		
21159	Reconstruction midface, LeFort III (extra and intracranial) with forehead advancement (eg, mono bloc), requiring bone grafts (includes obtaining autografts); without LeFort I		
21160	Reconstruction midface, LeFort III (extra and intracranial) with forehead advancement (eg, mono bloc), requiring bone grafts (includes obtaining autografts); with LeFort I		
21188	Reconstruction midface, osteotomies (other than LeFort type) and bone grafts (includes obtaining autografts)		
21193	Reconstruction of mandibular rami, horizontal, vertical, C, or L osteotomy; without bone graft		
21194	Reconstruction of mandibular rami, horizontal, vertical, C, or L osteotomy; with bone graft (includes obtaining graft)		
21195	Reconstruction of mandibular rami and/or body, sagittal split; without internal rigid fixation		
21196	Reconstruction of mandibular rami and/or body, sagittal split; with internal rigid fixation		
21198	Osteotomy, mandible, segmental;		
21206	Osteotomy, maxilla, segmental (eg, Wassmund or Schuchard)		
21208	Osteoplasty, facial bones; augmentation (autograft, allograft, or prosthetic implant)		
21209	Osteoplasty, facial bones; reduction		
21210	Graft, bone; nasal, maxillary or malar areas (includes obtaining graft)		
21215	Graft, bone; mandible (includes obtaining graft)		
21230	Graft; rib cartilage, autogenous, to face, chin, nose or ear (includes obtaining graft)		
21240	Arthroplasty, temporomandibular joint, with or without autograft (includes obtaining graft)		
21242	Arthroplasty, temporomandibular joint, with allograft		
21243	Arthroplasty, temporomandibular joint, with prosthetic joint replacement		

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21244	Reconstruction of mandible, extraoral, with transosteal bone plate (eg, mandibular staple bone plate)	
21245	Reconstruction of mandible or maxilla, subperiosteal implant; partial	
21246	Reconstruction of mandible or maxilla, subperiosteal implant; complete	
21247	Reconstruction of mandibular condyle with bone and cartilage autografts	
21248	Reconstruction of mandible or maxilla, endosteal implant (eg, blade, cylinder); partial	
21249	Reconstruction of mandible or maxilla, endosteal implant (eg, blade, cylinder); complete	
D5937	Trismus appliance (not for TMD treatment)	
D5982	Surgical stent	
D5987	Commissure splint	
D5988	Surgical splint	

Codes Requiring Retrospective Review

N/A

Experimental/Investigational

N/A

Common Diagnosis Codes

ICD-10-CM Diagnosis Codes: M26.00, M26.01, M26.02, M26.03, M26.04, M26.05, M26.06, M26.07, M26.09, M26.10, M26.11, M26.12, M26.19, M26.20, M26.21, M26.211, M26.212, M26.213, M26.219, M26.220, M26.221, M26.23, M26.24, M26.25, M26.29, M26.26.22, M26.220, M26.221, M26.23, M26.24, M26.25, M26.29, M26.30, M26.31, M26.32, M26.33, M26.34, M26.35, M26.36, M26.37, M26.39, M26.4, M26.5, M26.50, M26.51, M26.52, M26.53, M26.54, M26.55, M26.56, M26.57, M26.59, M26.60, M26.61, M26.62, M26.63, M26.64, M26.69, M26.70, M26.71, M26.72, M26.73, M26.74, M26.79, M26.81, M26.82, M26.89, M26

Common Diagnosis Codes associated with this policy have been provided for informational purposes only. The list of codes may not be all-inclusive and may be updated to reflect any applicable revisions to the ICD-10 code sets and/or medical necessity guidelines applied in this policy.

Common Procedure Codes

N/A

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are

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subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

Orthognathic surgery is the surgical correction of abnormalities of the mandible, maxilla or both. The underlying abnormality may be present at birth (e.g., cleft palate) or may become evident as the patient grows and develops or may be the result of traumatic injuries. The severity of these abnormalities cannot be adequately corrected through dental treatment alone. The goal of the surgery is to improve or restore function by correcting the underlying skeletal deformity.

Indications/Criteria

Documentation Requirements

Submitted documentation that clearly demonstrates functional impairment that adversely affects normal activities of the lower or upper jaw. Normal activities are defined as mastication, respiration, swallowing, drinking, and speech. If functional impairment is not clearly documented in the treating physician's medical record, it may be necessary to request medical records from other physicians and/or the primary care physician.

Orthognathic surgery is covered on a case-by-case basis with documented functional impairment. Requests for orthognathic surgery require prior authorization.

Documentation required to support the above information must include:

Anteroposterior Discrepancies

- Maxillary/mandibular incisor relationship; overjet of 5mm or more, or a 0 to a negative value (norm 2mm).
- Maxillary/mandibular anteroposterior molar relationship discrepancy of 4mm or more (norm 0 to 1mm).
- These values represent two or more standard deviations from published norms.

<u>Vertical Discrepancies</u>

- Presence of a vertical facial skeletal deformity which is two or more standard deviations from published norms for accepted skeletal landmarks.
- Open bite:
 - o no vertical overlap of anterior teeth; or
 - o unilateral or bilateral posterior open bite greater than 2mm.
- Deep overbite with impingement or irritation of buccal or lingual soft tissues of the opposing arch.

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• Supraeruption of a dentoalveolar segment due to lack of occlusion.

<u>Transverse Discrepancies</u>

- Presence of a transverse skeletal discrepancy which is two or more standard deviations from published norms.
- Total bilateral maxillary palatal cusp to mandibular fossa discrepancy of 4mm or greater, or a unilateral discrepancy of 3mm or greater, given normal axial inclination of the posterior teeth.

Asymmetries

 Anteroposterior, transverse, or lateral asymmetries greater than 3mm with concomitant occlusal asymmetry.

The customer must have one of the anatomical discrepancies listed above under Documentation Requirements of this policy. In addition, orthognathic surgery is covered when one of the following criteria has been met:

- the customer has a malocclusion resulting in persistent difficulty swallowing and/or choking resulting in the ability to chew only soft foods or to only drink liquids;
- the customer has a speech impairment related to anatomical jaw deformity significant enough to impair the customer's ability to communicate determined by a speech and language pathologist;
- the customer has malnutrition, significant weight loss, or failure-to-thrive secondary to facial skeletal deformity;
- the customer has significant airway obstruction caused by craniofacial skeletal abnormalities contributing to obstructive sleep apnea and has failed a trial of continuous positive airway pressure (CPAP or BiPAP) (Refer to the MVP Health Care Medical Policy for Obstructive Sleep Apnea: Surgical Treatment);
- the customer has TMJ disorder that presents with one or more of the following TMJ related symptoms:
 - o nutritional impairment requiring the customer to subsist on a soft dental diet;
 - o ear aches;
 - o headaches;
 - o masticatory myalgia;
 - o cervical myalgia;
 - clicking or popping of the joint;
 - locking of the joint;
 - o restriction of masticating function; or

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o restriction of jaw motion.

In addition to the above criteria, customers with TMJ disorder must have failed conservative therapy over a six (6) month period including all of the following:

- elimination of contributing aggravating factors such as chewing gum, chewing hard or tough foods; and
- o use of anti-inflammatory drugs over a six (6) week period unless contraindicated; and
- removable intra-oral appliances (including but not limited to the following examples; removable occlusal orthopedic appliance, occlusal splints, mandibular occlusal repositioning appliances (MORAs), mandibular repositioning appliance (MRA); and
- physical therapy (active or passive jaw exercises, thermal modalities, manipulation, electric stimulation modalities).

New York State has mandated health benefits for cleft palate that covers a child under the age of 18 and includes, but not limited to the following:

- Oral surgery of the lip, palate, jaw and related structures, including bone grafts;
- Facial surgery of the lip, palate, jaw, nose and related structures, including bone grafts;
- Prosthetic treatment and appliances and prosthodontia, including obturators, speech appliances, and feeding appliances;
- Orthodontic treatment and appliances and orthodontia;
- Otolaryngology treatment and management

Exclusions

- Orthognathic surgery performed solely to improve the appearance of the patient is considered cosmetic and; therefore, not covered.
- Orthognathic surgery to correct deformities of the maxillofacial structures which are not functionally limiting, such as asymmetry, prognathism, or retrognathism is not covered.
- Orthognathic surgery for the treatment of temporomandibular joint disease (TMJ) is not covered as the sole diagnostic criteria.
- Orthodontia/braces are not a covered benefit with orthognathic surgery.
- Dental implants are not covered as there are other alternative treatments available and, therefore, are not considered to be medically necessary.
- Vermont customers, refer to Vermont TMJ policy.

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Medicaid Variation

As documented in the NYS Medicaid Program Dental Policy and Procedure Code Manual, Medicaid Managed Care (MMC) plan coverage now includes revisions for crowns, root canals, and dental implants and the purpose of these changes is to expand coverage of these dental services when such dental services are medically necessary. Root canals, crowns, replacement dentures and dental implants are now covered benefits. Prior authorization requests for these services may not be denied on the basis that they are not covered services.

"Medically necessary" is set forth as "medical, dental and remedial care, services and supplies [...] which are necessary to prevent, diagnose, correct or cure conditions in the person that cause acute suffering, endanger life, result in illness or infirmity, interfere with such person's capacity for normal activity, or threaten some significant handicap..." - New York State Social Services Law § 365-a(2).

References (Reviewed 2023)

- 1. American Academy of Pediatric Dentistry. Guideline on Management of the Developing Dentition and Occlusion in Pediatric Dentistry. Revised 2019. Available: http://www.aapd.org/media/policies_guidelines/g_developdentition.pdf. Accessed on April 21, 2021.
- American Association of Oral and Maxillofacial Surgeons. Criteria for Orthognathic Surgery. 2020. Available: http://www.aaoms.org/docs/practice_resources/clinical_resources/ortho_criteria.pdf. Accessed on April 21, 2021.
- 3. American Association of Oral and Maxillofacial Surgeons. Parameters of Care: Clinical Practice Guidelines for Oral and Maxillofacial Surgery. 2017. Available: http://www.aaoms.org/images/uploads/pdfs/parcare_assessment.pdf. Accessed on April 21, 2021.
- 4. New York State Regulation 62 (11 NYCRR Section 52.16(c)(9) Section 3221.

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Customer Product	Medical Management Requirements*
New York Products	
НМО	Prior Auth
PPO In plan	Prior Auth
PPO OOP	Prior Auth
POS In plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Prior Auth
MVP Child Health Plus	Prior Auth
MVP Medicare Complete Wellness	Prior Auth
MV Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP Medicare WellSelect PPO	Prior Auth
MVP Medicare WellSelect Plus PPO	Prior Auth
MVP Medicare Patriot Plan PPO	Prior Auth
MVP DualAccess D-SNP HMO	Prior Auth
MVP DualAccess Complete D-SNP HMO	Prior Auth
MVP DualAccess Plus D-SNP HMO	Prior Auth
UVM Health Advantage Select PPO	Prior Auth
USA Care	Prior Auth
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	
POS in Plan	Prior Auth
POS OOP	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP VT HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

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Revision History:

04/01/2021 - updated to new format, added examples of malnutrition, added criteria for obstructive sleep apnea diagnosis, modernized intra-oral appliance descriptions, added examples of physical therapy. Added Medicaid Managed Care (MMC) variation.

12/01/2022 – Annual review, added CPT Code 21122 to prior authorization, added NYS mandated indications for coverage of cleft palate, removed Medicaid variation for cleft palate, updated references.

10/02/2023 – Added Medicaid Managed Care (MMC) plan coverage now includes revisions for crowns, root canals, replacement dentures and dental implants.

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Orthotic Devices (other than therapeutic diabetic footwear)

Type of Policy: DME

Prior Approval Date: 03/27/2025

Approval Date: 05/19/2025

Effective Date: 06/01/2025

Related Polices: Durable Medical Equipment

Therapeutic Footwear for

Diabetics

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

For Durable Medical Equipment (DME) that requires Prior Authorization, refer to the following link:

https://www.mvphealthcare.com/utilization

Codes Subject to Retrospective Review

N/A

Experimental/Investigational

E0738 - Upper extremity rehabilitation system providing active assistance to facilitate muscle re-education, includes microprocessor, all components and accessories

K1007 - Bilateral hip, knee, ankle, foot (HKAFO) device, powered, includes pelvic component, single or double upright(s), knee joints any type, with or without ankle joints any type, includes all components and accessories, motors, microprocessors, sensors

L1005 - Tension based scoliosis orthosis and accessory pads, includes fitting and adjustment

L2006 - Knee ankle foot device, any material, single or double upright, swing and stance phase microprocessor control with adjustability, includes all components (e.g., sensors, batteries, charger), any type activation, with or without ankle joint(s), custom fabricated

L8701 - Powered upper extremity range of motion assist device, elbow, wrist, hand with single or double upright(s), includes microprocessor, sensors, all components and accessories, custom fabricated

L8702 - Powered upper extremity range of motion assist device, elbow, wrist, hand, finger, single or double upright(s), includes microprocessor, sensors, all components and accessories, custom fabricated

Common Diagnosis Codes

Orthopedic Footwear:

ICD-10- CM Diagnosis Codes: Q72.00, Q72.30, Q72.70

Ankle-Foot and Knee-Ankle-Foot Orthoses:

ICD-10- CM Diagnosis Codes: M24.573, M24.576, M72.2

Knee Orthoses:

ICD-10- CM Diagnosis Codes: G35, G81.90, G80.9, G82.20, G57.00, G57.20, M06.9, M05.00, M12.00, M17.10, M17.5, M17.9, M22.40, M23.009, M23.205, M23.219, M23.319, M23.229, M23.329, M23.305, M23.339, M23.50, M23.8X9, M23.90, M24.569, M66.259, M84.369A, M84.453A, M84.469A, M87.08, Q68.2, Q74.1, S72.409A, S72.413A, S72.416A, S72.443A, S72.446A, S72.453A, S72.456A, S72.409B, S72.409C S72.413B, S72.413C, S72.416B, S72.416C, S72.443B, S72.443C, S72.446B, S72.446C, S72.453B, S72.453C, S72.456B, S72.456C, S72.499A, S72.499B, S72.499C, S81.009A, S82.009A, S82.009B, S82.009C, S82.101A, S82.101B, S82.102A, S82.102B, S82.109A, S82.161A, S82.162A, S82.169A, S82.209A, S82.209B, S82.209C, S82.311A, S82.312A, S82.319A, S82.409A, S82.409B, S82.409C, S82.811A, S82.812A, S82.821A, S82.822A, S82.819A, S82.829A, S82.831A, S82.831B, S82.832A, S82.832B, S82.839A, S82.839B, S82.839C, S82.109B, S82.109C, S82.66XB, S83.006A, S83.106A, S83.116A, S83.126A, S83.136A, S83.146A, S83.196A, S83.209A, S83.219A, S83.249A, S83.289A, S83.30XA, S83.419A, S83.429A, S83.509A, T84.019A, T84.039A, T84.029A, T84.049A, T84.059A, T84.069A, T84.099A, T84.119A, T84.129A, T84.199A, T84.498A, T84.50XA, T84.81XA, T84.82XA, T84.83XA, T84.84XA, T84.85XA, T84.86XA, T84.89XA, T84.9XXA

Common Procedure Codes

L1300, L1310, L1006

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are

Overview

An orthotic device is a rigid or semi-rigid brace added to the body to stabilize or immobilize an injured body part, prevent deformity, protect against further injury, or assist with activities of daily living function. Orthotic devices include, but are not limited to, custom molded shoe orthotics, spinal orthotics, knee-ankle-foot orthotics, and ankle braces.

Orthoses may be either prefabricated or custom fabricated. A prefabricated orthosis is one which is manufactured in quantity without a specific patient in mind. A prefabricated orthosis may be trimmed, bent, molded (with or without heat), or otherwise modified for use by a specific patient (i.e., custom fitted). An orthosis that is assembled from prefabricated components is considered prefabricated. A custom fabricated orthosis is one which is individually made for a specific patient starting with basic materials including, but not limited to, plastic, metal, leather, or cloth in the form of sheets, bars, etc. It involves substantial work such as cutting, bending, molding, sewing, etc. It may involve the incorporation of some prefabricated components. It involves more than trimming, bending, or making other modifications to a substantially prefabricated item.

Orthopedic footwear includes the following:

- orthopedic shoes (oxford, high top, depth inlay, and custom shoes for non-diabetics that are an integral part of a covered leg brace);
- heel replacements, sole replacements, and shoe transfers involving shoes on a brace;
- inserts and other shoe modifications that are on a shoe that is an integral part of a brace which is medically necessary for the proper functioning of a brace; and
- prosthetic shoes that are an integral part of a prosthesis for customers with a partial foot amputation.

MVP follows Medicare criteria for orthopedic footwear, knee-ankle-foot orthosis, knee orthosis, and spinal orthosis.

Myoelectric orthotic devices (L8701, L8702) were reportedly designed for upper limb deficiencies. They purportedly enable individuals who have been afflicted by a stroke or other neuromuscular conditions to self-initiate movement of a partially paralyzed arm using their own muscle signals. Supposedly, when the user tries to bend the affected limb, sensors in the brace detect the muscle signal, which activates the motor to move the arm in the desired direction. Examples of this brace include, but may not be limited to, the MyoPro myoelectric limb orthosis.

Wearable robotic exoskeletons have been developed to reportedly help individuals ambulate despite partial or complete paraplegia. The device is a wearable exoskeleton device that is intended to enable individuals with spinal cord injury to perform ambulatory functions with supervision of a specially trained companion. The device has fitted braces for the legs with motorized hip and knee joints, a backpack containing a computer and rechargeable batteries, an array of upper body motion sensors and a computer based wireless control system worn in the individual's wrist. Crutches are also used to provide the user with additional stability when walking, standing or rising from a chair.

Indications/Criteria

Orthopedic Footwear (none)

Foot orthotics are not covered under most MVP contracts unless the contract has the specific foot orthotic coverage. Refer to the specific benefit for foot orthotics coverage.

If a product excludes coverage for foot orthotics, it is not covered, and medical policy criteria do not apply.

For orthopedic footwear indications and criteria refer to the following link:

https://med.noridianmedicare.com/web/jddme/policies/lcd/active

Diabetic Footwear (none)

For diabetic footwear refer to MVP Therapeutic Footwear for Diabetics policy.

Ankle-Foot and Knee-Ankle-Foot Orthosis (L2006)

For ankle-foot and knee-ankle-foot orthosis indications and criteria refer to the following link:

https://med.noridianmedicare.com/web/jddme/policies/lcd/active

Knee Orthosis (L1834, L1840, L1844, L1846, L1860)

For knee orthosis indications and criteria refer to the following link:

https://med.noridianmedicare.com/web/jddme/policies/lcd/active

Spinal Orthosis: Thoracic-lumbar-sacral orthosis and lumbar-sacral orthosis (L0480, L0484, L0486, L0629, L0634, L0636, L0638, L0640)

For spinal orthosis indications and criteria refer to the following link:

https://med.noridianmedicare.com/web/jddme/policies/lcd/active

Scoliosis bracing for a spinal deformity in a skeletally immature child or adolescent are covered (using HCPCS code L1300) (e.g., Boston, Wilmington, Rosenberger, Charleston, Providence braces)

Documentation Requirements

The medical record must document medical necessity and require a physician's order for coverage.

Exclusions

- Braces for use in recreational activities are not a covered benefit.
- Orthopedic devices that can be purchased without a physician's order are not a covered benefit.
- The customer may be responsible for the applicable orthotic/durable medical equipment co-payment.
- Elastic or other fabric support garments (such as A4467 (belt, strap, garment, or covering, any type)) would encompass a wide range of supplies such as elastic ankle and wrist supports, arm slings, back/rib supports, cushions, pillows, wraps, and other over-the-counter orthopedic equipment or devices are not a covered durable medical benefit because they do not meet the definition of orthotics as they are not rigid or semi-rigid devices.
- Foot orthotics are not covered under most MVP contracts unless the contract has the specific foot orthotic rider for coverage. Refer to the specific benefit for foot orthotics coverage.
- Myoelectric upper extremity orthotic devices (L8701, L8702) such as the MyoPro (Myomo Inc.) are considered experimental, investigational or unproven for any indication because there is insufficient published evidence to assess the safety and/or impact on health outcomes or patient management.
- Wearable Robotic Exoskeletons (HCPCS Code: K1007) (e.g., ReWalk Personal System (ReWalk Robotics)) are considered experimental/investigational as they are not identified as widely used and generally accepted for the proposed uses as reported in nationally recognized peer-reviewed medical literature published.
- Microprocessor-controlled or electronically controlled knee ankle foot orthotics (KAFOs) (HCPCS Code: L2006) (i.e., C Brace Orthotronic Mobility System, E-mag) are considered experimental and investigational because of insufficient evidence that they improve ambulation compared to standard knee ankle foot orthotics (KAFOs).
- Robotic assisted therapy device/system using brain computer interface technology, such as the Ipsihand, (HCPCS code E0738) are considered experimental, investigational or unproven for any indication because there is insufficient published evidence to assess the safety and/or impact on health outcomes or patient management.
- Long-term efficacy for use of spinal unloading devices (e.g., LTX 3000TM, OrthotracTM) for the treatment of scoliosis has not been proven in peer reviewed literature and is considered investigational.

- The following braces have not been proven effective in the treatment of adolescent idiopathic scoliosis (AIS) and are considered to be investigational (This list may not be all-inclusive.):
 - Copes Dynamic Scoliosis Brace.
 - SpineCor Dynamic Corrective brace Tension based scoliosis orthosis (L1005) (e.g., SpineCor Dynamic Corrective brace) have not been proven effective in the treatment of adolescent idiopathic scoliosis (AIS) and is considered to be investigational.

MVP Medicaid Managed Care

MVP follows the New York State Medicaid Program Durable Medical Equipment, Orthotics, Prosthetics, and Supplies procedure codes and coverage guidelines at the eMedNY website indicated in the references.

Coverage for foot orthotics is limited to customers who require orthopedic footwear (shoes, shoe modifications or shoe additions) to correct, accommodate or prevent a physical deformity or range of motion malfunction in a diseased or injured part of the ankle or foot, or to support a weak or deformed structure of the ankle or foot.

Coverage is allowed at the frequency indicated in the New York State Medicaid Program Durable Medical Equipment, Orthotics, Prosthetics, and Supplies procedure codes and coverage guidelines.

Medicare

There are several Medicare Local Coverage Determinations (LCDs) for Orthotic Devices. For full coverage details of indications and limitations please refer to the Indications/Criteria section of this policy above.

Custom molded foot orthotics are excluded from coverage according the MVP Medicare contract unless they are attached to a brace. MVP follows the coverage indications in the LCD for Ankle-Foot/Knee-Ankle-Foot Orthosis (L33686).

Tension based scoliosis orthosis (HCPCS Code L1005) (e.g., SpineCor Dynamic Corrective brace) and scoliosis orthosis (HCPCS Code L1006) (e.g., Peak Scoliosis Bracing System and the TechnoSpine TLSO-Scoliosis Brace) are a covered benefit for Medicare plans to control and support against further progression of an idiopathic scoliosis curve. Additional custom fabrication is considered incorrect coding as these are prefabricated orthosis or complete products.

Centers for Medicare and Medicaid Services (CMS). NIHC, Corp. Local Coverage Determination (LCD) for Spinal Orthoses: TLSO and LSO (L33790) Revision Effective Date 01/01/2020. Available: https://www.cms.gov/medicare-coverage-database/new-search.

References (Updated 2025)

- 1. Asselin PK, Avedissian M, Knezevic S, et al. Training persons with spinal cord injury to ambulate using a powered exoskeleton. J Vis Exp. 2016;(112).
- 2. Coillard et al. A prospective randomized controlled trial of the natural history of idiopathic scoliosis versus treatment with the SpineCor brace. Sosort Award 2011 winner. Eur J Phys Rehabil Med 2014. 50(5):479-87.eMedNY. Provider Manuals. DME. Policy Guidelines. New York State Medicaid Program. Durable Medical Equipment Manual. Policy Guidelines. Durable Medical Equipment, Orthotics, Prosthetics and Supplies Policy Guidelines. Available:

https://www.emedny.org/ProviderManuals/index.aspx

- 3. Guo J, Lam TP, Wong MS, Ng BK, Lee KM, Liu KL et al. A prospective randomized controlled study on the treatment outcome of SpineCor brace versus rigid brace for adolescent idiopathic scoliosis with follow-up according to the SRS standardized criteria. Eur Spine J. 2014 Dec;23(12):2650-7.
- 4. Gutman G, Benoit M, Joncas J, Beauséjour M, Barchi S, Labelle H, et al. The effectiveness of the SpineCor brace for the conservative treatment of adolescent idiopathic scoliosis. Comparison with the Boston brace. Spine J. 2016 May;16(5):626-31.
- 5. Hayes Search & Summary: MyoPro Orthosis (Myomo, Inc.) for Upper Extremity Paralysis/Paresis After Stroke. ©2021 Hayes, a sympr company, October 4, 2021. ARCHIVED November 4, 2021.
- 6. Hayes Search & Summary: ReWalk Personal System (ReWalk Robotics) for Home Use In Spinal Cord Injury. ©2021 Hayes a sympir company, July 16, 2020, ARCHIVED August 16, 2021
- 7. Holmes CD, Wronkiewicz M, Somers T, et al. IpsiHand Bravo: An improved EEG-based brain-computer interface for hand motor control rehabilitation. Annu Int Conf IEEE Eng Med Biol Soc. 2012:2012:1749-1752.
- 8. L1005 Tension Based Scoliosis Orthosis And Accessory Pads, Includes Fitting And Adjustment Correct Coding. Noridian Healthcare Solutions Publication. Posted November 12, 2020. Available: L1005 Tension Based Scoliosis Orthosis And Accessory Pads, Includes Fitting And Adjustment Correct Coding JA DME Noridian (noridianmedicare.com).
- 9. Miller LE, Zimmermann AK, Herbert WG. Clinical effectiveness and safety of powered exoskeleton-assisted walking in patients with spinal cord injury: Systematic review with meta-analysis. Med Devices (Auckl). 2016;9:455-466.
- 10. Noridian Healthcare Solutions article Correct Coding and Coverage Braces Constructed Primarily of Elastic or Other Fabric Materials Revised 03/16/2017. Available: https://med.noridianmedicare.com/web/jddme/search-result/-

<u>/view/2230703/correct-coding-and-coverage-braces-constructed-primarily-of-elastic-or-other-fabric-materials-revised</u>

- 11. Noridian Healthcare Solutions. Durable Medical Equipment Medicare Administrative Contractor. LCD for <u>Ankle-Foot/Knee-Ankle-Foot Orthosis</u> (L33686). Revision Effective Date 01/01/2020. Available:
- https://med.noridianmedicare.com/web/jddme/policies/lcd/active
- 12. Noridian Healthcare Solutions. Durable Medical Equipment Medicare Administrative Contractor. LCD for <u>Knee Orthosis</u> (L33318). Revision Effective Date 01/01/20. Available: https://med.noridianmedicare.com/web/jddme/policies/lcd/activex
- 13. Noridian Healthcare Solutions. Durable Medical Equipment Medicare Administrative Contractor. LCD for <u>Orthopedic Footwear</u> (L33641). Revision Effective Date 01/01/20. Available: https://med.noridianmedicare.com/web/jddme/policies/lcd/active
- 14. Noridian Healthcare Solutions. Durable Medical Equipment Medicare Administrative Contractor. LCD for <u>Spinal Orthoses</u>: TLSO and LSO_(L33790). Revision Effective Date 01/01/20. Available: https://med.noridianmedicare.com/web/jddme/policies/lcd/active
- 15. Platz T, Gillner A, Borgwaldt N, et al. Device-training for individuals with thoracic and lumbar spinal cord injury using a powered exoskeleton for technically assisted mobility: Achievements and user satisfaction. BioMed Res Int. 2016; 2016: 8459018.
- 16. Rustamov N, Souders L, Sheehan L, et al. IpsiHand brain-computer interface therapy induces broad upper extremity motor recovery in chronic stroke. medRxiv [Preprint]. 2023 Aug 28:2023.08.26.23294320.
- 17. Talaty M, Esquenazi A, Briceno JE. Differentiating ability in users of the ReWalk Powered Exoskeleton: An analysis of walking kinematics. 2013 IEEE International Conference on Rehabilitation Robotics, Seattle, Washington, June 24-26, 2013.

Customer Product	Medical Management Requirements*
New York Products	
HMO	Prior Auth
PPO In Plan	Prior Auth
PPO OOP	Prior Auth
POS In Plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Prior Auth
MVP Child Health Plus	Prior Auth
MVP Harmonious Health Care Plan	Prior Auth
MVP Medicare Complete Wellness	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP Medicare WellSelect PPO	Prior Auth
MVP Medicare WellSelect Plus PPO	Prior Auth
MVP Medicare Patriot Plan PPO	Prior Auth
MVP DualAccess D-SNP HMO	Prior Auth
MVP DualAccess Complete D-SNP HMO	Prior Auth
MVP DualAccess Plus D-SNP HMO	Prior Auth
UVM Health Advantage Select PPO	Prior Auth
USA Care	Potential for Retrospective Review
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	500 5.15
POS In Plan	Prior Auth
POS OOP	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP VT HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit
See SPD See Specific Plan Design

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MVP Health Care Medical Policy Revision History:

06/01/2021 – Annual review, added HCPCS code descriptions, references and websites sections updated.

06/01/2024 – Annual review with no changes to the indications or criteria.

12/1/2024 – Ipsihand added to exclusions as E&I (HCPCS code E0738).

01/01/2025 – The Scoliosis Bracing Medical Policy is being archived so imported scoliosis bracing indications and exclusions from archived policy into this policy. Updated references. L1300, L1310 and L1006 removed from prior authorization. L1005 added to prior authorization.



Oxygen and Oxygen Equipment

Type of Policy: Medical

Prior Approval Date: 12/19/2022

Approval Date: 11/04/2024

Effective Date: 02/01/2025

Related Polices: Durable Medical Equipment

Medical Policy

Durable Medical Equipment

Payment Policy

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

N/A

Codes Subject to Retrospective Review

N/A

Experimental/Investigational

N/A

Common Diagnosis Codes

N/A

Common Procedure Codes

E0424, E0425, E0430, E0431, E0433, E0434, E0435, E0439, E0440, E0441, E0442, E0443, E0444, E0445, E0447, E1390, E1391, E1392, E1405, E1406, K0738

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are

subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy.

Overview

Oxygen equipment refers to devices and systems used to provide store or deliver oxygen for various medical purposes. Medical oxygen equipment is often used to support patients with respiratory conditions such as chronic obstructive pulmonary disease (COPD), pneumonia, or asthma. Common types of medical equipment include:

- 1. Oxygen concentrators: Devices that take in ambient air, remove nitrogen, and produce concentrated oxygen for patient use. They are commonly used in home or hospital settings.
- 2. Oxygen cylinders or tanks: Portable or stationary containers that store compressed oxygen. They are often used when a high flow rate of oxygen is required or as a backup for other equipment.
- 3. Oxygen masks and nasal cannulas: Devices used to deliver oxygen from a source to a patient. Masks cover the nose and mouth while nasal cannulas are thin tubes placed into the nostrils.
- 4. Portable oxygen systems: Lightweight systems that allow patients to remain mobile while receiving oxygen therapy. These systems may include portable oxygen concentrators or small oxygen cylinders.

Oxygen and oxygen equipment are essential for supporting life treating medical conditions.

Documentation Requirements

Documentation for initial coverage requires information in the medical record showing:

- The treating practitioner has ordered and evaluated the results of a qualifying blood gas study performed at the time of need; and
- In order to provide initial coverage for customers in Groups I, II and III, there must be evidence in the medical record documenting one of the following A-C criteria:
 - A. A symptomatic, hypoxemic patient who meets criteria for Group I or II; or,
 - B. A symptomatic, normoxemic patient with a medical condition that improves with oxygen therapy; or,
 - C. For customers with concurrent Obstructive Sleep Apnea (OSA), the qualifying oxygen saturation test is performed following optimal treatment of the OSA as described in the Coverage Indications, Limitations, and/or Medical Necessity.

The beneficiary's medical record must have documentation that describes any concerns for variations in oxygen measurements that may result from such factors as the patient's

age, the patient's skin pigmentation, the altitude level, or a decrease in oxygen carrying capacity.

Initial coverage of home oxygen and oxygen equipment must include the most recent qualifying PO₂ blood gas study or SpO₂ documented as part of the medical record or written on the prescription.

In order to continue coverage of oxygen and oxygen equipment, there must be evidence in the medical record documenting:

Group I

While there is no formal requirement for re-evaluation and retesting, providers should ensure that once qualified for home oxygen therapy, the oxygen therapy and oxygen equipment remain reasonable and necessary.

Group II

A re-evaluation and a repeat qualifying blood gas test by the treating practitioner between the 61st and 90th days after initiation of therapy and,

A new order by the treating practitioner.

Group III

A re-evaluation by the treating practitioner between the 61st and 90th days after initiation of therapy, and,

A new order by the treating practitioner.

Indications/Criteria

Home Oxygen Therapy

Initial coverage of home oxygen therapy and oxygen equipment is reasonable and necessary for Groups I and II if all of the following conditions are met:

- 1. The treating practitioner has ordered and evaluated the results of a qualifying blood gas study performed at the time of need; and,
- 2. The beneficiary's blood gas study meets the criteria stated below; and,
- 3. The qualifying blood gas study was performed by a treating practitioner or by a qualified provider or supplier of laboratory services; and,
- 4. The provision of oxygen and oxygen equipment in the home setting will improve the beneficiary's condition.

Time of need is defined as during the patient's illness when the presumption is that the provision of oxygen will improve the patient's condition in the home setting. For an inpatient hospital patient anticipated to require oxygen upon going home, the time of need would be within 2 days of discharge.

Group I criteria include any of the following:

- 1. An arterial PO2 at or below 55 mm Hg or an arterial oxygen saturation at or below 88 percent taken at rest (awake) while breathing room air; or,
- 2. An arterial PO2 at or below 55 mm Hg, or an arterial oxygen saturation at or below 88 percent, taken during sleep for a beneficiary who demonstrates an arterial PO2 at or above 56 mm Hg or an arterial oxygen saturation at or above 89 percent while awake. In this instance, oxygen and oxygen equipment is only reasonable and necessary during sleep; or,
- 3. A decrease in arterial PO2 more than 10 mm Hg, or a decrease in arterial oxygen saturation more than 5 percent from baseline saturation, taken during sleep and associated with symptoms of hypoxemia such as impairment of cognitive processes and nocturnal restlessness or insomnia (not all inclusive). In this instance, oxygen and oxygen equipment is only reasonable and necessary during sleep; or,
- 4. An arterial PO2 at or below 55 mm Hg or an arterial oxygen saturation at or below 88 percent, taken during exercise for a beneficiary who demonstrates an arterial PO2 at or above 56 mm Hg or an arterial oxygen saturation at or above 89 percent during the day while at rest. In this instance, portable oxygen and oxygen equipment is only reasonable and necessary while awake and during exercise.

Group II criteria include all of the following:

- A. An arterial PO2 of 56-59 mm Hg or an arterial blood oxygen saturation of 89 percent; and,
- B. Any of the following:
 - 1.Dependent edema suggesting congestive heart failure; or,
 - 2.Pulmonary hypertension or cor pulmonale, determined by measurement of pulmonary artery pressure, gated blood pool scan, echocardiogram, or "P" pulmonale on EKG (P wave greater than 3 mm in standard leads II, III, or AVF); or,
 - 3. Erythrocythemia with a hematocrit greater than 56 percent.

Group III criteria:

Initial coverage of home oxygen therapy and oxygen equipment is reasonable and necessary for customers in Group III, if all of the following conditions are met:

- 1. Absence of hypoxemia defined in Group I and Group II above; and,
- 2. A medical condition with distinct physiologic, cognitive, and/or functional symptoms documented in high-quality, peer-reviewed literature to be improved by oxygen therapy, such as cluster headaches (not all inclusive).

Group IV criteria:

Oxygen therapy and oxygen equipment will also be denied as not medically necessary if any of the following conditions are present:

- 1. Angina pectoris in the absence of hypoxemia. This condition is not the result of a low oxygen level in the blood and there are other preferred treatments; or,
- 2. Dyspnea without cor pulmonale or evidence of hypoxemia; or,
- 3. Severe peripheral vascular disease resulting in clinically evident desaturation in one or more extremities but in the absence of systemic hypoxemia. There is no evidence that increased PO2 will improve the oxygenation of tissues with impaired circulation; or,
- 4. Terminal illnesses that do not affect the ability to breathe.

Obstructive Sleep Apnea (OSA), Polysomnography and Home Sleep Tests:

Some customers may require the simultaneous use of home oxygen therapy and oxygen equipment with a PAP device.

In the case of OSA, it is required that the OSA be appropriately and sufficiently treated before oxygen saturation results obtained during sleep testing are considered qualifying for oxygen therapy and oxygen equipment. This must be demonstrated before oxygen saturation results obtained during polysomnography are considered qualifying for oxygen therapy and oxygen equipment.

For customers with OSA, a qualifying oxygen saturation test may only occur during a titration polysomnographic study (either split night or stand-alone). The titration PSG is one in which all of the following criteria are met:

- 1. The titration is conducted over a minimum of two (2) hours; and,
- 2. During titration:
 - A. The AHI/RDI is reduced to less than or equal to an average of ten (10) events per hour; or,
 - B. If the initial AHI/RDI was less than an average of ten (10) events per hour, the titration demonstrates further reduction in the AHI/RDI; and,
- 3. Nocturnal oximetry conducted for the purpose of oxygen therapy and oxygen equipment reimbursement qualification may only be performed after optimal PAP settings have been determined and the beneficiary is using the PAP device at those settings; and,
- 4. The nocturnal oximetry conducted during the PSG demonstrates an oxygen saturation ≤ 88% for 5 minutes total (which need not be continuous).

Home Sleep Oximetry Studies

Customers may self-administer home-based overnight oximetry tests under the direction of a Medicare-enrolled Independent Diagnostic Testing Facility (IDTF).

A DME supplier or another shipping entity may deliver a pulse oximetry test unit and related technology to a beneficiary's home under the following circumstances:

- the customer's treating physician has contacted the IDTF to order an overnight pulse oximetry test before the test is performed;
- the test is performed under the direction and/or instruction of a Medicare-approved IDTF;
- the test unit is sealed and tamper-proof such that test results cannot be accessed by anyone other than the IDTF who is responsible for transmitting a test report to the treating physician:
 - the IDTF must send the test results to the physician; and
 - o the IDTF may send the test results to the supplier under limited circumstances:
 - if the supplier is currently providing, or has an order to provide, oxygen or other respiratory services to the customer; or
 - if the customer has signed a release permitting the supplier to receive the report;
- the oxygen saturation or arterial PO₂ study obtained during exercise:
 - there must be three oxygen saturation or arterial PO₂ studies in the patient's medical record:
 - testing at rest without oxygen; and
 - testing during exercise without oxygen applied; and
 - testing during exercise with oxygen applied;
 - o only the oxygen saturation or arterial PO₂ blood gas test value is reported on the Certificate of Medical Necessity (CMN);
 - o other values must be available upon request; and
 - o the oxygen saturation or arterial PO₂ may be performed on oxygen as long as the reported blood gas values meet the Group I or Group II criteria.

Portable Oxygen Systems

A portable oxygen system is covered if the beneficiary is mobile within the home for Groups I and II, and the qualifying blood gas study was performed while at rest (awake) or during exercise. If the only qualifying blood gas study was performed during sleep, portable oxygen is not medically necessary.

If a portable oxygen system is covered, the supplier must provide whatever quantity of oxygen the customer uses; reimbursement is the same, regardless of the quantity of oxygen dispensed (one month supply = one unit of contents).

Oxygen Contents:

Payment for stationary and portable contents is included in the fee schedule allowance for stationary equipment. No payment can be made for oxygen contents in a month in which payment is made for stationary equipment.

Concentrators will be covered on a rental basis.

Oxygen Accessories:

Accessories, including but not limited to, trans-tracheal catheters (A4608), cannulas (A4615), tubing (A4616), mouthpieces (A4617), face tent (A4619), masks (A4620, A7525), oxygen conserving devices (A9900), oxygen tent (E0455), humidifiers (E0555), nebulizer for humidification (E0580), regulators (E1353), and stand/rack (E1355) are included in the allowance for rented oxygen equipment. The supplier must provide any accessory ordered by the treating practitioner. Accessories used with customer-owned oxygen equipment will be denied as non-covered.

Travel Oxygen:

It is the Customer's responsibility to arrange for oxygen during their travels. MVP will not cover items or services provided or used outside the United States and its territories.

MVP Healthcare will only pay one supplier for oxygen during any one rental month.

Oxygen services furnished by an airline to a beneficiary are non-covered. Payment for oxygen furnished by an airline is the responsibility of the customer and not the responsibility of the supplier.

Oximeters (E0445):

• Oximeters are covered on a case-by-case basis and only to monitor supplemental oxygen use in the home for infants with chronic lung disease (e.g., bronchopulmonary dysplasia, congenital heart disease, neurological disease).

New Orders:

A new order must be obtained and kept on file by the supplier, but neither a new Order nor a repeat blood gas study are required for the following situations:

- prescribed maximum flow rate changes but remains within one of the following categories: (a) less than 1 LPM; (b) 1-4 LPM; (c) greater than 4 LPM;
- change from one type of system to another (i.e., concentrator, liquid, gaseous);
- Change from one type of portable system to another (i.e., gaseous, or liquid tanks, portable concentrator, trans-filling system).

Exclusions

- Customers with arterial PO $_2$ levels \geq 60 mm Hg or arterial blood oxygen saturations \geq 90 percent.
- When both arterial blood gas (ABG) and oximetry tests have been performed on the same day under the same conditions (i.e., at rest/awake, during exercise, or during sleep), the ABG result will be used to determine if the coverage criteria were met. If an ABG test at rest/awake is non-qualifying, but an exercise or sleep oximetry test on the same day is qualifying, the oximetry test result will determine coverage.
- When oxygen saturation or arterial PO₂ is performed during sleep for portable oxygen systems, the portable oxygen is considered not medically necessary.
- Purchased oxygen systems will be denied as non-covered.
- Oximeters and replacement probes will be denied as non-covered because they are monitoring devices that provide information to physicians to assist in managing the patient's treatment.
- Emergency or stand-by oxygen systems will be denied as not medically necessary since they are precautionary and not therapeutic in nature.
- Respiratory therapists' services are non-covered under the DME benefit.
- The Breathe Technologies Life2000 Ventilation System is not medically necessary because there are no literature reviews, evidence of improved medical outcomes or research by specialists that describe the safety, value, or effectiveness (success) for this ventilator over other ventilators.
- The myAIRVO™ 2 Humidified High Flow Therapy System is not medically necessary because there are no literature reviews, evidence of improved medical outcomes or research by specialists that describe the safety, value or effectiveness (success) for this humidified high flow nasal canula/positive airway pressure device over other devices that can provide humidified high flow oxygen and/or positive airway pressure.

Medicaid Managed Care Variation

Oximeter (E0445)

- Covered only in combination with oxygen therapy
- In cases of complex cardiac conditions such as but not limited to; patients with univentricular heart, or unrepaired cyanotic heart disease, an oximeter device is covered without supplemental oxygen therapy.
- Not to be billed with apnea monitors or ventilators unless treatment plan calls for weaning from these devices.

• The 30-day rental fee for pulse oximeters includes all supplies.

References (Reviewed 2025)

- 1. Allen, J, et al. et al. American Thoracic Society. Statement on the care of the child with chronic lung disease of infancy and childhood. American Journal of Respiratory Critical Care Medicine. 2003 Aug 1; 168(3):356-396.
- 2. Breathe Technologies Inc., Life2000TM Ventilation System. 2018. Accessed Dec. 8, 2022 Available: Life2000® Ventilation System for Home Care | Hillrom
- 3. Centers for Medicare & Medicaid Services (CMS) Medicare Coverage Database NCD for Home Use of Oxygen (240.2). Implementation Date: 01/03/2023. Available: MCD Search (cms.gov)
- 4. Hygrometric Performances of Different High-Flow Nasal Cannula Devices: Bench Evaluation and Clinical Tolerance Respir Care. 2021 Nov;66(11):1720-1728. doi: 10.4187/respcare.09085. Epub 2021 Sep 21.
- 5. New York State Medicaid Program. Durable Medical Equipment Manual Policy Guidelines. Version2022 (6/1/2022). Available: https://www.emedny.org/ProviderManuals/DME/index.aspx.
- 6. Noridian Healthcare Solutions, LLC. Durable Medical Equipment Medicare Administrative Contractor. LCD for Oxygen and Oxygen Equipment (L33797). Revision Effective Date 041/01/2023. Available: MCD Search (cms.gov)
- 7. Noridian Healthcare Solutions, LLC. Durable Medical Equipment Medicare Administrative Contractor LCD for Nebulizers (L33370). Revision Effective Date 06/05/2022. Available: MCD Search (cms.gov)

Customer Product	Medical Management Requirements*
New York Products	•
НМО	Potential for Retrospective Review
PPO in Plan	Potential for Retrospective Review
PPO OOP	Potential for Retrospective Review
POS in Plan	Potential for Retrospective Review
POS OOP	Potential for Retrospective Review
Essential Plan	Potential for Retrospective Review
MVP Medicaid Managed Care	Potential for Retrospective Review
MVP Child Health Plus	Potential for Retrospective Review
MVP Harmonious Health Care Plan	Potential for Retrospective Review
MVP Medicare Complete Wellness	Potential for Retrospective Review
MVP Medicare Preferred Gold HMO POS	Potential for Retrospective Review
MVP Medicare Secure HMO POS	Potential for Retrospective Review
MVP Medicare Secure Plus HMO POS	Potential for Retrospective Review
MVP Medicare WellSelect PPO	Potential for Retrospective Review
MVP Medicare WellSelect Plus PPO	Potential for Retrospective Review
MVP Medicare Patriot Plan PPO	Potential for Retrospective Review
MVP DualAccess D-SNP HMO	Potential for Retrospective Review
MVP DualAccess Complete D-SNP HMO	Potential for Retrospective Review
MVP DualAccess Plus D-SNP HMO	Potential for Retrospective Review
UVM Health Advantage Select PPO	Potential for Retrospective Review
USA Care PPO	Potential for Retrospective Review
Healthy NY	Potential for Retrospective Review
MVP Premier	Potential for Retrospective Review
MVP Premier Plus	Potential for Retrospective Review
MVP Premier Plus HDHP	Potential for Retrospective Review
MVP Secure	Potential for Retrospective Review
MVP EPO	Potential for Retrospective Review
MVP EPO HDHP	Potential for Retrospective Review
MVP PPO	Potential for Retrospective Review
MVP PPO HDHP	Potential for Retrospective Review
Student Health Plans	Potential for Retrospective Review
ASO	See SPD
Vermont Products	
POS in Plan	Potential for Retrospective Review
POS OOP	Potential for Retrospective Review
MVP Medicare Preferred Gold HMO POS	Potential for Retrospective Review
MVP Medicare Secure Plus HMO POS	Potential for Retrospective Review
MVP VT HMO	Potential for Retrospective Review
MVP VT HDHP HMO	Potential for Retrospective Review
MVP VT Plus HMO	Potential for Retrospective Review
MVP VT Plus HDHP HMO	Potential for Retrospective Review
MVP Secure	Potential for Retrospective Review
ASO	See SPD

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g., HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Revision History:

4/13/2022 – myAirvo 2 device added to exclusions.

01/01/2023 – Updates done based on Medicare LCD/NCD. Updated documentation requirements; updated qualifications for continued oxygen equipment rental, Added Group IV criteria, Added Obstructive Sleep Apnea (OSA), Polysomnography and Home Sleep Test criteria, updated portable oxygen systems criteria, added Oxygen Accessories, updated references.

02/01/2025 – Annual review with no changes to the indications or criteria. References reviewed.



Panniculectomy and Abdominoplasty

Type of Policy: Surgical

Prior Approval Date: 06/06/2022

Approval Date: 05/06/2024

Effective Date: 08/01/2024

Related Polices: Gender Affirming Treatment

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

CPT Codes:

15830 - Excision, excessive skin and subcutaneous tissue (includes lipectomy); abdomen, infraumbilical panniculectomy

15847 - Excision, excessive skin and subcutaneous tissue (includes lipectomy), abdomen (eg, abdominoplasty) (includes umbilical transposition and fascial plication) (List separately in addition to code for primary procedure)

Experimental/Investigational

N/A

Common Diagnosis Codes

ICD-10 Diagnosis Codes: L03.319, L03.329, L26. L30.4, L58.8, L92.0, L95.1, L98.2, M79.3

Common Procedure Codes

N/A

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-

authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

Panniculectomy is the removal of an excessive amount of redundant skin/fat in the abdominal area as a result of massive weight loss following bariatric surgery or medical management of morbid obesity. The excessive skin and fat folds may result in health issues such as intertrigo and recurring infections of the skin.

Abdominoplasty is a type of surgery that is used to tighten loose muscles and remove excess skin from the abdomen. Often referred to as a "tummy tuck" and is considered to be cosmetic surgery.

Policy Criteria

Prior to coverage for a panniculectomy, customers must have tried and failed maximum conservative therapy under the direction of an appropriate specialist for conditions listed in this policy.

Panniculectomy

Panniculectomy will be considered medically necessary when the following criteria have been met:

- documentation in the customer's record indicating that the panniculus hangs below the level of the pubis as demonstrated by pre-operative photographs; and
 - o persistent recurrent skin infections under the folds of the panniculus; or
 - o intertrigo with maceration; and
- documentation that skin infections or intertrigo has been refractory to 3 months of medical management by customer's dermatologist or primary care physician (PCP).
 In addition to good hygiene practices, treatments should include topical antifungals, topical and/or systemic corticosteroids, and/or local or systemic antibiotics unless contraindicated or intolerant.

Post Weight Loss Panniculectomy

- In addition to the criteria listed under Indications/Criteria of this policy, medical documentation must indicate that the patient has maintained a stable weight over the past six (6) months.
- For panniculectomy performed as a result of significant weight loss due to bariatric surgery, medical record documentation must indicate that the bariatric surgery was performed at least eighteen (18) months prior to requesting the panniculectomy

procedure and the customer's weight has been stable during the most recent six (6) month period.

Abdominoplasty

Abdominoplasty is considered to be cosmetic for all indications, other than gender affirming care.

• For Gender Affirming care please refer to MVP Health Care Medical Policy on Gender Affirming Treatment.

Exclusions

- Panniculectomy requested primarily for cosmetic, psychological, or psychosocial reasons will be considered not medically necessary.
- The following procedures and codes are cosmetic in nature and are considered to be not medically necessary:
 - o abdominoplasty (15847 tightens and removes excess skin of the abdomen);
 - o belt lipectomy (15832; 15835 -removal of skin/fat from thighs and buttocks);
 - o torsoplasty (15834 includes liposuction of hips/flanks and breast augmentation);
 - o brachioplasty (15836 arm "lift")
 - o circumferential lipectomy ("back lift", may include liposuction); and
 - o lower body lift (15835; 15832 treats lower trunk and thighs).

Medicare

Based on review, there is no Medicare National Coverage Decision (NCD) or Medicare Local Coverage Decision (LCD) for Panniculectomy and Abdominoplasty.

References (Updated 2024).

- 1. American Society of Plastic Surgeons (ASPS). Practice Parameter for Surgical Treatment of Skin Redundancy for Obese and Massive Weight Loss Patients. Jul 2006. Last updated Jan 2007. Available: www.plasticsurgery.org.
- 2. American Society of Plastic Surgeons (ASPS). Practice Parameter for Abdominoplasty and Panniculectomy Unrelated to Obesity or Massive Weight Loss. Jul 2006. Last updated Jan 2007. Available: www.plasticsurgery.org.
- 3. Acarturk TO, Wachtman G, Heil B, Landecker A, Courcoulas AP, Manders EK. Panniculectomy as an adjuvant to bariatric surgery. Ann Plast Surg. 2004;53(4):360-366, discussion 367.
- 4. HAYES Health Technology Assessment. Panniculectomy For Treatment Of Symptomatic Panniculi. HAYES, Inc.; © 2021 Hayes, a symplr company. May 19, 2016; Annual Review September 4, 2020. Archived June 19, 2021.

- 5. American Society of Plastic Surgeons (ASPS). ASPS Recommended Insurance Coverage Criteria for Third-Party Payers. Abdominoplasty. 2006 Jul. Last updated 2016 Jan. Reaffirmed 2018 Sept. Available: http://www.plasticsurgery.org/for-medical-professionals/legislation-and-advocacy/health-policy-resources/recommended-insurance-coverage-criteria.htm.
- 6. American Society of Plastic Surgeons (ASPS). ASPS Recommended Insurance Coverage Criteria for Third-Party Payers. Panniculectomy. 2006 July. Last updated 2019 Jan. Re-approved 2019 March. Available: http://www.plasticsurgery.org/for-medical-professionals/legislation-and-advocacy/health-policy-resources/recommended-insurance-coverage-criteria.html.
- 7. Derickson M, Phillips C, Barron M, Kuckelman J, Martin M, DeBarros M. Panniculectomy after bariatric surgical weight loss: Analysis of complications and modifiable risk factors. Am J Surg. 2018 May;215(5):887-890. doi: 10.1016/j.amjsurg.2018.02.008. Epub 2018 Feb 7. PMID: 29439774.
- 8. Giordano S, Garvey PB, Baumann DP, Liu J, Butler CE. Concomitant Panniculectomy Affects Wound Morbidity but Not Hernia Recurrence Rates in Abdominal Wall Reconstruction: A Propensity Score Analysis. Plast Reconstr Surg. 2017 Dec;140(6):1263-1273. doi: 10.1097/PRS.00000000000003855. PMID: 28820845.
- 9. Kuruoglu D, Salinas CA, Tran NV, Nguyen MT, Martinez-Jorge J, Bite U, Harless CA, Sharaf B. Abdominal Panniculectomy: An Analysis of Outcomes in 238 Consecutive Patients over 10 Years. Plast Reconstr Surg Glob Open. 2021 Nov 24;9(11):e3955. doi: 10.1097/GOX.0000000000003955. PMID: 34840922; PMCID: PMC8613336.
- 10. Jeyarajah R, Harford WV. Abdominal Hernias and Gastric Volvulus. In: Feldman: Sleisenger & Fordtran's Gastrointestinal and Liver Disease, 9th ed. Copyright © 2010 Saunders, an Imprint of Elsevier.

Customer Product	Medical Management Requirements*
New York Products	-
HMO	Prior Auth
PPO in Plan	Prior Auth
PPO OOP	Prior Auth
POS in Plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Prior Auth
MVP Child Health Plus	Prior Auth
MVP Harmonious Health Care Plan	Prior Auth
MVP Medicare Complete Wellness	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP Medicare WellSelect PPO	Prior Auth
MVP Medicare WellSelect Plus PPO	Prior Auth
MVP Medicare Patriot Plan PPO	Prior Auth
MVP DualAccess D-SNP HMO	Prior Auth
MVP DualAccess Complete D-SNP HMO	Prior Auth
MVP DualAccess Plus D-SNP HMO	Prior Auth
UVM Health Advantage Select PPO	Prior Auth
USA Care	Potential for Retrospective Review
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	
POS in Plan	Prior Auth
POS OOP	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP VT HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD

[♦] Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Revision History:

08/01/2022 – Annual review; all criteria must now be met for panniculectomy and added examples of treatment that must be tried and failed; removed indications for abdominoplasty and added to exclusions.

08/01/2024 – Annual review; no changes to criteria, updated overview.



Pectus Deformity Repair

Type of Policy: Surgical

Prior Approval Date: n/a

Approval Date: 12/02/2024

Effective Date: 04/01/2025

Related Polices: none

Codes Requiring Prior Authorization

21740 – Reconstructive repair of pectus excavatum or carinatum; open

21742 – Reconstructive repair of pectus excavatum or carinatum; minimally invasive approach (Nuss procedure), without thoracoscopy

21743 - Reconstructive repair of pectus excavatum or carinatum; minimally invasive approach (Nuss procedure), with thoracoscopy

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

Codes Requiring Retrospective Review

N/A

Experimental/Investigational

N/A

Common Diagnosis Codes

ICD-10 Diagnosis Codes: M95.4, Q67.6, E55.0, E64.3

Common Diagnosis Codes associated with this policy have been provided for informational purposes only. The list of codes may not be all-inclusive and may be updated to reflect any applicable revisions to the ICD-10 code set and/or medical necessity quidelines applied in this policy.

Common Procedure Codes

CPT Codes: none

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

Pectus deformities are anomalies of the thoracic cage caused by excessive growth of the cartilage in the chest.

Pectus Excavatum, also known as funnel chest or sunken chest, is characterized by a depression in the anterior chest wall. Cardiac and pulmonary compression can occur depending on the size of the deformity. Although the deformity may be identified in infancy, it can progress with growth. Surgical repair of Pectus Excavatum is usually reserved for severe deformities. Surgical repair typically occurs during adolescence while the chest is still soft and malleable.

Pectus Carinatum is characterized by a protrusion of the sternal and costal cartilages. Although cardiopulmonary disorders are rare with Pectus Carinatum, symptoms can include chest wall pain, back pain, scoliosis, kyphosis, dyspnea, and reduced endurance. Orthotic bracing is the first line treatment for thoracic reshaping, often yielding better results than surgical correction.

Indications/Criteria

Coverage is considered when the following criteria are met:

- symptoms/findings consistent with pectus excavatum/carinatum; and
- sternal depression or protrusion by physical exam; and
- findings normal/consistent with pectus excavatum/carinatum; and
- CT/MRI findings; or
- History of orthotic bracing or not feasible for carinatum.

For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures, Pectus Excavatum.

The complete Change Healthcare InterQual imaging criteria are available for providers online at www.mvphealthcare.com or by calling 1-800-568-0458.

Exclusions

Request not meeting InterQual® criteria.

Medicare

Based upon review, there is no Medicare National, Local Coverage Determination (NCD or LCD) or policy specifically addressing pectus deformity repair.

References (2024)

1. InterQual® Clinical Decision Support Criteria. Change Healthcare LLC, Copyright © 2020 Change Healthcare.

Member Product	Medical Management Requirements*
New York Products	-
НМО	Prior Authorization
PPO in Plan	Prior Authorization
PPO OOP	Prior Authorization
POS in Plan	Prior Authorization
POS OOP	Prior Authorization
Essential Plan	Prior Authorization
MVP Medicaid Managed Care	Prior Authorization
MVP Child Health Plus	Prior Authorization
MVP Harmonious Health Care Plan	Prior Authorization
MVP Medicare Complete Wellness	Prior Authorization
MVP Medicare Preferred Gold HMO POS	Prior Authorization
MVP Medicare Secure HMO POS	Prior Authorization
MVP Medicare Secure Plus HMO POS	Prior Authorization
MVP Medicare WellSelect PPO	Prior Authorization
MVP Medicare WellSelect Plus PPO	Prior Authorization
MVP Medicare Patriot Plan (PPO)	Prior Authorization
USA Care PPO	Potential for Retrospective Review
MVP DualAccess D-SNP HMO	Prior Authorization
MVP DualAccess Complete D-SNP HMO	Prior Authorization
MVP DualAccess Plus D-SNP HMO	Prior Authorization
UVM Health Advantage Select PPO	Prior Authorization
Healthy NY	Prior Authorization
MVP Premier	Prior Authorization
MVP Premier Plus	Prior Authorization
MVP Premier Plus HDHP	Prior Authorization
MVP Secure	Prior Authorization
MVP EPO	Prior Authorization
MVP EPO HDHP	Prior Authorization
MVP PPO	Prior Authorization
MVP PPO HDHP	Prior Authorization
Student Health Plans	Prior Authorization
ASO	See SPD
Vermont Products	
POS in Plan	Prior Authorization
POS OOP	Prior Authorization
MVP Medicare Preferred Gold HMO POS POS	Prior Authorization
MVP Medicare Secure Plus HMO POS	Prior Authorization
MVP VT HMO	Prior Authorization
MVP VT HDHP HMO	Prior Authorization
MVP VT Plus HMO	Prior Authorization
MVP VT Plus HDHP HMO	Prior Authorization
MVP Secure	Prior Authorization
ASO	See SPD

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review.

Retro ReviewRetrospective Review RequiredNot CoveredService is not a covered benefit.See SPDSee Specific Plan Design

MVP Health	Care Medical Policy	
Revision His	story:	
04/01/2025 -	- New Policy created from the InterQual Criteria Medical Policy.	



Penile Implant for Erectile Dysfunction

Type of Policy: Surgical

Prior Approval Date: 10/04/2021

Approval Date: 09/11/2023

Effective Date: 12/01/2023

Related Polices: MVP Erectile Dysfunction Medical Policy

Gender Affirming Treatment

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

CPT Code:	Description:
54400	Insertion of penile prosthesis; non-inflatable (semi-rigid)
54401	Insertion of penile prosthesis; inflatable (self-contained)
54405	Insertion of multi-component, inflatable penile prosthesis, including
	placement of pump, cylinders, and reservoir
54406	Removal of all components of a multi-component, inflatable penile
	prosthesis without replacement of prosthesis
54408	Repair of component(s) of a multi-component, inflatable penile
	prosthesis
54410	Removal and replacement of all component(s) of a multi-
	component, inflatable penile prosthesis at the same operative
	session
54411	Removal and replacement of all components of a multi-component
	inflatable penile prosthesis through an infected field at the same
	operative session
54415	Removal of non-inflatable (semi-rigid) or inflatable (self-contained)
	penile prosthesis, without replacement of prosthesis
54416	Removal and replacement of non-inflatable (semi-rigid) or inflatable
	(self-contained) penile prosthesis at the same operative session

54417	Removal and replacement of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis through an infected field at the same operative session
C1813	Prosthesis, penile, inflatable
C2622	Prosthesis, penile, noninflatable

Codes Subject to Retrospective Review

N/A

Experimental/Investigational

N/A

Common Diagnosis Codes

ICD-10 Diagnosis Codes: F52.21, F52.22, F52.8, N52.01, N52.02, N52.03, N52.1, N52.2, N52.31, N52.32, N52.33, N52.34, N52.39, N52.8, N52.9

Common Procedure Codes

N/A

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy.

Overview

Erectile Dysfunction (ED) is defined by the American Urological Association's (AUA) 2018 guideline as the consistent or recurrent inability to attain and/or maintain an erection sufficient for sexual satisfaction, including satisfactory sexual performance.

Management/treatment options should be based on the needs of the individual and his partner and should be appropriate for the age of the man and his health condition. In most cases, first-line treatment includes oral medications. (Refer to MVP's Erectile Dysfunction Medical Policy for coverage of drugs to treat erectile dysfunction.)

There are two forms of penile prosthesis available: non-inflatable or inflatable. The non-inflatable (semi-rigid malleable rods) device consists of two semi-rigid rods that are surgically implanted in the corpora cavernosa. Inflatable devices consist of paired cylinders surgically implanted inside the penis that can be expanded using pressurized fluid. Tubes connect the cylinders to a reservoir filled with radiopaque fluid implanted in the abdomen and a subcutaneous pump implanted in the scrotum. Penile rigidity is achieved when the cylinders are filled with fluid.

Documentation Requirements

Documentation is required to support medical necessity.

Documentation that a complete sexual, psychosocial, and medical history has been done to determine the customer's perception of the problem and expectations, desires, and needs. If possible, the partner should be included in this evaluation.

Documentation must include that the diagnosis of erectile dysfunction has been differentiated from other forms of sexual problems, such as lack of sexual desire, premature or delayed ejaculation, and delayed orgasm.

Documentation of screening for potentially reversible causes of erectile dysfunction, such as prescription and non-prescription drug use, substance abuse, depression, and relationship problems or marital tensions.

Indications/Criteria

Penile implants for the treatment of erectile dysfunction are indicated for those customers who meet the following conditions:

- persistent organic erectile dysfunction that has occurred for at least six months;
- treatment may be initiated prior to six months, in the case of an acute event such as penile trauma or radical pelvic surgery (e.g., prostatectomy or cystectomy), or in the case of drug-induced ED caused by treatment of a co-morbid condition.
- a physical examination with follow-up on abnormal findings, such as suspected endocrine diseases or abnormal prostate;
- for men with failure, contraindication or intolerance of all the following forms of therapy:
 - o oral erectogenic agents (PDE5 inhibitors);
 - intracavernosal injections (ICI);
 - o alprostadil; and
 - vacuum erection devices (VED): penile vacuum devices use a hand pump and cylindrical component to create a vacuum around the penis, drawing blood into the penis, resulting in an erection.

Surgical removal with or without reimplantation of a penile implant is only covered for the following medically necessary indications:

- Infection
- Device failure
- Urinary obstruction
- Intractable pain

Exclusions

- Not meeting criteria under Indications/criteria in this policy.
- Psychogenic erectile dysfunction such as:
 - Inhibited sexual desire or excitement; or
 - Delayed orgasm; or
 - o Premature or delayed ejaculation
- Alcohol or substance abuse
- Surgical reimplantation of a functional penile implant for any reason except those stated in the policy indications and criteria, is considered not medically necessary.
- Low-intensity extracorporeal shock wave therapy (ESWT) is considered experimental and investigational.
- Intracavernosal stem cell therapy is considered experimental and investigational.

MVP Medicaid Managed Care

To implement Chapter 645 of the Laws of 2005, which seeks to ensure that the Medicaid program will not provide coverage for erectile dysfunction (ED) drugs, procedures or supplies to convicted sex offenders, prior approval is required with MVP Health Care. The New York State Department of Health update is available:

https://www.health.ny.gov/health_care/medicaid/program/update/2006/jan2006.htm

Vacuum erection systems (L7900) are limited to diagnosis of impotence, with an order from an urologist or neurologist. Available:

https://www.emedny.org/ProviderManuals/DME/index.aspx

Medicare Variation (Refer to MVP Erectile Dysfunction Medical Policy)

Vacuum Erection Systems (L7900, L7902)

Vacuum Erection Systems are not covered by Medicare.

Vacuum erection devices and related accessories are statutorily non-covered based on the Achieving a Better Life Experience (ABLE) Act of 2014. Refer to the DME MAC LCD for Vacuum Erection Devices (L34824). Available: MCD Search (cms.gov)

There is no CMS National Coverage Determinations (NCD) or Local Coverage Determinations (LCD) for Penile Implants.

There is a CMS National Coverage Determinations (NCD) for Diagnosis and Treatment of Impotence (230.4). No Effective date. Available: www.cms.hhs.gov/

Refer to MVP Erectile Dysfunction Medical Policy for coverage of drugs to treat erectile dysfunction.

References (Updated 2023)

- 1. Dey, Jayant, Shepherd, Mark D., Evaluation and Treatment of Erectile Dysfunction in Men with Diabetes Mellitus, Mayo Clin. Proc., 2002; 77:276-282.
- 2. Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD) for Diagnosis and Treatment of Impotence (230.4). Available: www.cms.gov/
- 3. McVary, KT. Clinical Practice. Erectile Dysfunction. New England Journal of medicine. 2007 Dec. 13; 357(24):2472-81.
- 4. American Association of Clinical Endocrinologists (AACE) and American College of Endocrinology (ACE). 2003. AACE clinical practice guidelines for the evaluation and treatment of male sexual dysfunction. Male Sexual Dysfunction Task Force. Available: https://pro.aace.com/disease-state-resources/reproductive-and-gonad/clinical-practice-quidelines/aace-medical-0
- 5. Guay, A.T., et al. American Association of Clinical Endocrinologists Medical Guidelines for Clinical Practice for the Evaluation and Treatment of Male Sexual Dysfunction: A couple's problem-2003 Update. Endocrine Practice. 2003 Jan/Feb 9 (1) 77-95.
- 6. American Urological Association (AUA). Erectile Dysfunction: AUA Guideline. Last updated 2018. Available at: <u>Erectile Dysfunction (ED) Guideline American Urological Association (auanet.org)</u>
- 7. Insurance Department of the State of New York. Thirty-sixth amendment to regulation No. 62 (11 NYCRR 52). Minimum standards for the form, content and sale of health insurance, including standards for full and fair disclosure. October 2008.
- 8. Lee DJ, Najari BB, Davison WL, et al. Trends in the utilization of penile prostheses in the treatment of erectile dysfunction in the United States. J Sex Med. 2015; 12(7):1638-1645.
- 9. Lightfoot AJ, et al. Inflatable penile prosthesis: an update. Current Opinion Urology. 2010 Nov; 20(6):459-64.
- 10. Hellstrom WJ, Montague DK, Moncada I, et al. Implants, mechanical devices, and vascular surgery for erectile dysfunction. J Sex Med. 2010; 7(1 Pt 2):501-523.
- 11. Santucci RA. Penile prosthesis implantation. Updated Jan 23, 2012. Available: http://www.emedicine.com/med/topic3047.htm
- 12. Trost L, Wanzek P, Bailey G. A practical overview of considerations for penile prosthesis placement. Nat Rev Urol. 2016; 13(1):33-46.
- 13. Lightfoot AJ, Rosevear HM, Kreder KJ. Inflatable penile prostheses: an update. Curr Opin Urol. 2010 Nov; 20(6):459-64.

- 14. Centers for Medicare & Medicaid Services (CMS). MLN Matters. Number: SE1511. Effective Date: July 1, 2015. Discontinued Coverage of Vacuum Erection Systems (VES) Prosthetic Devices in Accordance with the Achieving a Better Life Experience Act of 2014. Available: https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE1511.pdf
- 15. eMedNY. Provider Manuals. DME. Procedure Codes. New York State Medicaid Program. Durable Medical Equipment, Orthotics, Prosthetics, and Supplies. Procedure Codes and Coverage Guidelines. Available: https://www.emedny.org/ProviderManuals/DME/index.aspx
- 16. Office of Medical Management Department of Health Medicaid Update January 2006 Vol. 21, No. 1. Available: https://www.health.ny.gov/health_care/medicaid/program/update/2006/jan2006.htm #ed
- 17. Chapter 645 of the Laws of 2005; the text of the law is available at http://public.leginfo.state.ny.us/menugetf.cgi, (search by chapter number).

Customer Product	Medical Management Requirements*
New York Products	
НМО	Prior Auth
PPO in Plan	Prior Auth
PPO OOP	Prior Auth
POS in Plan	Prior Auth
POS OOP	Priro Auth
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Prior Auth
MVP Child Health Plus	Not Covered
MVP Harmonious Health Care Plan	Prior Auth
MVP Medicare Complete Wellness	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP Medicare WellSelect PPO	Prior Auth
MVP Medicare WellSelect Plus PPO	Prior Auth
MVP Medicare Patriot Plan PPO	Prior Auth
MVP DualAccess D-SNP HMO	Prior Auth
MVP DualAccess Complete D-SNP HMO	Prior Auth
MVP DualAccess Plus D-SNP HMO	Prior Auth
UVM Health Advantage Select PPO	Prior Auth
USA Care PPO	Potential for Retrospective Review
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	
POS in Plan	Prior Auth
POS OOP	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP VT HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review

No Prior Authorization Required. May be subject to Retrospective Review

Potential for Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit
See SPD See Specific Plan Design

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Revision History:

12/01/2021 - Annual review with no changes to the indications or criteria. Changes were made to the format and expanded definitions for criteria points.

12/01/2023 – Annual review, overview updated with the definition based on American Urological Association, documentation requirements updated with what had previously been required as indications, indications for persistent organic erectile dysfunction increased to six months except as indicated; added contraindication or intolerance to therapy, added criteria for surgical removal and bulleted indications. Moved psychogenic erectile dysfunction and alcohol or substance abuse to the exclusions.



Percutaneous Left Atrial Appendage (LAA) Closure Devices

Type of Policy: Medical

Prior Approval Date: 03/06/2023

Approval Date: 07/01/2024

Effective Date: 10/01/2024

Related Polices: Cardiac Procedures

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

CPT/HCPCS Code:	Description:
33340	Percutaneous transcatheter closure of the left atrial appendage with endocardial implant, including fluoroscopy, transseptal puncture, catheter placement(s), left atrial angiography, left atrial appendage angiography, when performed, and radiological supervision and interpretation

Experimental/Investigational Codes Requiring Retrospective Review

CPT/HCPC Code:	Description:
33999	Unlisted procedure, cardiac surgery

Common Diagnosis Codes

Common Diagnosis Codes associated with this policy have been provided for informational purposes only. The list of codes may not be all-inclusive and may be updated to reflect any applicable revisions to the ICD-10 code set and/or medical necessity quidelines applied in this policy.

148.0 – 148.21 Atrial fibrillation (code range)

148.91 Unspecified atrial fibrillation

Common Procedure Codes

CPT Codes: N/A

HCPCS Codes: N/A

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

Minimally invasive procedures for closure of the left atrial appendage (LAA) have emerged as a crucial strategy for reducing the risk of stroke in patients with atrial fibrillation (AF). These procedures aim to address the increased stroke risk associated with atrial fibrillation (AF) by sealing off the LAA, which is a common sight for the formation of blood clots.

Percutaneous LAA closure procedures involve accessing the LAA through a minimally invasive percutaneous procedure, typically guided by imaging techniques such as transesophageal echocardiography (TEE) or fluoroscopy. A closure device such as a Watchman or Amplatzer device, is then deployed within the LAA to block off blood flow and prevent clot formation.

Minimally invasive procedures for LAA closure offer a promising option for stroke risk reduction in patients with AF who are not suitable candidates for long term anticoagulation therapy. However, patient selection, procedural technique, and follow-up care are critical considerations in ensuring optimal outcomes and minimizing complications. Ongoing research and technological advancements continue to refine these approaches and improve patient outcomes in the management of AF and stroke risk.

Indications/Criteria

Left atrial appendage (LAA) closure devices are covered according to the following criteria:

- 1. The device has received U.S. Food and Drug Administration (FDA) premarket approval (PMA) for that device's FDA-approved indications; and
- 2. The customer must have: A CHADS2 score ≥ 2 (congestive heart failure, hypertension, age >75, diabetes, stroke/transient ischemia attack/thromboembolism) or CHA2DS2-VASc score ≥ 3 (congestive heart failure, hypertension, age ≥ 65, diabetes, stroke/transient ischemia attack/thromboembolism, vascular disease, sex category); and
- 3. A formal shared decision-making interaction with an **independent non-interventional** cardiologist using an evidence-based decision tool on oral

- anticoagulation in patients with non-valvular atrial fibrillation (NVAF) prior to LAA closure. Additionally, the shared decision-making interaction must be documented in the medical record; and
- 4. Documentation of a collective decision regarding medical necessity by a Multi-Disciplinary Team (MDT). The MDT must be involved pre-operatively and post-operatively, and include the requesting Interventional cardiologist and, in addition, at least two independent non-interventionalists, which may include the patient's primary cardiologist along with another non-interventional cardiologist or a neurologist who has experience caring for stroke patients. Attestation that for this individual the long-term risk of systemic anticoagulation outweighs the risk of the device implantation as evidenced by one or more of the following reasons:
 - a. Customer has thromboembolism while compliant with a therapeutic dosing of a Non-Vitamin K Antagonist oral anticoagulant (e.g., Apixaban, Rivaroxaban, etc.) or Warfarin (or other Vit K antagonist agent) with a documented INR in therapeutic range at presentation; or
 - b. Customer has major bleed (intracranial bleed, significant gastrointestinal bleeding (not just guaiac positive stools), which is not treatable/reversible, and therefore poses a recurrent risk, while on therapeutic (not supratherapeutic) oral anticoagulation (i.e., while INR is in therapeutic range); or
 - c. Customer has other absolute medical contraindication to long-term anticoagulation; and
- 5. The procedure must be furnished in a hospital with an CMS approved structural heart disease (SHD) and/or electrophysiology (EP) program and CMS approved provider; and
- The patient is enrolled in and the MDT and hospital must participate in, a prospective, national, audited registry such as the ACC/NCDR LAAO Registry.

Exclusions

- Percutaneous left atrial appendage (LAA) closure for any other indication is considered experimental, investigational and unproven; or
- Contraindications to the use of short-term anticoagulants (e.g., warfarin, NOACs) or long-term antiplatelet agents (e.g., aspirin or clopidogrel, not an all-inclusive list); or
- History of repair or use of closure device for PFO or atrial septal defect; or
- Intracardiac thrombus visualized by echocardiography; or
- Known sensitivity to any portion of the device material; or

LAA anatomy will not accommodate a closure device

Use of devices which have not been approved by the FDA for the specific indications including:

- Use of the Lariat Suture Delivery Device in left atrial appendage (LAA) closure to reduce the risk of stroke in adult patients with nonvalvular atrial fibrillation (NVAF) is considered investigational as there is limited published medical literature that this device is safe and effective for the prevention of stroke and all other indications.
- Use of the Cardioblate Gemini Surgical Ablation System (Medtronic Inc.) in left atrial appendage (LAA) closure is investigational as there is limited evidence pertaining to the effectiveness of minimally invasive surgical (MIS) procedures for atrial ablation is of low quality and that the device is safe during postoperative recovery.
- Use of the AtriClip LAA Exclusion System (AtriCure Inc) in left atrial appendage (LAA) closure is investigational and will only be considered as part of a randomized controlled trial. The device is only approved by the FDA for use as part of an open cardiovascular surgery.

Medicare Variation

Percutaneous Left Atrial Appendage (LAA) Closure Therapy

The Centers for Medicare & Medicaid Services (CMS) cover percutaneous left atrial appendage closure LAAC) for nonvalvular atrial fibrillation (NVAF) through Coverage with Evidence Development (CED).

Refer to the Medicare NCD Percutaneous Left Atrial Appendage Closure (LAAC) for full coverage and restriction details for Percutaneous Left Atrial Appendage (LAA) Closure Therapy at: <u>Home - Centers for Medicare & Medicaid Services | CMS</u>

References (2024)

- 1. Aminian A, et al. Embolization of left atrial appendage closure devices: A systematic review of cases reported with the WATCHMAN device and the Amplatzer cardiac plug. Catheter Cardiovasc Interv 2015 July; 86(1):128-135.
- 2. Bajaj NS, et al. Percutaneous left atrial appendage occlusion for stroke prophylaxis in nonvalvular atrial fibrillation: a systematic review and analysis of observational studies. JACC Cardiovasc Interv 2014 Mar;7(3):296-304.
- 3. Bajaj NS, et al. Comparison of approaches for stroke prophylaxis in patients with non-valvular atrial fibrillation: network meta-analyses of randomized controlled trials. PLoS One 2016 Oct 5;11(10):e0163608.
- 4. Barakat AF, et al. Initial experience with high-risk patients excluded from clinical trials: safety of short-term anticoagulation after left atrial appendage closure device. Circ Arrhythm Electrophysiol 2016 June;9(6).

- 5. Bartus K, et al. Feasibility of closed-chest ligation of the left atrial appendage in humans. Heart Rhythm 2011 Feb;8(2):188-93.
- 6. Bartus K, et al. Percutaneous left atrial appendage suture ligation using the LARIAT device in patients with atrial fibrillation: initial clinical experience. J Am Coll Cardiol 2013 Jul 9;62(2):108-18.
- 7. Bartus K, et al. Left atrial appendage ligation with the next generation LARIAT(+) suture delivery device: early clinical experience. Int J Cardiol 2016 July 15;244-247.
- 8. Bergmann MW, et al. Real-world safety and efficacy of WATCHMAN LAA closure at one year in patients on dual antiplatelet therapy: results of the DAPT subgroup from the EWOLUTION all-comers study. EuroIntervention 2018 Apr 20;13(17):2003-2011.
- 9. Bode WD, et al. Left atrial appendage occlusion for prevention of stroke in nonvalvular atrial fibrillation: a meta-analysis. J Interv Card Electrophysiol 2015 June;43(1):79-89.
- 10. Boersma LV, et al. Implant success and safety of the left atrial appendage closure with the WATCHMAN device: peri-procedural outcomes from the EWOLUTION registry. Eur Heart J 2016 Aug;37(31):2465-74.
- 11. Bonnet G, et al. Initial experience with the WATCHMANTM left atrial appendage system for stroke prevention in atrial fibrillation: a single-center registry. Arch Cardiovasc Dis 2016 Dec;109(12):689-695.
- 12. Briceno DF, et al. Left atrial appendage occlusion device and novel oral anticoagulants versus warfarin for stroke prevention in nonvalvular atrial fibrillation: systematic review and meta-analysis of randomized controlled trials. Circ Arrhythm Electrophysiol 2015 Oct;8(5):1057-1064.
- 13. Centers for Medicare and Medicaid Services (CMS) National Coverage Determination (NCD) for Percutaneous Left Atrial Appendage Closure (LAAC) (20.34) effective February 8, 2016. Available: MCD Search (cms.gov)
- 14. Chatterjee S, et al. Safety and procedural success of left atrial appendage exclusion with the Lariat device: a systematic review of published reports and analytic review of the FDA MAUDE database. JAMA Intern med 2015 July;175(7): 1104-1109.
- 15. De Backer O, et al. Percutaneous left atrial appendage occlusions for stroke prevention in atrial fibrillation: an update. Open Heart 2014 Jun 6;1(1):e000020.
- 16. US Food & Drug Administration (FDA). Summary of safety and effectiveness data: Amplatzer Amulet left atrial appendage occluder. https://www.fda.gov. Published August 14, 2021.
- 17. Della Rocca DG, Magnocavallo M, Gianni C, Mohanty S, Natale VN, Al-Ahmad A, et al. Procedural and short-term follow-up outcomes of Amplatzer Amulet occluder

- versus Watchman FLX device: A meta-analysis. Heart Rhythm. 2022 Jun;19(6):1017-1018.
- 18. Hayes Comparative Effectiveness Review of Percutaneous Left Appendage Closure To Reduce Stroke Risk in Patients With Atrial Fibrillation. Hayes, a TractManager Company, ©2020 TractManager. February 13, 2018. Annual Review February 8, 2022.
- 19. Hayes Health Technology Assessment. Left Atrial Appendage Exclusion with the AtriClip System in Patients with Atrial Fibrillation. Hayes, a TractManager Company, ©2020 TractManager. March 11, 2021. Annual review: February 9, 2022.
- 20. Holmes DR, Reddy VY, Turi ZG, et al. Percutaneous closure of the left atrial appendage versus warfarin therapy for prevention of stroke in patients with atrial fibrillation: a randomized non-inferiority trial. Lancet. 2009;374(9689):534-542.
- 21. January CT, Wann LS, Alpert JS, et al. 2014 AHA/ACC/HRS guideline for the management of patients with atrial fibrillation: a report of the American College of Cardiology/American Heart Association Task Force on practice guidelines and the Heart Rhythm Society. Circulation. 2014a;130(23):e199-e267.
- 22. January CT, Wann LS, Alpert JS, et al. 2014 AHA/ACC/HRS guideline for the management of patients with atrial fibrillation: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the Heart Rhythm Society. J Am Coll Cardiol. 2014b;64(21): e1-e76.
- 23. Lakkireddy D, Thaler D, Ellis CR, Swarup V, Gambhir A, Hermiller J, et al. 3-Year Outcomes From the Amplatzer Amulet Left Atrial Appendage Occluder Randomized Controlled Trial (Amulet IDE). JACC Cardiovasc Interv. 2023 Aug 14;16(15):1902-1913.
- 24. Lakkireddy D, Thaler D, Ellis CR, Swarup V, Sondergaard L, Carroll J, et al. Amplatzer™ Amulet™ Left Atrial Appendage Occluder Versus Watchman™ Device For Stroke Prophylaxis (Amulet IDE): A Randomized Controlled Trial. Circulation. 2021 Aug 30.
- 25. Ledwoch J, Franke J, Gonzaga M, et al. Left atrial appendage closure: first in man with the 4th generation WATCHMAN device. *Catheter Cardiovasc Interv.* 2016;87(4):787-794.
- 26. Lee VW, Tsai RB, Chow IH, et al. Cost-effectiveness analysis of left atrial appendage occlusion compared with pharmacological strategies for stroke prevention in atrial fibrillation. BMC Cardiovasc Disord. 2016;16(1):167.
- 27. Santucci A, et al. Appraising the safety and efficacy profile of left atrial appendage closure in 2016 and the future clinical perspectives. Results of the EAPCI LAAC survey. Eurointervention 2016 May 17;12(1):112-118.
- 28. U.S. Food and Drug Administration. PMA Document Control Center WO66-G609 WATCHMAN LAA Closure Technology. Available: https://www.accessdata.fda.gov/cdrh_docs/pdf13/P130013A.pdf

29. Zhou X, et al. left atrial appendage occlusion in atrial fibrillation for stroke prevention: a systematic review. Int J Cardiol 2016 Jan 15;203:55-59.

Customer Product	Medical Management Requirements*
New York Products	
HMO	Prior Authorization
PPO in Plan	Prior Authorization
PPO OOP	Prior Authorization
POS in Plan	Prior Authorization
POS OOP	Prior Authorization
Essential Plan	Prior Authorization
MVP Medicaid Managed Care	Prior Authorization
MVP Child Health Plus	Prior Authorization
MVP Harmonious Health Care Plan	Prior Authorization
MVP Medicare Complete Wellness	Prior Authorization
MVP Medicare Preferred Gold HMO POS	Prior Authorization
MVP Medicare Secure HMO POS	Prior Authorization
MVP Medicare Secure Plus HMO POS	Prior Authorization
MVP Medicare WellSelect PPO	Prior Authorization
MVP Medicare WellSelect Plus PPO	Prior Authorization
MVP DualAccess D-SNP HMO	Prior Authorization
MVP DualAccess Complete D-SNP HMO	Prior Authorization
MVP DualAccess Plus D-SNP HMO	Prior Authorization
UVM Health Advantage Select PPO	Prior Authorization
USA Care PPO	Potential for Retrospective Review
Healthy NY	Prior Authorization
MVP Premier	Prior Authorization
MVP Premier Plus	Prior Authorization
MVP Premier Plus HDHP	Prior Authorization
MVP Secure	Prior Authorization
MVP EPO	Prior Authorization
MVP EPO HDHP	Prior Authorization
MVP PPO	Prior Authorization
MVP PPO HDHP	Prior Authorization
Student Health Plans	Prior Authorization
ASO	See SPD
Vermont Products	
POS in Plan	Prior Authorization
POS OOP	Prior Authorization
MVP Medicare Preferred Gold HMO POS	Prior Authorization
MVP Medicare Secure Plus HMO POS	Prior Authorization
MVP VT HMO	Prior Authorization
MVP VT HDHP HMO	Prior Authorization
MVP VT Plus HMO	Prior Authorization
MVP VT Plus HDHP HMO	Prior Authorization
MVP Secure	Prior Authorization
ASO	See SPD

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review.

Retro ReviewRetrospective Review RequiredNot CoveredService is not a covered benefit.See SPDSee Specific Plan Design

Revision History:

6/1/2021 – New policy effective.

06/01/2023 – Annual review with no changes to the indications or criteria; references reviewed and updated as necessary.

10/01/2024 – Added coverage for Amplatzer LAA device.



Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture

Type of Policy: Surgical

Prior Approval Date: 04/04/2022

Approval Date: 11/10/2023

Effective Date: 11/13/2023

Related Polices: N/A

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

CPT Codes:

22510 -Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; cervicothoracic

22511 -Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; lumbosacral

22512 -Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; each additional cervicothoracic or lumbosacral vertebral body (List separately in addition to code for primary procedure)

22513 -Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (eg, kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; thoracic

22514 -Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (eg,

kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; lumbar

22515 -Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (eg, kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; each additional thoracic or lumbar vertebral body (List separately in addition to code for primary procedure)

C7507 -Percutaneous vertebral augmentations, first thoracic and any additional thoracic or lumbar vertebral bodies, including cavity creations (fracture reductions and bone biopsies included when performed) using mechanical device (e.g., kyphoplasty), unilateral or bilateral cannulations, inclusive of all imaging guidance

C7508 -Percutaneous vertebral augmentations, first lumbar and any additional thoracic or lumbar vertebral bodies, including cavity creations (fracture reductions and bone biopsies included when performed) using mechanical device (e.g., kyphoplasty), unilateral or bilateral cannulations, inclusive of all imaging guidance

Codes Requiring Retrospective Review

CPT Codes:

0200T -Percutaneous sacral augmentation (sacroplasty), unilateral injection(s), including the use of a balloon or mechanical device, when used, 1 or more needles, includes imaging guidance and bone biopsy, when performed

0201T -Percutaneous sacral augmentation (sacroplasty), bilateral injections, including the use of a balloon or mechanical device, when used, 2 or more needles, includes imaging guidance and bone biopsy, when performed

Experimental/Investigational

CPT Codes: 0200T, 0201T

Common Diagnosis Codes

ICD-10 Diagnosis Codes: M80.08XA, M80.08XD, M80.08XG, M80.08XK, M80.08XP, M80.08XS, M80.88XA, M80.88XD, M80.88XG, M80.88XK, M80.88XP, M80.88XS, M84.58XA, M84.58XD, M84.58XG, M84.58XK, M84.58XS

Common Procedure Codes

N/A

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Percutaneous Vertebral Augmentation for Osteoporotic Compression Fracture

Overview

Percutaneous vertebral augmentation (PVA) is a minimally invasive procedure used to treat vertebral compression fractures by injecting bone cement (usually methylmethacrylate) directly into the vertebral body. This stabilizes the structure and provides immediate pain relief in many cases. Percutaneous vertebral augmentation (PVA is performed under anesthesia (including moderate sedation) and fluoroscopic or computed tomography (CT) guidance. Follow-up CT scanning may be performed within eight hours in order to assess the distribution of the cement within the vertebrae and to detect any unwanted leaks.

Indications/Criteria

Percutaneous Vertebral Augmentation (PVA,) (percutaneous vertebroplasty (PVP), or kyphoplasty (PKP) may be covered when the following indications are met:

- 1) All the following criteria are required:
 - a) Acute (<6 weeks) or subacute (6-12 weeks) osteoporotic vertebral compression fractures of the thoracic spine and lumbar spine (T1-L5) by recent (within 30 days) advanced imaging (bone marrow edema on MRI or bone scan/SPECT/CT uptake)
 - b) Symptomatic pain with one of the following:
 - i) Hospitalized with severe pain (Numeric Rating Scale (NRS) or Visual Analog Scale (VAS) pain score ≥ 8)
 - ii) Non-hospitalized with moderate to severe pain (NRS or VAS ≥5) despite optimal non-surgical management
 - (1) Worsening pain
 - (2) Stable to improved pain (but NRS or VAS still \geq 5) (with \geq 2 of the following):
 - (a) Progression of vertebral body height loss
 - (b) > 25% vertebral body height reduction
 - (c) Kyphotic deformity
 - (d) Severe impact of a vertebral compression fractures on daily functioning

Exclusions

- 1) Failure to meet medical necessity criteria listed under Indications/Criteria in this policy.
- 2) Vertebroplasty and vertebral augmentation (percutaneous) are not to be considered prophylactic procedures for osteoporosis of the spine. They also should not be used for chronic back pain of long-standing duration, even if associated with old

compression fractures, unless pain is localized to a specific chronic fracture and medical therapy has failed.

- 3) Exclusion criteria (Can have NONE of the following):
 - a) Absolute contraindication
 - (1) Current back pain is not primarily due to the identified acute vertebral compression fractures
 - (2) Osteomyelitis, discitis, or active systemic infection
 - (3) Pregnancy
 - b) Relative contraindication
 - (1) Greater than three vertebral fractures
 - (2) Allergy to bone cement or opacification agents
 - (3) Uncorrected Coagulopathy
 - (4) Spinal instability
 - (5) Myelopathy from the fracture
 - (6) Neurologic deficit
 - (7) Neural impingement
 - (8) Fracture retropulsion/canal compromise
- Percutaneous sacroplasty for treatment of sacral insufficiency fractures (0200T, 0201T)

Percutaneous sacroplasty for treatment of sacral insufficiency fractures or any other indication is not covered. There is insufficient evidence in peer reviewed literature that percutaneous sacroplasty for treatment of sacral insufficiency fractures or any other indication results in proven beneficial outcomes and, therefore, is considered investigational.

Medicare

MVP follows the Medicare criteria. For a complete description of the indications and limitations of coverage for vertebroplasty and PVA for Medicare customers, please refer to the Local Coverage Determination (LCD) for PVA for Osteoporotic Vertebral Compression Fracture (VCF) (L33569): MCD Search (cms.gov)

References (Reviewed 2022)

1. National Government Services. Local Coverage Determination (LCD) for Vertebroplasty and Vertebral Augmentation (Percutaneous) (L33569). Revision

- Effective Date 12/01/2020.Available: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx
- 2. Theodorou, D.J., Theodorou, S.J., Duncan, T.D., Garfin, S.R., Wong, W.H., Percutaneous balloon kyphoplasty for the correction of spinal deformity in painful vertebral body compression fractures. [Abstract]. Clin Imaging 2002 Jan-Feb; 26(1):1-5.
- 3. Taylor, R.S., Taylor, R.J., Fritzell, P. Balloon kyphoplasty and vertebroplasty for vertebra compression fractures: a comparative systematic review of efficacy and safety. [Abstract]. Spine 2006 Nov 1; 31(23):2747-55.
- 4. American College of Radiology. ACR-ASNR-ASSR-SIR-SNIS Practice Guideline for the Performance of Vertebral Augmentation. Revised 2017 (Resolution 16).
- 5. Predey TA, MD, Sewall LE, MD, and Smith SJ, MD. Percutaneous Vertebroplasty: New treatment for vertebral compression fractures. Radiologic Decision Making. American Family Physician. Aug 15, 2002/Vol 66, No 4. Available: www.aafp.org/afp
- Freedman BA, MAJ, MC, Heller, JG, MD. Kummel Disease: A Not-So-Rare Complication of Osteoporotic Vertebral Compression Fractures. J Am Board Fam Med 2009; 22:75-78.
- 7. Whitlow CT, Mussat-Whitlow BJ, Mattern CW, Baker MD, Morris PP. Sacroplasty versus vertebroplasty: comparable clinical outcomes for the treatment of fracture-related pain. AJNR Am J Neuroradiol. 2007;28(7):1266-1270. Available: http://www.ajnr.org/content/28/7/1266.long.
- 8. Frey ME, Depalma MJ, Cifu DX, Bhagia SM, Carne W, Daitch JS. Percutaneous sacroplasty for osteoporotic sacral insufficiency fractures: a prospective, multicenter, observational pilot study. Spine J. 2008;8(2):367-373.
- 9. HAYES Health Technology Assessment Percutaneous Sacroplasty for Treatment of Sacral Insufficiency Fractures HAYES, Inc.; © 2021 Hayes, a symplr company. November 12, 2018. Annual Review January 27, 2021. Archived December 12, 2021.
- 10. Strub WM, Hoffmann M, Ernst RJ, Bulas RV. Sacroplasty by CT and fluoroscopic guidance: is the procedure right for your patient? AJNR Am J Neuroradiol. 2007;28(1):38-41. Available: http://www.ajnr.org/cgi/content/full/28/1/38.
- 11. Tsoumakidou G, Too CW, Koch G, et al. CIRSE Guidelines on Percutaneous Vertebral Augmentation. *Cardiovasc Intervent Radiol.* 2017;40(3):331-342.
- 12. Clark W, Bird P, Gonski P, et al. Safety and efficacy of vertebroplasty for acute painful osteoporotic fractures (VAPOUR): a multicentre, randomised, double-blind, placebocontrolled trial. *Lancet*. 2016;388(10052):1408-1416.

- 13. Chandra RV, Meyers PM, Hirsch JA, et al. Vertebral augmentation: report of the Standards and Guidelines Committee of the Society of NeuroInterventional Surgery. *J Neurointerv Surg.* 2014;6(1):7-15.
- 14. Hirsch JA, Beall DP, Chambers MR, et al. Management of vertebral fragility fractures: A clinical care pathway developed by a multispecialty panel using the RAND/UCLA Appropriateness Method. *Spine J.* 2018. Hayes Health Technology Assessment. Comparative Effectiveness Of Percutaneous Vertebroplasty Versus Sham, Conservative Treatment, Or Kyphoplasty For Osteoporotic Vertebral Compression Fractures. HAYES, Inc.; © 2021 Hayes, a symplr company. December 8, 2016. Annual review May 5, 2021. Archived January 8, 2022.
- 15. Hinde K, Maingard J, Hirsch JA, Phan K, Asadi H, Chandra RV. Mortality Outcomes of Vertebral Augmentation (Vertebroplasty and/or Balloon Kyphoplasty) for Osteoporotic Vertebral Compression Fractures: A Systematic Review and Meta-Analysis. 2020:191294.
- 16. UpToDate- Osteoporotic thoracolumbar vertebral compression fractures: Clinical manifestations and treatment. 2018.

Customer Product	Medical Management Requirements*	
New York Products		
HMO	Prior Auth	
PPO in Plan	Prior Auth	
PPO OOP	Prior Auth	
POS in Plan	Prior Auth	
POS OOP	Prior Auth	
Essential Plan	Prior Auth	
MVP Medicaid Managed Care	Prior Auth	
MVP Child Health Plus	Prior Auth	
MVP Harmonious Health Care Plan	Prior Auth	
MVP Medicare Complete Wellness	Prior Auth	
MVP Medicare Preferred Gold HMO POS	Prior Auth	
MVP Medicare Secure HMO POS	Prior Auth	
MVP Medicare Secure Plus HMO POS	Prior Auth	
MVP Medicare WellSelect PPO	Prior Auth	
MVP Medicare WellSelect Plus PPO	Prior Auth	
MVP Medicare Patriot Plan PPO	Prior Auth	
MVP DualAccess D-SNP HMO	Prior Auth	
MVP DualAccess Complete D-SNP HMO	Prior Auth	
MVP DualAccess Plus D-SNP HMO	Prior Auth	
UVM Health Advantage Select PPO	Prior Auth	
USA Care PPO	Potential for Retrospective Review	
Healthy NY	Prior Auth	
MVP Premier	Prior Auth	
MVP Premier Plus	Prior Auth	
MVP Premier Plus HDHP	Prior Auth	
MVP Secure	Prior Auth	
MVP EPO	Prior Auth	
MVP EPO HDHP	Prior Auth	
MVP PPO	Prior Auth	
MVP PPO HDHP	Prior Auth	
Student Health Plans	Prior Auth	
ASO	See SPD	
Vermont Products	See SPD	
POS in Plan	Prior Auth	
POS OOP	Prior Auth Prior Auth	
MVP Medicare Preferred Gold HMO POS	Prior Auth Prior Auth	
MVP Medicare Preferred Gold HMO POS MVP Medicare Secure Plus HMO POS	Prior Auth Prior Auth	
MVP VT HMO	Prior Auth Prior Auth	
MVP VT HMO MVP VT HDHP HMO	Prior Auth Prior Auth	
MVP VT Plus HMO	Prior Auth	
MVP VT Plus HDHP HMO	Prior Auth	
MVP Secure	Prior Auth	
ASO	See SPD	

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Retrospective Review Required
Not Covered Service is not a covered benefit
See SPD See Specific Plan Design

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MVP Health Care Medical Policy
Revision History:
06/01/2022 – Annual review; removed multidisciplinary team consensus from the indications criteria, references and websites updated.



Personal Care and Consumer Directed Services for MVP Medicaid Managed Care

Type of Policy: Medical

Prior Approval Date: 04/04/2022

Approval Date: 04/01/2024

Effective Date: 06/01/2024

Related Polices: Personal Care/Consumer

Directed Personal Assistance Services – Service Units Billings

Payment Policy

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

All the below procedure codes require prior authorization for MVP Medicaid Managed Care Plans:

Service Type:	Unit of Measure:	Procedure Code:	Modifier:	Code Description:
PCS Level 1	Per 15 min	S5130	U1	Homemaker Service
Nursing	Per Visit	T1001	None	Nursing
Supervision	Per visit	11001	None	Assessment/evaluation
PCS Level 2	Per 15 min.	T1019	U1	PCS Level 2
PCS Live In	Per Diem	T1020	None	PCS Live In
CDPAS	Per 15 min.	T1019	U6	CDPAS Basic
CDPAS Live In	Per Diem	T1020	U6	CDPAS Live In
UAS Assessment	Per Visit	T2024	None	Nursing Assessment

Codes Requiring Retrospective Review

N/A

Experimental/Investigational

N/A

Common Diagnosis Codes

Personal Care and Consumer Directed Services

N/A

Common Procedure Codes

N/A

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

Personal Care Services are services that provide partial or total assistance with personal hygiene, dressing, feeding and nutrition, and environmental support functions. These services must be necessary for the maintenance of the patient's health and safety in his or her own home and provided by a qualified individual in accordance with a plan of care.

Payment for personal care services will not be made to a patient's spouse, parents of children under 21, son, son-in-law, daughter, or daughter-in-law but may be made to another relative if the other relative is not residing in the patient's home or is residing in the patient home solely because the amount of care required makes his/her presence necessary. Parents of adult children (age 21 or older) can be hired to work as their adult children's Consumer Directed Personal Assistant Services (CDPAS) personal assistants so long as they are not the designated representative.

Two levels of personal care services have been designated:

Level 1 – performance of nutritional and environmental support functions for the customer (making and changing beds, dishwashing, house cleaning, etc.) Level 1 services are limited to eight hours per week.

Level 2 – performance of nutritional and environmental support functions and some or total assistance to the customer (bathing patient, grooming patient, transferring patient, feeding patient, assist customer in taking their own medication, etc.)

The Consumer Directed Personal Assistant Program (CDPAP) is a self-directed home care model available to customers who need home care services and are capable of managing their own care.

Consumer Directed Personal Assistant Services (CDPAS) provide partial or total assistance with personal hygiene, dressing, feeding and nutrition, and environmental support functions. These services must be necessary for the maintenance of the patient's health and safety in his or her own home and provided by a qualified individual in accordance with a plan of care.

- Customers have flexibility and freedom in choosing their caregivers.
- The customer or the person acting on the customer's behalf (such as the parent of a disabled or chronically ill child) assumes full responsibility for hiring, training, supervising, and terminating the employment of persons providing the services.
- Customers work with an agency called a Fiscal Intermediary (FI), which on behalf of the customer administers payroll, benefits, and tax withholdings.

Personal Care and Consumer Directed services can be provided outside of the home. These services can be provided at locations where the customers life activities may take them such as school, work, or provider offices. When a personal assistant accompanies the customer to a provider office it is to assist the customer with a task and not to act as a medical facilitator. A medical facilitator is someone who provides information and receives information about the customer's medical condition, such as a family member or health care agent. MVP is not required to authorize hours beyond the hours assessed as appropriate for the home, but the hours authorized can be provided in the home or other locations.

The scope of the personal care services benefit includes live-in 24 hour personal care services which means the provision of care for a customer who, because of the customer's medical condition and disabilities, requires some or total assistance with one or more personal care functions during the day and night and whose need for assistance during the night is infrequent or can be predicted and where the assessment determines that the customer's home has adequate sleeping accommodations for the personal care services worker. Examples of adequate accommodations include an available spare bedroom, room partition, or a fold-out sofa. The personal assistant must also be able to get at least eight hours of sleep and at least five of those hours should be uninterrupted.

A customer's spouse, parents of children under 21, or designated representative may not be the consumer directed personal assistant for that customer; however, a consumer directed personal assistant may include any other adult relative of the customer who does not reside with the customer or any other adult relative who resides with the customer because the amount of care the customer requires makes such relative's presence necessary.

Consumer Directed Personal Assistant Services (CDPAS) have combined personal care Level 1 and Level 2 into one benefit. Nursing care in the home (T1001) is not a benefit under CDPAP.

Indications/Criteria

This policy pertains to MVP Medicaid Managed Care and HARP customers.

Requests for personal care services must be accompanied by the following documentation using the NYS approved forms and the MVP Weekly Personal Care Services Time Tasking Tool (TTT):

- The Personal Care Services Time Tasking Tool (TTT) can be found here: <u>Provider</u> <u>Forms Library (mvphealthcare.com)</u>
- For members who are new to the Personal Care Services/CDPAS Program, they must contact New York Independent Assessor Program (NYIAP) to schedule Community Health Assessment (CHA) and Practitioner Order (PO). Once those documents are completed, the member will contact the Long-Term Services and Supports at 800-767-7424 to schedule and speak to a Care Manager for review of CHA, completion of Time Tasking Tool and Plan of Care. The Care Manager will inform the member of determination of hours.
- a physician's order that describes the patient's medical condition, the personal care services required by the patient, the medication regime and whether the patient can be safely cared for at home. The medical professional who completes the order form must not recommend the number of hours of services that the consumer should be authorized to receive. In all cases, the physician's signature is required.
- a social assessment (completed by the contracted agency) including the following:
 - Discussion with customer to determine perception of their circumstances and preferences;
 - Evaluation of the extent and type of potential contribution of informal caregivers
 - Demonstration that all alternative arrangements for meeting the customer's medical needs have been explored and/or are infeasible including, but not limited to, the provision of personal care services in combination with other formal services or in combination with contributions of informal caregivers.
- a nursing assessment (completed by the contracted agency) of the customer's appropriateness for services and assessment of the appropriateness and costeffectiveness of the services being requested. The assessment should include all the following:
 - o a review and interpretation of the physician's order;
 - an evaluation of the functions and tasks required by the patient and the degree of assistance required for each function and task, using the MVP Weekly Personal Care Services Time Tasking Tool (TTT); and
 - o the development of a person-centered service plan
- Care management review of all information received to evaluate the recommendations made by the assessing nurse at the time of the first/initial authorization. In determining the appropriateness of a consumer to receive, or

continue receiving personal care services, assessment of whether the customer's needs are best met by other services or programs in lieu of personal care services should be done. In such instances, should care management determine such service(s) are available, it must first consider the use of such services in developing the customer's plan of care.

The customer receiving personal care services must:

- have a stable medical condition which is not expected to exhibit sudden
 deterioration or improvement (this is determined by the physician's order form and
 to certify that the individual can be safely cared for at home and that the information
 provided in the physician's order form accurately describes the individual's medical
 condition and regimens, including any medication regimens, and the individual's
 need for assistance at the time of the medical examination.) If a customer is referred
 for both skilled nursing and personal care services, a care management review will be
 completed to coordinate the appropriate level(s) of care to meet customer's needs in
 the most cost-effective way;
- have a medical condition that does not require frequent medical or nursing
 judgment to determine changes in the customer's plan of care (this is determined by
 the physician's order form and to certify that the individual can be safely cared for at
 home and that the information provided in the physician's order form accurately
 describes the individual's medical condition and regimens, including any medication
 regimens, and the individual's need for assistance at the time of the medical
 examination.); and
- be self-directing (i.e., capable of making choices about his or her activities of daily living, understand the impact of the choice and assume responsibility for the results of the choice) or have a self-directing individual or agency who has assumed those responsibilities; or other such factors as documented in 18-NYCC 505.14.

Level 1 services are limited to eight hours per week.

Authorization for personal care services usually does not exceed twelve months at a time. If the customer's condition is likely to change significantly in a shorter time period than twelve months, that should be reflected at the time-of-service authorization and re-assessment and re-authorization may be required earlier than twelve months. In this case, if not specified at time of initial order, documentation should state all the following:

- the customer's particular condition or circumstance whether medical condition, mental condition, or social circumstance – that has changed since the last assessment or authorization;
- identify the specific change that has occurred in that particular medical or mental condition or social circumstance since the last assessment or authorization; and

• state why the services should be reduced or discontinued as a result of that change in the enrollee's medical or mental condition or social circumstances.

If services are to continue longer than twelve months, continuation of services requires re-assessment every twelve months with submission for reauthorization and approval of continued services.

A nursing assessment (completed by the contracted agency) must conduct a reassessment of the consumer when an unexpected change in the consumer's social circumstances, mental status or medical condition occurs during the authorization or reauthorization period that would affect the type, amount or frequency of consumer directed personal assistance provided during such period. The nursing agency is responsible for making necessary changes in the authorization or reauthorization, when they become aware of a change, on a timely basis in accordance with the following procedures:

- a. When the change in the consumer's service needs results solely from an unexpected change in the consumer's social circumstances including, but not limited to, loss or withdrawal of informal supports or a designated representative, the nursing agency must review the social assessment, document the consumer's changed social circumstances and make changes in the authorization or reauthorization as needed. A new physician's order and nursing assessment are not required; or
- b. When the change in the consumer's service needs results from a change in the consumer's medical condition, including loss of the consumer's ability to instruct, supervise or direct the consumer directed personal assistant, the social services district must obtain a new physician's order, social assessment and nursing assessment.

Adjustment to the approved hours of Personal Care Services should be made based on the most recent nursing assessment performed using the MVP Weekly Personal Care Services Time Tasking Tool (TTT).

- For Level 1 Personal Care Services: If a delay in submission of the re-authorization request is brought to the attention of the Long Term Supports and Services (LTSS) team prior to the denial date, a three business day grace period for continuation of services at the level of hours previously approved may be granted by an LTSS supervisor.
- For Level 2 Personal Care Services: If a delay in submission of the re-authorization request is brought to the attention of the LTSS team prior to the denial date, a grace period (not to exceed 10 days) for continuation of services at the level of hours previously approved may be granted at the discretion of an LTSS supervisor.

- All persons providing personal care services must be subject to on-going program supervision, both administrative and nursing supervision.
- Nursing supervision must assure that the patient's needs are appropriately met by the agency for the level, amount, frequency, and duration of personal care services and the person providing such services is competently and safely performing the tasks specified in the plan of care. Nursing supervision must include an orientation visit at time of initial case assignment, and evaluation of the patient's needs to determine if level, amount, frequency, and duration to continue is appropriate and evaluation of the ability of the person providing the services.

Exclusions

- The customer's medical, mental, economic, or social circumstances have changed in that the personal care services provided under the previous authorization or reauthorization are no longer appropriate or can be provided in fewer hours than they were previously.
- The customer refuses to cooperate with the required assessment of services. This exclusion will be denied administratively. *
- Customer's home is a health/safety concern for the personal care aide. This exclusion will be denied administratively. *
- Customer is non-compliant with personal care aide appointments and/or nurse assessment visits. This exclusion will be denied administratively. *
- A technological development renders certain services unnecessary or less time consuming.
- The customer can be more appropriately and cost-effectively served through other Medicaid programs and services.
- The customer's health and safety cannot be assured with the provision of personal care services.
- The customer's medical condition is not stable.
- The customer is not self-directing and has no one to assume those responsibilities.
- The services the customer needs exceed the personal care aide's scope of practice.
- The customers services are suspended for medical reasons such as hospitalizations, a new assessment may be required.
- Personal Care Services will not be covered if the member chooses to leave the country for vacation or an emergency.

 The customer resides in a facility, participates in another program, or receives other services which are responsible for the provision of needed personal care services.
 This exclusion will be denied administratively. *

References (Reviewed 2024)

- 1. New York State. Department of Health. Personal Care Services Program. Available: https://www.health.ny.gov/health.care/medicaid/program/longterm/pcs.htm
- New York State Department of Health Medicaid. eMedNY. Provider Manuals. Personal Care and Consumer Directed Personal Assistance Program (CDPAP) Manuals. Available: https://www.emedny.org/ProviderManuals/PersonalCare/index.aspx
- 3. NYS Regulation VOLUME C (Title 18) NYCRR § Section 505.14 Personal care services: Available: <u>Title: Section 505.14 Personal care services | New York Codes, Rules and Regulations (ny.gov)</u>
- 4. NYS Regulation VOLUME C (Title 18) NYCRR § Section 505.28 Consumer directed personal assistance program. Available: <u>Title: Section 505.28 Consumer directed personal assistance program | New York Codes, Rules and Regulations (ny.gov)</u>
- 5. NYS Regulation VOLUME D (Title 10) Title: Article 7 Certified Home Health Agencies and Licensed Home Care Services Agencies. Available:

 https://regs.health.ny.gov/content/article-7-certified-home-health-agencies-and-licensed-home-care-services-agencies

^{*} Exclusion will be denied administratively.

Customer Product	Medical Management Requirements*
New York Products	
HMO	Not Covered
PPO in Plan	Not Covered
PPO OOP	Not Covered
POS in Plan	Not Covered
POS OOP	Not Covered
Essential Plan	Not Covered
MVP Medicaid Managed Care	Prior Auth
MVP Child Health Plus	Not Covered
MVP Harmonious Health Care Plan	Prior Auth
MVP Medicare Complete Wellness	Not Covered
MVP Medicare Preferred Gold HMO POS	Not Covered
MVP Medicare Secure HMO POS	Not Covered Not Covered
MVP Medicare Secure Plus HMO POS	Not Covered
MVP Medicare WellSelect PPO	Not Covered Not Covered
MVP Medicare WellSelect Plus PPO	Not Covered Not Covered
MVP Medicare Patriot Plan PPO	Not Covered Not Covered
MVP DualAccess D-SNP HMO	Not Covered Not Covered
MVP DualAccess Complete D-SNP HMO	Not Covered
MVP DualAccess Plus D-SNP HMO	Not Covered
UVM Health Advantage Select PPO	Not Covered
USA Care	Not Covered
Healthy NY	Not Covered
MVP Premier	Not Covered
MVP Premier Plus	Not Covered
MVP Premier Plus HDHP	Not Covered
MVP Secure	Not Covered
MVP EPO	Not Covered
MVP EPO HDHP	Not Covered
MVP PPO	Not Covered
MVP PPO HDHP	Not Covered
Student Health Plans	Not Covered
ASO	See SPD
Vermont Products	
POS in Plan	Not Covered
POS OOP	Not Covered
MVP Medicare Preferred Gold HMO POS	Not Covered
MVP Medicare Secure Plus HMO POS	Not Covered
MVP VT HMO	Not Covered
MVP VT HDHP HMO	Not Covered
MVP VT Plus HMO	Not Covered
MVP VT Plus HDHP HMO	Not Covered
MVP Secure	Not Covered
ASO	See SPD

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g., HDHP HMO auth requirements are the same as listed for HMO).

*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Retrospective Review Required
Not Covered Service is not a covered benefit
See SPD See Specific Plan Design

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Revision History:

06/01/2022 –Eliminated the exclusion for inpatient or SNF admission. Added exclusion clarification that services are suspended, not excluded. Updated references, links, and websites.

06/01/2024 – Annual review; added exclusion for travel, added criteria that members must contact New York Independent Assessor Program (NYIAP) to schedule Community Health Assessment (CHA) and Practitioner Order (PO), added continuation of services requires re-assessment every twelve months, references checked for accuracy.



MVP Health Care Behavioral Health Medical Necessity Criteria

Personalized Recovery Oriented Services (PROS)

Type of Policy:Behavioral Health

Prior Approval Date: 04/27/2022

Provisional Approval Date: 05/06/2024

Provisional Effective Date: 08/01/2024

Related Polices: Assertive Community Treatment

(ACT)

Home and Community Based

Services - Pediatric

Children's Family Treatment and

Support Services (CFTSS)

Home and Community Based

Services - Adult

Codes Requiring Authorization

Authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

N/A

Codes Requiring Retrospective Review

N/A

Experimental/Investigational

N/A

Common Procedure Codes

Service	Rate	Procedure Code
	Code(s)	/ Modifier
PROS Preadmission	4510	H0002 HE
PROS Community Rehabilitation Services	4520-4524	H2019 U1-U5
PROS Clinical Treatment	4525	T1015 HE
PROS Intensive Rehabilitation	4526	H2018 HE

PROS Ongoing Rehabilitation & Support	4527	H2025 HE
Trices origining remainmentation as support	1361	

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

PROS is a comprehensive recovery-oriented program for individuals with severe and persistent mental illness. Through a single plan of care, the program model integrates treatment, support, and rehabilitation in a manner that facilitates the individual's recovery. The PROS model is person-centered, strength based, and comprised of a menu of group and individual services designed to assist a participant to overcome mental health barriers and achieve a desired life role. As PROS is individualized, a person can participate in one service or multiple services as needed. Examples of goals for program participants are: getting and keeping a job, finishing school or a training program, improving family and social relationships, independent living, and improving health and wellness.

There are four components in the PROS program:

1. Community Rehabilitation and Support (CRS)

The CRS component includes services designed to engage and assist individuals in managing their illness and restoring those skills and supports necessary for living successfully in the community. Some services within the CRS component include:

- a. Wellness Self-Management
- b. Basic Living Skills
- c. Community Living Exploration
- d. Benefits & Financial Management
- e. Individualized recovery planning
- f. Structured skill development and support

2. Intensive Rehabilitation (IR)

The IR component is designed to intensively assist individuals in attaining specific life roles such as those related to competitive employment, independent housing and school. The IR component may also be used to provide targeted interventions to reduce the risk of hospitalization or relapse, loss of housing or involvement with the criminal justice system, and to help individuals manage their symptoms. Some services within IR include:

- a. Family psychoeducation/intensive family support
- b. Integrated treatment for dual disorders
- c. Intensive rehabilitation group acquisition
- d. Intensive relapse prevention

3. Ongoing Rehabilitation and Support (ORS)

The ORS component is designed to assist individuals in managing symptoms and overcoming functional impairments as they integrate into a competitive workplace. ORS interventions shall focus on supporting individuals in maintaining competitive integrated employment. Such services shall be provided off-site.

4. <u>Clinical Treatment</u>, an optional component of a PROS program.

The clinical treatment component is designed to help stabilize, ameliorate and control an individual's symptoms of mental illness. Clinical treatment interventions must be highly integrated into the support and rehabilitation focus of the PROS program. The frequency and intensity of clinical treatment services shall be commensurate with the needs of the target population. Some services within clinical treatment include:

- a. Clinical counseling and therapy
- b. Health assessment
- c. Medication management
- d. Symptom monitoring
- e. Psychiatric assessment

PROS and Home and Community Based Services (HCBS)

PROS is a comprehensive program that integrates clinical treatment and rehabilitation services, whereas HCBS include a menu of specific services that individuals choose to support their recovery in a person-centered manner. Individuals receiving PROS services will not be eligible to receive most HCBS because PROS services are meant to address core recovery and rehabilitation needs.

Admission, Continued Stay, and Discharge Criteria

To be eligible for PROS admission a person must:

- Be 18 years of age or older;
- Have a designated mental illness diagnosis¹;
- Have a functional disability² due to the severity and duration of mental illness;
 and
- o Be recommended for admission by a Licensed Practitioner of the Healing Arts³

 Complete and sign a recipient attestation form indicating their choice to participate in the PROS program and specified program components

Following admission, an initial service recommendation plan (ISRP) is developed and identifies the primary service needs and a list of services in which the individual will participate. The IRSP is valid for up to sixty (60) days after admission, or until the individualized recovery plan (IRP) is developed. The IRP is then reviewed for progress every six (6) months, or sooner if conditions warrant it. For those receiving IR or ORS, the IRP is assessed every three (3) months.

Discharge from PROS is indicated when admission criteria is no longer met.

¹<u>Designated mental illness diagnosis</u> is a Diagnostic and Statistical Manual of Mental Disorders (DSM) diagnosis (or International Classification of Diseases (ICD) equivalent other than: 1) alcohol or drug disorders; 2) developmental disabilities; 3) organic brain syndromes; 4) social conditions (V-Codes))

Note: The mental illness diagnosis is not required to be the primary diagnosis. For preadmission screening services, "unspecified illness" (R69) may be used.

²Functional disability is a deficit that rises to the level of impairment in one or more of the following areas: self-care; activities of family living; interpersonal relations; or adaptation to change or task performance in work or work-like settings.

³<u>Licensed practitioner of the healing arts</u> is a nurse practitioner, physician, physician assistant, psychiatric nurse practitioner; psychiatrist, psychologist, registered professional nurse, Licensed Clinical Social Worker (LCSW); and Licensed Master Social Worker (LMSW) if supervised by an LCSW, licensed psychologist, or psychiatrist employed by the agency.

References (2024)

- New York State Office of Mental Health Guidelines for Medicaid Managed Care Organizations regarding Utilization Management for Personalized Recovery Oriented Services (PROS) August 6, 2015. Available: https://www.omh.ny.gov/omhweb/bho/docs/pros-utilization-management.pdf
- 2. New York State Office of Mental Health New York State Medicaid Advantage Plus (MAP) Plans Behavioral Health Billing and Coding Manual July 1, 2022. Available: 2022-07-22 map behave bill-code manual.pdf (ny.gov)
- 3. New York State Office of Mental Health PROS Homepage. Available: PROS (ny.gov)
- 4. Personalized Recovery Oriented Program Operations, 14 CRR-NY 512.7. Available: (<u>View Document New York Codes, Rules and Regulations (westlaw.com</u>))
- Guidelines for Medicaid Managed Care Organizations regarding Utilization Management for Personalized Recovery Oriented Services (PROS), Revised 8/23/2022, Effective 11/21/2022. Available: <u>Guidelines for Medicaid Managed Care Organizations</u> regarding UM for PROS 9/28/2022 (ny.gov)

Customer Product	Management Requirements*
New York Products	
HMO	Not A Covered Benefit
PPO in Plan	Not A Covered Benefit
PPO OOP	Not A Covered Benefit
POS in Plan	Not A Covered Benefit
POS OOP	Not A Covered Benefit
Essential Plan	Not A Covered Benefit
MVP Medicaid Managed Care	Potential for Retrospective Review
MVP Child Health Plus	Not A Covered Benefit
MVP Harmonious Health Care Plan	Potential for Retrospective Review
MVP Medicare Complete Wellness	Not a Covered Benefit
MVP Medicare Preferred Gold HMO POS	Not A Covered Benefit
MVP Medicare Secure HMO POS	Not A Covered Benefit
MVP Medicare Secure Plus HMO POS	Not A Covered Benefit
MVP Medicare WellSelect PPO	Not A Covered Benefit
MVP Medicare WellSelect Plus PPO	Not A Covered Benefit
MVP Medicare Patriot Plan PPO	Not a Covered Benefit
MVP DualAccess D-SNP HMO	Not A Covered Benefit
MVP DualAccess Complete D-SNP HMO	Not A Covered Benefit
MVP DualAccess Plus D-SNP HMO	Not A Covered Benefit
UVM Health Advantage Select PPO	Not A Covered Benefit
UVM Health Advantage Secure PPO	Not A Covered Benefit
UVM Health Advantage Preferred PPO	Not A Covered Benefit
USA Care	Not A Covered Benefit
Healthy NY	Not A Covered Benefit
MVP Premier	Not A Covered Benefit
MVP Premier Plus	Not A Covered Benefit
MVP Premier Plus HDHP	Not A Covered Benefit
MVP Secure	Not A Covered Benefit
MVP EPO	Not A Covered Benefit
MVP EPO HDHP	Not A Covered Benefit
MVP PPO	Not A Covered Benefit
MVP PPO HDHP	Not A Covered Benefit
Student Health Plans	Not A Covered Benefit
ASO	Not A Covered Benefit
Vermont Products	Not / Covered Benefit
	Net A Course d Dougst
POS in Plan	Not A Covered Benefit
POS OOP MVD Medicara Professed Cold LIMO DOS	Not A Covered Benefit
MVP Medicare Preferred Gold HMO POS	Not A Covered Benefit
MVP Medicare Secure Plus HMO POS	Not A Covered Benefit
UVM Health Advantage Select PPO	Not A Covered Benefit
UVM Health Advantage Secure PPO	Not A Covered Benefit
UVM Health Advantage Preferred PPO	Not A Covered Benefit
MVP VT HMO	Not A Covered Benefit
MVP VT HDHP HMO	Not A Covered Benefit
MVP VT Plus HMO MVP VT Plus HDHP HMO	Not A Covered Benefit Not A Covered Benefit
MVP VI Plus HDHP HMO MVP Secure	Not A Covered Benefit Not A Covered Benefit
ASO	Not A Covered Benefit

[♦] Note: authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

*Management Requirements

Authorization Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not A Covered Benefit Service is not a covered benefit.
See SPD See Specific Plan Design

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Revision History:

12/01/2021 – Annual Review with no changes to the indications and criteria. Updated policy to new format.

04/01/2022 – T1015 removed from policy, no authorization as of 2/20/20; H0002 removed from policy, codes for PROS authorization added to policy.

06/01/2022 – H2018 HE or UB, HE, H2019, H2025, T1015 removed from prior authorization.

08/01/2024 - Annual Review; added the table for services/rate codes/procedure codes, updated the goals of PROS in the overview, added a list of the components to PROS and provided more detail on CRS, updated the admission, continued stay, and discharge criteria section, added the program operations legislation and the UM guidelines to the references.



Phototherapeutic Keratectomy (PTK) and Refractive Surgery

Type of Policy: Surgical

Prior Approval Date: 03/06/2023

Approval Date: 02/17/2025

Effective Date: 06/01/2025

Related Polices: N/A

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

N/A

Codes Requiring Retrospective Review

CPT Codes:	Description:
65760	Keratomileusis
65765	Keratophakia
65767	Epikeratoplasty
65771	Radial keratotomy

Experimental/Investigational

N/A

Common Diagnosis Codes

ICD-10- CM Diagnosis Codes

H52.00 – H52.4 Disorders of refraction (code range)

Common Diagnosis Codes associated with this policy have been provided for informational purposes only. The list of codes may not be all-inclusive and may be updated to reflect any applicable revisions to the ICD-10 code set and/or medical necessity quidelines applied in this policy.

Common Procedure Codes

CPT Codes:	Descriptions:	
0402T	Collagen cross-linking of cornea, including removal of the corneal epithelium and intraoperative pachymetry, when performed (Report medication separately)	
65400	Excision of lesion, cornea (keratectomy, lamellar, partial), except pterygium	
65435	Removal of corneal epithelium; with or without chemocauterization (abrasion, curettage)	
65436	Removal of corneal epithelium; with application of chelating agent (eg, EDTA)	
65450	Destruction of lesion of cornea by cryotherapy, photocoagulation or thermocauterization	
65710	Keratoplasty (corneal transplant); anterior lamellar	
65770	Keratoprosthesis	
C1818	Integrated keratoprosthesis	
L8610	Ocular Implant	
S0800	Laser in situ keratomileusis (LASIK)	
S0810	Photorefractive keratectomy (PRK)	
S0812	Phototherapeutic keratectomy (PTK)	

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

Phototherapeutic keratectomy (PTK) is a covered benefit for customers with documented decreased visual acuity or symptoms of pain and discomfort of sufficient severity to cause disability and when specific criteria are met. Phototherapeutic keratectomy is the removal of superficial corneal tissue, utilizing laser surgery in order to treat disease or correct deformity. The excimer laser photo ablates the damaged corneal tissue in a procedure which is confined to the ocular surface and is conducted under topical anesthesia.

Indications/Criteria

Excimer laser phototherapeutic ablation is indicated in individuals with diseased or significantly scarred corneas. Phototherapeutic keratectomy (S0812) is indicated in individuals who have undergone previous corneal transplantation or cataract extraction

and as a result of the surgical intervention present with surface irregularities or anisometropia.

Phototherapeutic keratectomy (S0812) is also indicated for the treatment of:

- traumatic recurrent erosions not responding to medical treatment;
- recurrent erosions associated with anterior basement membrane dystrophy not responding to medical treatment;
- anterior central corneal opacities and scars associated with visual loss (post-trauma, post-infection, other pathologic conditions);
- irregular corneal surfaces associated with visual loss, or patient discomfort such as:
 - Salzmann's nodular dystrophy;
 - spheroid degeneration;
 - post-surgical scars;
 - keratoconus nodules;
 - calcific band keratopathy; and
 - o after pterygium removal;
- certain non-healing corneal ulcers (such as vernal shield ulcers) recalcitrant to medical treatment;
- corneal dystrophies associated with visual loss such as:
 - anterior basement membrane dystrophy;
 - Reis Buckler's dystrophy with visual loss;
 - o lattice dystrophy with visual loss;
 - o granular dystrophy with visual loss; and
 - o other stromal dystrophies with visual loss;
- injury to the cornea may include the following symptoms:
 - o keratitis (inflammation) of the cornea; or
 - o pain; or
 - o blurred vision; or
 - o tearing or eye discharge; or
 - sensitivity to light; or
 - o redness; or
 - corneal scarring.

 symptomatic anisometropia/anisokonia associated with surgically induced myopic shift of greater than three diopters or astigmatism (such as can occur in penetrating keratoplasty). When attempts to correct with eyeglasses, contacts, or other refractive devices to an acuity of 20/40 are unsuccessful or use of eyeglasses and contacts are contraindicated. Documentation supports that conservative treatment has been unsuccessful.

Keratoprosthesis

- Keratoprosthesis (CPT 65770) is considered medically necessary for the surgical treatment of severe corneal opacification with a history of 1 or more corneal transplant graft failures or an ocular condition with a known low success rate for a corneal transplant (e.g., Stevens-Johnson syndrome, ocular cicatricial pemphigoid, autoimmune conditions with rare ocular involvement, ocular chemical burns).
- Keratoprosthesis procedures using all non-FDA approved devices and for all other indications are investigational and unproven.

Collagen Cross-Linking for Keratoconus

- Conventional corneal collagen cross-linking (C-CXL) (CPT® Code 0402T) using riboflavin and ultraviolet type A is considered medically necessary as a treatment of progressive keratoconus or keratectasia (corneal ectasia).
- Corneal collagen cross-linking using riboflavin and ultraviolet A is considered investigational for all other indications, except as treatment of progressive keratoconus or keratectasia (corneal ectasia) as noted above.

Exclusions

- When the procedure is deemed cosmetic such as in the correction of spherical myopia to eliminate cosmetic contact lenses or spectacles, it would be considered not medically necessary.
- Phototherapeutic keratectomy (PTK) (S0812) is considered not medically necessary for any other indication not listed under the indications/criteria section.
- Other forms of corneal collagen cross-linking such as the use of transepithelial corneal cross-linking (T-CXL), accelerated corneal cross-linking (A-CXL), topographyguided corneal cross-linking (TG-CXL) or partial epithelium-off (P-CXL) are investigational and experimental.
- All forms of elective refractive keratoplasty are considered cosmetic and, as such, are not medically necessary. These procedures do not improve customer outcomes beyond what is achievable with corrective lenses (eyeglasses, contact lenses or other refractive devices). These procedures include:
 - Lamellar keratoplasty (non-penetrating keratoplasty) (65710)
 - Keratomileusis (65760)

- Keratophakia (65765)
- Epikeratoplasty (65767)
- Radial Keratotomy (65771)
- Laser in situ keratomileusis (LASIK)(S0800)
- Photorefractive keratectomy (PRK)(S0810)

Medicare Variation

The correction of common refractive errors by eyeglasses, contact lenses or other prosthetic devices is specifically excluded from coverage. The use of radial keratotomy (65771) and/or keratoplasty (65760, 65765, 65767) for the purpose of refractive error compensation is considered a substitute or alternative to eyeglasses or contact lenses, which are specifically excluded. In addition, many in the medical community consider such procedures cosmetic surgery, which is excluded by Medicare. Therefore, radial keratotomy and keratoplasty to treat refractive defects are not covered.

Keratoplasty that treats specific lesions of the cornea, such as phototherapeutic keratectomy (S0812) that removes scar tissue from the visual field, deals with an abnormality of the eye and may not be considered cosmetic surgery.

Non-covered codes for Medicare products: 65760, 65765, 65767, 65771, S0800, S0810, S0812

For a complete description of the indications and limitations of coverage for refractive keratoplasty for Medicare customers, please refer to the National Coverage Determination (NCD) for Refractive Keratoplasty (100-3) Section number 80.7. Available: MCD Search

References (Reviewed 2025)

- National Institute for Health and Clinical Excellence. Photorefractive laser keratectomy for corneal surface irregularities. Interventional procedures guidance 22 Sept 2010. Changes since publication: 3 January 2012: minor maintenance Available: www.nice.org.uk
- 2. Centers for Medicare and Medicaid Services, National Coverage Decision (NCD) Pub: 100-3; Section 80.7 for Refractive Keratoplasty. Effective date May 1, 1997. Available: www.cms.gov/
- 3. Sumit Garg, MD; Ann Z McColgin , et al. American Academy of Ophthalmology® Phototherapeutic Keratectomy. November 12, 2013. Available: https://www.aao.org/munnerlyn-laser-surgery-center/phototherapeutic-keratectomy-3

- 4. Hayes Comparative Effectiveness Of Corneal Cross-Linking For Treatment Of Keratoconus. Hayes, a TractManager Company, ©2022 TractManager. February 15, 2018. Annual Review: January 13, 2022.
- 5. American Academy of Ophthalmology (AAO). Corneal Collagen Cross-Linking. September 20, 2021b. Accessed September 1, 2022. Available at URL address: https://eyewiki.aao.org/Corneal_Collagen_Cross-Linking

Customer Product	Medical Management Requirements*	
New York Products		
HMO	Retrospective Review	
PPO In Plan	Retrospective Review	
PPO OOP	Retrospective Review	
POS In Plan	Retrospective Review	
POS OOP	Retrospective Review	
Essential Plan	Retrospective Review	
MVP Medicaid Managed Care	Retrospective Review	
MVP Child Health Plus	Retrospective Review	
MVP Medicare Complete Wellness	Retrospective Review	
MVP Medicare Preferred Gold HMO POS	Retrospective Review	
MVP Medicare Secure HMO POS	Retrospective Review	
MVP Medicare Secure Plus HMO POS	Retrospective Review	
MVP Medicare WellSelect PPO	Retrospective Review	
MVP Medicare WellSelect Plus PPO	Retrospective Review	
MVP Medicare Patriot Plan PPO	Retrospective Review	
MVP DualAccess D-SNP HMO	Retrospective Review	
MVP DualAccess Complete D-SNP HMO	Retrospective Review	
MVP DualAccess Plus D-SNP HMO	Retrospective Review	
UVM Health Advantage Select PPO	Retrospective Review	
USA Care PPO	Potential for Retrospective Review	
Healthy NY	Retrospective Review	
MVP Premier	Retrospective Review	
MVP Premier Plus	Retrospective Review	
MVP Premier Plus HDHP	Retrospective Review	
MVP Secure	Retrospective Review	
MVP EPO	Retrospective Review	
MVP EPO HDHP	Retrospective Review	
MVP PPO	Retrospective Review	
MVP PPO HDHP	Retrospective Review	
Student Health Plans	Retrospective Review	
ASO	See SPD	
Vermont Products		
POS In Plan	Retrospective Review	
POS OOP	Retrospective Review	
MVP Medicare Preferred Gold HMO POS	Retrospective Review	
MVP Medicare Secure Plus HMO POS	Retrospective Review	
MVP VT HMO	Retrospective Review	
MVP VT HDHP HMO	Retrospective Review	
MVP VT Plus HMO	Retrospective Review	
MVP VT Plus HDHP HMO	Retrospective Review	
MVP Secure	Retrospective Review	
ASO	See SPD	

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. Maybe subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Revision History:

06/01/2021 – update format, removed investigational review from keratoprosthesis (65770) and made a covered benefit, added coverage and exclusions for Collagen Cross-Linking for Keratoconus (0402T)

06/01/2023 – Annual review with no changes to indications or criteria.

06/01/2025 - Annual review with no changes to indications or criteria, updated link for CMS.



Phototherapy, Photochemotherapy, and Excimer Laser Therapy for Dermatologic Conditions

Type of Policy: Medical

Prior Approval Date: 11/01/2021

Approval Date: 12/04/2023

Effective Date: 02/01/2024

Related Polices: Psoriasis Drugs Policy

Vitiligo

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

N/A

Codes Subject to Retrospective Review

N/A

Experimental/Investigational

N/A

Common Diagnosis Codes

ICD-10 Diagnostic Codes: C84.00, C84.01, C84.02, C84.03, C84.04, C84.05, C84.06, C84.07, C84.08, C84.09, C85.80, C85.89, L20.0, L20.81, L20.82, L20.84, L20.89, L25.9, L29.9, L41.0, L41.1, L41.8, L43.8, L66.1

Common Procedure Codes

CPT Codes: 96900, 96910, 96912, 96913, 96920, 96921, 96922, A4633, E0691, E0692, E0693, E0694

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are

subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy.

Overview

This policy addresses the use of phototherapy, photochemotherapy, and excimer laser therapy for psoriasis and other dermatologic conditions. For systemic and biologic agents for psoriasis refer to the MVP Psoriasis Drugs Policy.

Phototherapy is exposure to the skin with non-ionizing, ultraviolet (UV) radiation for therapeutic benefit. It involves exposure to ultraviolet A (UVA) radiation, ultraviolet B (UVB) radiation, or various combinations of UVA and UVB radiation.

Photochemotherapy is the therapeutic use of UV radiation in combination with medication. Photochemotherapy involves the use of psoralen followed by UVA radiation (PUVA).

Combination therapy is the use of UV radiation with other treatments such as coal tar. The use of coal tar with UVB radiation is Goekerman's treatment.

Excimer laser, a xenon-chloride (XeCl) laser generates an ultraviolet laser light source of UVB radiation that can concentrate energy to a specific area of the body while avoiding damage to surrounding skin.

Documentation Requirements

Documentation needs to be submitted that previous forms of conventional treatment have been tried and failed, or there is an intolerance or contraindication to conventional treatment. Conventional treatment includes the appropriate use of topical medications and therapies. The percentage of the affected body surface should be documented as well.

Indications/Criteria

All of the following treatments must be performed by a participating dermatologist.

Phototherapy, Photochemotherapy, and Combination Therapy

Phototherapy, photochemotherapy, and combination therapy are covered when there has been a failure, intolerance, or contraindication to conventional medical management for the following medical conditions:

- severe refractory atopic dermatitis/eczema; or
- severe urticaria pigmentosa (cutaneous mastocytosis); or
- severe parapsoriasis; or
- psoriasis; or
- severe lichen planus; or

- cutaneous T-cell lymphoma, including mycosis fungoides; or
- Morphea (localized scleroderma).

UVB Therapy

For UVB therapy the following will apply:

- for psoriasis affecting 10% or more of the cutaneous body surface;
- covered after a trial of conventional medical management with inadequate response to topical or oral drug therapies alone (if indicated);
- initial coverage for outpatient UVB light therapy, including narrow band UVB, is limited to ten (10) sessions per course of treatment usually over a span of three to four weeks. A daily session should include all areas for treatment;
- outpatient UVB light therapy, including narrow band UVB, will be covered up to a
 maximum total of 30 treatments. Documentation must support improvement after
 ten (10) treatments. (Treatment cycles are considered for each episode of
 exacerbation); and
- additional coverage for outpatient UVB light therapy, including narrow band UVB, may be approved. When improvement is documented, and therapy is to continue past 30 treatments, an ultraviolet light unit, UVB, for home use may be purchased (See DME section of policy).

Photochemotherapy and Combination Therapy

PUVA or Goeckerman treatment is covered for the following:

- intractable recalcitrant psoriasis;
- disabling psoriasis affecting 20% or more of the body surface;
- psoriasis that interferes with activities of daily living; or
- other skin disorders as listed above.

Covered after a trial of conventional medical management with inadequate response to topical or oral drug therapies alone (if indicated);

Coverage for PUVA therapy is limited to 30 treatments unless improvement is documented. A positive re-evaluation is required prior to the approval of any further treatments.

Maintenance treatment for psoriasis and other skin disorders requiring PUVA therapy or laser therapy will be considered on a case-by-case basis upon review of the Medical Director.

Laser Treatment for Psoriasis

Laser treatment for psoriasis is covered for the following:

- localized mild to moderate plaque type psoriasis, defined as 10% or less of the total body surface area affected; and
- failure of an adequate trial of topical medical therapy or when topical treatment is contraindicated. An adequate trial is defined as a minimum of three (3) months of treatment.

Inpatient hospitalization for severe psoriasis requires a second opinion from a participating dermatologist and prior-authorization.

UVB Home Phototherapy Devices:

- Coverage is considered for moderate to severe plaque psoriasis and moderate to severe atopic dermatitis.
- Ultraviolet UVB cabinets are not medically necessary unless more than 10% of the body is affected and the Ultraviolet UVB 6-foot panel is medically inappropriate.
- the device is not available without a prescription and the device and treatment regimen are prescribed by a physician.

Exclusions

PUVA therapy is considered not medically necessary for the following:

- any indication not listed in the Indications/Criteria section;
- vitiligo; or
- alopecia areata.

PUVA therapy is not covered if the following conditions exist:

- pregnancy;
- history of melanoma/skin cancer (e.g., basal or squamous cell); or
- history of arsenic/radiation exposure.

Laser therapy is considered not medically necessary for:

- any indication not listed in the Indications/Criteria section;
- vitiligo; or
- for customers with Koebner's phenomenon (psoriatic lesion that develops at the site of an injury or skin condition).

Home Units (DME items):

- replacement bulbs and repair and/or replacement of failed equipment are not covered while under warranty;
- UVA (PUVA) light unit for home use and tanning beds for UVB phototherapy are considered not medically necessary;

Medicare

There is a Medicare National Coverage Determination (NCD): Treatment of Psoriasis (250.1) which is consistent with current MVP Health Care criteria. Available: MCD Search (cms.gov)

References (Reviewed 2023)

- 1. Armstrong AW, Siegel MP, Bagel J, et al. From the medical board of the National Psoriasis Foundation: treatment targets for plaque psoriasis. J Am Acad Dermatol. 2017;76(2):290-298. https://www.jaad.org.
- 2. Botts S, Gee M, Chang C, Young I, Saito L. Design and implementation of population-based specialty care programs. Am J Health-Syst Pharm. 2017; 74:1437-45
- 3. Amornpinyokeit, N, et al. 8-Methoxpsoralen cream plus targeted narrowband ultraviolet B for psoriasis. Photodermatology, Photoimmunology, Photomedicine. 2006 Dec; 22(6); 285-9.
- 4. Clayton TH, et al. The treatment of severe atopic dermatitis in childhood with narrowband ultraviolet B phototherapy. Clinical and Experimental Dermatology. 2007 Jan; 32(1):28-33. Psoriasis: Current Treatments, American Academy of Dermatology 2005.
- 5. Brown, S., et al. Atopic and non-atopic eczema. BMJ. 2006 March 11; 332(7541):584-8.
- 6. Menter A, Korman NJ, Elmets CA, Feldman SR, Gelfand JM, Gordon KB, Gottlieb A, Koo JY, Lebwohl M, Lim HW, Van Voorhees AS, Beutner KR, Bhushan R. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 5. Guidelines of care for the treatment of psoriasis with phototherapy and photochemotherapy. J Am Acad Dermatol. 2010 Jan; 62(1):114-35.
- Sidbury, R., MD, et al. American Academy of Dermatology© (AAD). <u>Guidelines</u> of care for the management of atopic dermatitis. Section 3. Management and treatment with phototherapy and systemic agents. Journal of American Academy of Dermatology. May 2014; 71:327-49.
- 8. Gokdemir, G, et al. Narrowband UVB phototherapy for early stage mycosis fungoides; evaluation of clinical and histopathological changes. Journal of European Academy of Dermatology and Venereology. 2006 Aug; 20 (7):804-9.
- 9. Centers for Medicare & Medicaid Services (CMS). Medicare Coverage Database.

 National Coverage Determination (NCD) for Treatment of Psoriasis (250.1). Available:

 MCD Search (cms.gov)
- 10. Centers for Medicare & Medicaid Services (CMS). Medicare Coverage Database.

 National Coverage Determination (NCD) for Durable Medical Equipment Reference
 List (280.1) for Ultraviolet Cabinets. Available: MCD Search (cms.gov)

- 11. National Comprehensive Cancer Network® (NCCN). NCCN Guidelines™. Non-Hodgkin's lymphoma Mycosis Fungoides/Sezary Syndrome. Version2.2020.
- 12. Tzaneva S, Kittler H, Holzer G, Reljic D, Weber M, Hönigsmann H, Tanew A. 5-Methoxypsoralen plus ultraviolet (UV) A is superior to medium-dose UVA1 in the treatment of severe atopic dermatitis: a randomized crossover trial. Br J Dermatol. 2010 Mar; 162(3):655-60.
- 13. National Cancer Institute. Mycosis Fungoides and the Sézary Syndrome (PDQ®): treatment. Health professional version. January, 2016. Available: http://www.cancer.gov/types/lymphoma/hp/mycosis-fungoides-treatment-pdq
- 14. Pavlotsky F, Nathansohn N, Kriger G, Shpiro D, Trau H. Ultraviolet-B treatment for cutaneous lichen planus: our experience with 50 patients. Photodermatol Photoimmunol Photomed. 2008 Apr; 24(2):83-6.
- 15. Ritchlin C, Kavanaugh A, Gladman D, et al. Treatment recommendations for psoriatic arthritis. Ann Rheum Dis. 2009;68:1387-1394. https://www.ard.bmj.com.
- 16. Agency for Healthcare Research and Quality (AHRQ). Effective Health Care Program. Comparative effectiveness review number 85. Biologic and Nonbiologic Systemic Agents and Phototherapy for Treatment of Chronic Plaque Psoriasis. Nov 2012. Available: https://effectivehealthcare.ahrq.gov/products/psoriasis-chronic
- 17. Mudigonda T, Dabade TS, Feldman SR. A review of targeted ultraviolet B phototherapy for psoriasis. J Am Acad Dermatol. 2012 Apr; 66(4):664-72. doi: 10.1016/j.jaad.2011.07.011.
- 18. Paul C, Gallini A, Archier E, Castela E, Devaux S, Aractingi S, Aubin F, Bachelez H, Cribier B, Joly P, Jullien D, Le Maître M, Misery L, Richard MA, Ortonne JP. Evidence-based recommendations on topical treatment and phototherapy of psoriasis: systematic review and expert opinion of a panel of dermatologists. J Eur Acad Dermatol Venereol. 2012 May; 26 Suppl 3:1-10. doi: 10.1111/j.1468-3083.2012.04518.x.
- 19. Pariser DM, Bagel J, Gelfand JM, Korman NJ, Ritchlin CT, Strober BE, Van Voorhees AS, Young M, Rittenberg S, Lebwohl MG, Horn EJ; National Psoriasis Foundation. National Psoriasis Foundation clinical consensus on disease severity. Arch Dermatol. 2007 Feb; 143(2):239-42.
- 20. Jacob J, Pona A, Cline A, Feldman S. Home UV Phototherapy. Dermatol Clin 38 (2020) 109–126

Customer Product	Medical Management Requirements*
New York Products	
HMO	Potential for Retrospective Review
PPO In Plan	Potential for Retrospective Review
PPO OOP	Potential for Retrospective Review
POS In plan	Potential for Retrospective Review
POS OOP	Potential for Retrospective Review
Essential Plan	Potential for Retrospective Review
MVP Medicaid Managed Care	Potential for Retrospective Review
MVP Child Health Plus	Potential for Retrospective Review
MVP Medicare Complete Wellness	Potential for Retrospective Review
MVP Medicare Preferred Gold HMO POS	Potential for Retrospective Review
MVP Medicare Secure HMO POS	Potential for Retrospective Review
MVP Medicare Secure Plus HMO POS	Potential for Retrospective Review
MVP Medicare WellSelect PPO	Potential for Retrospective Review
MVP Medicare WellSelect Plus PPO	Potential for Retrospective Review
MVP Medicare Patriot Plan	Potential for Retrospective Review
MVP DualAccess D-SNP HMO	Potential for Retrospective Review
MVP DualAccess Complete D-SNP HMO	Potential for Retrospective Review
MVP DualAccess Plus D-SNP HMO	Potential for Retrospective Review
UVM Health Advantage Select PPO	Potential for Retrospective Review
USA Care PPO	Potential for Retrospective Review
Healthy NY	Potential for Retrospective Review
MVP Premier	Potential for Retrospective Review
MVP Premier Plus	Potential for Retrospective Review
MVP Premier Plus HDHP	Potential for Retrospective Review
MVP Secure	Potential for Retrospective Review
MVP EPO	Potential for Retrospective Review
MVP EPO HDHP	Potential for Retrospective Review
MVP PPO	Potential for Retrospective Review
MVP PPO HDHP	Potential for Retrospective Review
Student Health Plans	Potential for Retrospective Review
ASO	Potential for Retrospective Review
Vermont Products	
POS In Plan	Potential for Retrospective Review
POS OOP	Potential for Retrospective Review
MVP Medicare Preferred Gold HMO POS	Potential for Retrospective Review
MVP Medicare Secure Plus HMO POS	Potential for Retrospective Review
MVP VT HMO	Potential for Retrospective Review
MVP VT HDHP HMO	Potential for Retrospective Review
MVP VT Plus HMO	Potential for Retrospective Review
MVP VT Plus HDHP HMO	Potential for Retrospective Review
MVP Secure	Potential for Retrospective Review
ASO	Potential for Retrospective Review

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Revision History:

06/01/2021 – Annual Review; updated to new format; added generalized intractable psoriasis to coverage for home devices.

02/01/2022 – Updated coverage for home UVB phototherapy devices to be for moderate to severe plaque psoriasis and moderate to severe atopic dermatitis. Eliminated the requirement for 30 office treatments. Removed prior authorization for E0691, E0692, E0693, E0694.

02/01/2024 – Annual Review; added indications, added Medicare section; reviewed and updated references.



Power Mobility Devices

Type of Policy: DME

Prior Approval Date: 11/01/2021

Approval Date: 08/07/2023

Effective Date: 10/01/2023

Related Polices: Wheelchairs (Manual)

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

For the list of Durable Medical Equipment (DME) that requires Prior Authorization, go to Reference Library - MVP Health Care

Codes Requiring Retrospective Review

N/A

Experimental/Investigational

N/A

Common Diagnosis Codes

N/A

Common Procedure Codes

N/A

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

Power mobility devices (PMD) may include electric wheelchairs and power-operated vehicles (POV) such as scooters that are utilized by patients in the home who are usually totally non-ambulatory and have severe weakness of the upper extremities due to a neurologic or muscular disease or condition.

A push-rim activated power assisted wheelchair (PAPW) is an accessory that upgrades a manual wheelchair by providing motorized hubs and programmable controls to reduce the effort required to operate the chair. Push-rim mobility technology provides the portability of a manual wheelchair with the independence of a power wheelchair. A PAPW accessory for a manual wheelchair must meet specific criteria for coverage.

Indications/Criteria

Documentation Requirements

When prescribing a power wheelchair or power scooter the physician or other treating practitioner who performed the face-to-face encounter must submit the written prescription accompanied by documentation supporting medical necessity of the device. The encounter should be tailored to the individual patient's conditions. The medical history should contain a well-documented description of the patient's functional abilities and limitations on a typical day. It should contain as much objective data as possible that is relevant to mobility needs including weight and height, and all relevant body systems (i.e. cardiopulmonary, musculoskeletal, neurological). The physical examination should be focused on the body systems that are responsible for the patient's ambulatory difficulty or impact on the patient's ambulatory ability. Included in all exams must be a detailed description of the patient's observed ability or inability to transfer and/or walk. This face-to-face encounter must be conducted within six (6) months prior to the order date on the power mobility device.

This should include pertinent parts of the medical record and include the documentation of the beneficiary's face-to-face encounter including information such as the history, physical examination, diagnostic tests, summary of findings, diagnoses, and treatment plans. The patient's medical records include the physician's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals, or test reports.

The physician may refer the beneficiary to a licensed/certified medical professional (LCMP), such as a physical therapist (PT) or occupational therapist (OT), who has experience and training in mobility evaluations to perform part of the face-to-face encounter. This person may have no financial relationship with the supplier. If all or some of the medical examination is completed by another medical professional, the ordering physician must sign off on the report and incorporate it into their records. The report of the physician's visit shall state concurrence or any disagreement with the LCMP examination.

Medical record documentation should be sufficient to:

- delineate the history of events that led to the request for the PMD;
- identify the mobility deficits to be corrected by the PMD;
- establish that other treatments do not obviate the need for the PMD (walkers, crutches, manual wheelchair);
- establish that the beneficiary lives in an environment that supports the use of the PMD:
- establish that the beneficiary or caregiver is capable of operating the PMD; and
- establish that the beneficiary can transfer safely in and out of the PMD and has adequate trunk stability to be able to safely ride in the PMD.

In most cases, the information recorded at the face-to-face encounter will be sufficient. However, there may be some cases where the physician or treating practitioner has treated a patient for an extended period of time and the information recorded at the face-to-face encounter refers to previous notes in the medical record. In this instance, those previous notes would also be needed.

SPECIALTY EVALUATION:

The specialty evaluation that is required for beneficiary's who receive a Group 2 Single Power Option or Multiple Power Options PWC, any Group 3 PWC, or a push-rim activated power assist device is in addition to the requirement for the face-to-face encounter. The specialty evaluation provides detailed information explaining why each specific option or accessory – i.e., power seating system, alternate drive control interface, or push-rim activated power assist – is needed to address the beneficiary's mobility limitation.

HOME ASSESSMENT:

The supplier or practitioner must perform an on-site evaluation of the patient's home to verify that the patient can adequately maneuver the device that is provided considering physical layout, doorway width, doorway thresholds, and surfaces. There must be a written report of this evaluation provided in the request.

Replacement:

Replacement of a power mobility device at the end of its five (5) year useful lifetime requires a complete reassessment following the same rules as if a new initial device was being provided.

Note: Coverage for power mobility devices (PMD) and accessories will be furnished in the most medically appropriate manner that meets the needs of the customer.

Basic Coverage Criteria

All of the following basic criteria (A - C) must be met for a power mobility device (K0800-K0898) or a push-rim activated power assist device (E0986) to be covered. Additional coverage criteria for specific devices are listed below.

A. The patient has a mobility limitation that significantly impairs his/her ability to participate in one or more mobility-related activities of daily living (MRADLs) such as toileting, feeding, dressing, grooming, and bathing in customary locations in the home.

Note: A mobility limitation is one that:

- prevents the patient from accomplishing an MRADL entirely; or
- places the patient at a reasonably determined heightened risk of morbidity or mortality secondary to the attempts to perform an MRADL; or
- prevents the patient from completing an MRADL within a reasonable time frame;
- B. the patient's mobility limitation cannot be sufficiently and safely resolved by use of an appropriately fitted cane or walker;
- C. the patient does not have sufficient upper extremity function to self-propel an optimally-configured manual wheelchair in the home to perform MRADLs during a typical day.
 - Limitations of strength, endurance, range of motion, or coordination, presence of pain, or deformity or absence of one or both upper extremities are relevant to the assessment of upper extremity function.
 - An optimally-configured manual wheelchair is one with an appropriate wheelbase, device weight, seating options, and other appropriate non-powered accessories.

Power Operated Vehicles (K0800-K0808, K0812)

A POV is covered when all of the basic coverage criteria (A - C) have been met and when **all** (D - I) of the following criteria also are met:

- D. the patient is able to:
 - safely transfer to and from a POV; and
 - operate the tiller steering system; and
 - maintain postural stability and position while operating the POV in the home; and
- E. the patient's mental capabilities (e.g., cognition, judgment) and physical capabilities (e.g., vision) are sufficient for safe mobility using a POV in the home; and

- F. the patient's home provides adequate access between rooms, maneuvering space, and surfaces for the operation of the POV that is provided; and
- G. the patient's weight is less than or equal to the weight capacity of the POV that is provided and greater than or equal to 95% of the weight capacity of the next lower weight class POV i.e., a Heavy Duty POV is covered for a patient weighing 285 450 pounds; a Very Heavy Duty POV is covered for a patient weighing 428 600 pounds;
- H. use of a POV will significantly improve the patient's ability to participate in MRADLs and the patient will use it in the home; and
- the patient has not expressed an unwillingness to use a POV in the home.
 Power operated vehicles (POV) include all options and accessories that are provided at the time of initial issue, including but not limited to batteries, battery chargers, seating systems, etc.
 - Group 2 POVs (K0806-K0808) have added capabilities that are not needed for use in the home.

Power Wheelchairs (K0813-K0891, K0898)

A power wheelchair is covered when a customer meets **all** of the **basic** coverage criteria (A-C) and does not meet coverage criterion D, E, or F for a POV, but meets either J or K below, meets **all** of the criteria in L (1-4), and meets specific coverage for Group 1,2,3,4,5 power wheelchairs below:

- J. The beneficiary has the mental and physical capabilities to safely operate the power wheelchair that is provided; or
- K. If the beneficiary is unable to safely operate the power wheelchair, the beneficiary has a caregiver who is unable to adequately propel an optimally configured manual wheelchair, but is available, willing, and able to safely operate the power wheelchair that is provided; and
 - 1. The beneficiary's weight is less than or equal to the weight capacity of the power wheelchair that is provided and greater than or equal to 95% of the weight capacity of the next lower weight class PWC i.e., a Heavy Duty PWC is covered for a beneficiary weighing 285 450 pounds; a Very Heavy Duty PWC is covered for a beneficiary weighing 428 600 pounds; an Extra Heavy Duty PWC is covered for a beneficiary weighing 570 pounds or more.
 - 2. The beneficiary's home provides adequate access between rooms, maneuvering space, and surfaces for the operation of the power wheelchair that is provided.

- 3. Use of a power wheelchair will significantly improve the beneficiary's ability to participate in MRADLs and the beneficiary will use it in the home. For beneficiaries with severe cognitive and/or physical impairments, participation in MRADLs may require the assistance of a caregiver.
- 4. The beneficiary has not expressed an unwillingness to use a power wheelchair in the home.

CRITERIA FOR SPECIFIC TYPES OF POWER WHEELCHAIRS:

Group 1 PWC (K0813-K0816) or a Group 2 PWC (K0820-K0829) is covered if all of the coverage criteria (A – C, J or K, and all of L) for a PWC are met and the wheelchair is appropriate for the beneficiary's weight.

Group 2 Single Power Option PWC (K0835 – K0840) or Group 3 PWC with Single Power Option (K0856-K0860) is covered if all of the coverage criteria (A – C, J or K, and all of L) for a PWC are met and if:

- A. Criterion 1 or 2 is met; and
- B. Criteria 3 and 4 are met.
 - 1. The beneficiary requires a drive control interface other than a hand or chinoperated standard proportional joystick (examples include but are not limited to head control, sip and puff, switch control).
 - 2. The beneficiary meets coverage criteria for a power tilt or a power recline seating system (see Wheelchair Options and Accessories policy for coverage criteria) and the system is being used on the wheelchair.
 - 3. The beneficiary has had a specialty evaluation that was performed by a licensed/certified medical professional, such as a physical therapist (PT) or occupational therapist (OT), or physician who has specific training and experience in rehabilitation wheelchair evaluations and that documents the medical necessity for the wheelchair and its special features (see Documentation Requirements section). The PT, OT, or physician may have no financial relationship with the supplier.
 - 4. The wheelchair is provided by a supplier that employs a RESNA-certified Assistive Technology Professional (ATP) who specializes in wheelchairs and who has direct, in-person involvement in the wheelchair selection for the beneficiary.

Group 2 Multiple Power Option PWC (K0841-K0843) or Group 3 PWC with Multiple Power Options (K0861-K0864) is covered if all of the coverage criteria (A – C, J or K, and all of L) for a PWC are met and if:

- A. Criterion 1 or 2 is met; and
- B. Criteria 3 and 4 are met.
 - 1. The beneficiary meets coverage criteria for a power tilt and recline seating system (see Wheelchair Options and Accessories policy) and the system is being used on the wheelchair.
 - 2. The beneficiary uses a ventilator which is mounted on the wheelchair.
 - 3. The beneficiary has had a specialty evaluation that was performed by a licensed/certified medical professional, such as a PT or OT, or physician who has specific training and experience in rehabilitation wheelchair evaluations and that documents the medical necessity for the wheelchair and its special features (see Documentation Requirements section). The PT, OT, or physician may have no financial relationship with the supplier.
 - 4. The wheelchair is provided by a supplier that employs a RESNA-certified Assistive Technology Professional (ATP) who specializes in wheelchairs and who has direct, in-person involvement in the wheelchair selection for the beneficiary.

Group 3 PWC with no power options (K0848-K0855) is covered if:

- A. All of the coverage criteria (A C, J or K, and all of L) for a PWC are met; and all of the following are met:
 - 1. The beneficiary's mobility limitation is due to a neurological condition, myopathy, or congenital skeletal deformity; and
 - 2. The beneficiary has had a specialty evaluation that was performed by a licensed/certified medical professional, such as a PT or OT, or physician who has specific training and experience in rehabilitation wheelchair evaluations and that documents the medical necessity for the wheelchair and its special features (see Documentation Requirements section). The PT, OT, or physician may have no financial relationship with the supplier; and
 - 3. The wheelchair is provided by a supplier that employs a RESNA-certified Assistive Technology Professional (ATP) who specializes in wheelchairs and who has direct, in-person involvement in the wheelchair selection for the beneficiary.

Group 4 PWCs (K0868-K0886) have added capabilities that are not needed for use in the home. Therefore, if these wheelchairs are provided, they will be denied as not reasonable and necessary.

Pediatric Power Wheelchair (PWC)

A) Group 5 (Pediatric) PWC with Single Power Option (K0890) or with Multiple Power Options (K0891) will be covered when all of the following criteria have been met:

- all of the Basic Coverage Criteria (A-C) listed under Indications/Criteria of this policy have been met, and
- the beneficiary does not meet coverage criterion for a power operated vehicle (POV), and
- the beneficiary has the mental and physical capabilities to safely operate the power wheelchair that is provided, or
- if the beneficiary is unable to safely operate the power wheelchair, the beneficiary has a caregiver who is unable to adequately propel an optimally configured manual wheelchair, but is available, willing, and able to safely operate the power wheelchair that is provided, and
- the beneficiary's weight is less than or equal to the weight capacity of the power wheelchair that is provided and greater than or equal to 95% of the weight capacity of the next lower weight class PWC i.e., a Heavy Duty PWC is covered for a beneficiary weighing 285 450 pounds; a Very Heavy Duty PWC is covered for a beneficiary weighing 428 600 pounds; an Extra Heavy Duty PWC is covered for a beneficiary weighing 570 pounds or more, and
- the beneficiary's home provides adequate access between rooms, maneuvering space, and surfaces for the operation of the power wheelchair that is provided, and
- use of a power wheelchair will significantly improve the beneficiary's ability to
 participate in mobility-related activities of daily living (MRADL) and the beneficiary
 will use it in the home. For beneficiaries with severe cognitive and/or physical
 impairments, participation in MRADLs may require the assistance of a caregiver, and
- the beneficiary has not expressed an unwillingness to use a power wheelchair in the home, and
- the beneficiary is expected to grow in height, and
- any coverage criteria pertaining to the specific wheelchair type are met.

Push-rim Activated Power Assist Device

A push-rim activated power assist device (E0986) for a manual wheelchair is covered when **all** of the following criteria are met:

- all of the criteria for a power wheelchair have been met (A-C); and
- the patient has been self-propelling in a manual wheelchair for at least one year; and
- the patient has had a specialty evaluation that was performed by a licensed/certified medical professional, such as a PT, OT, or physician who has specific training and experience in rehabilitation wheelchair evaluations and that documents the need for

the device in the patient's home. The PT, OT, or physician may have no financial relationship with the supplier; and the wheelchair is provided by a supplier that employs a RESNA-certified Assistive Technology Supplier (ATS) or Assistive Technology Practitioner (ATP) who specializes in wheelchairs and who has direct, inperson involvement in the wheelchair selection for the patient.

Custom Motorized power wheelchair base:

A custom motorized/power wheelchair base (K0013) will be covered if:

- 1. The beneficiary meets the general coverage criteria for a power wheelchair (A C, J or K, and all of L); and
- 2. The specific configurational needs of the beneficiary are not able to be met using wheelchair cushions, or options or accessories (prefabricated or custom fabricated), which may be added to another power wheelchair base.

A custom motorized/power wheelchair base (K0013) must be uniquely constructed or substantially modified for a specific beneficiary according to the description and orders of the beneficiary's treating practitioner. A custom motorized/power wheelchair base is not reasonable and necessary if the expected duration of need for the chair is less than three months (e.g., post-operative recovery).

 For Commercial and Medicare customers only: One month's rental of a power wheelchair or power operated vehicle (K0462) is covered if a patient-owned wheelchair or power operated vehicle is being repaired.

Other Power Wheelchair Specifications:

A POV or power wheelchair with Captain's Chair is not appropriate for a patient who needs a separate wheelchair seat and/or back cushion. A skin protection and/or positioning seat or back cushion should not be provided (see Wheelchair Seating LCD) for a power wheelchair with a Captain's Chair (Refer to Wheelchair Seating LCD and Policy Article for information concerning coverage of general use, skin protection, or positioning cushions when they are provided with a POV or power wheelchair with Captain's Chair.)

For patients who do not have special skin protection or positioning needs, a power wheelchair with Captain's Chair provides appropriate support. Therefore, if a general use cushion is provided with a power wheelchair with a sling/solid seat/back instead of Captain's Chair, the wheelchair and the cushion(s) will be covered only if either criterion 1 or criterion 2 is met:

1. The cushion is provided with a covered power wheelchair base that is not available in a Captain's Chair model – i.e., codes K0839, K0840, K0843, K0860 – K0864, K0870, K0871, K0879, K0880, K0886, K0890, K0891; or

2. A skin protection and/or positioning seat or back cushion that meets coverage criteria is provided.

If one of these criteria is not met, both the power wheelchair with a sling/solid seat and the general use cushion will be denied as not reasonable and necessary.

If a heavy duty, very heavy duty, or extra heavy duty PWC or POV is provided and if the beneficiary's weight is outside the range listed in criterion G or L above (i.e., for heavy duty – 285 – 400 pounds, for very heavy duty – 428 – 600 pounds, for extra heavy duty – 570 pounds or more), it will be denied as not reasonable and necessary. Wheelchair Options and Accessories

All options and accessories (e.g., power tilt and/or recline seating systems (E1002-E1010), adjustable arm trough, elevating leg rests, drive control systems, etc.) must meet medical necessity criteria as indicated in the Medicare National Coverage Policy L33792 Wheelchair Options and Accessories.

Wheelchair Seating (E2603 - E2610, E2613 - E2617, E2620 - E2625)

Positioning and skin protection seat and back cushions must meet medical necessity criteria as indicated in the Medicare National Coverage Policy L33312 Wheelchair Seating.

Power seat elevation equipment for group 3 complex rehab power wheelchairs (E2298) and group 2 power wheelchair with built in seat elevation (K0830, K0831) is medically necessary for individuals when the following conditions are met:

- 1. The individual has undergone a specialty evaluation that confirms the individual's ability to safely operate the seat elevation equipment in the home. This evaluation must be performed by a licensed/certified medical professional such as a physical therapist (PT), occupational therapist (OT), or other practitioner, who has specific training and experience in rehabilitation wheelchair evaluations; and,
- 2. At least one of the following apply:
 - a. The individual performs weight bearing transfers to/from the power wheelchair while in the home, using either their upper extremities during a non-level (uneven) sitting transfer and/or their lower extremities during a sit to stand transfer. Transfers may be accomplished with or without caregiver assistance and/or the use of assistive equipment (e.g. sliding board, cane, crutch, walker, etc.); or,
 - b. The individual requires a non-weight bearing transfer (e.g. a dependent transfer) to/from the power wheelchair while in the home. Transfers may be accomplished with or without a floor or mounted lift; or,
 - c. The individual performs reaching from the power wheelchair to complete one or more mobility related activities of daily living (MRADLs) such as toileting, feeding, dressing, grooming and bathing in customary locations within the

home. MRADLs may be accomplished with or without caregiver assistance and/or the use of assistive equipment.

For Medicare National Coverage Policy on Wheelchair Options and Accessories and Wheelchair Seating go to:

https://med.noridianmedicare.com/web/jadme/policies/lcd/active

Exclusions

- The beneficiary does not meet criteria listed in Indications/Criteria of this policy.
- The beneficiary has demonstrated that he/she has sufficient upper extremity function to propel a manual wheelchair in the home to participate in MRADLs during a typical day. The manual wheelchair should be optimally configured (seating options, wheelbase, device weight, and other appropriate accessories) for this determination.
 - Limitations of strength, endurance, range of motion, coordination, and absence or deformity in one or both upper extremities are relevant.
 - A beneficiary with sufficient upper extremity function may qualify for a manual wheelchair. The appropriate type of manual wheelchair, i.e., light weight, etc., should be determined based on the beneficiary's physical characteristics and anticipated intensity of use.
 - The beneficiary's home should provide adequate access, maneuvering space and surfaces for the operation of a manual wheelchair.
 - The beneficiary's ability to safely use a manual wheelchair has been assessed and documented.
 - A manual wheelchair may be appropriate if the beneficiary is unable to selfpropel a manual wheelchair, and there is a caregiver who is available, willing, and able to provide assistance.
- There are conditions that limit the beneficiary's ability to participate in MRADLs at home such as impairment of cognition or judgment and/or vision such that the provision of mobility assistive equipment (MAE) might not enable a customer to participate in MRDLs if the co-morbidity prevents effective use of the wheelchair or reasonable completion of the tasks even with MAE.
- If a power mobility device is covered, a manual wheelchair provided at the same time, or subsequently, will usually be denied as not medically necessary.
- The power mobility device is primarily for use outdoors.
- Options and accessories that are designed specifically for use outside the home, for recreational activities (i.e. sports), or for convenience are considered not medically necessary.

- An additional wheelchair to be used as back-up is considered to be a convenience and is considered to be not medically necessary.
- A power mobility device will be denied as not reasonable and necessary if the underlying condition is reversible and the length of need is less than three (3) months (e.g., following lower extremity surgery which limits ambulation).
- An add-on to convert a manual wheelchair to a joystick-controlled power mobility device (E0983) or to a tiller-controlled power mobility device (E0984) will be denied as not reasonable and necessary.
- Power standing feature (E2301) are non-covered because they are not primarily medical in nature.
- A power wheelchair with seat elevator included is statutorily a non-covered (K0830, K0831).
- The LUCI power mobility add-on for collision, object, and drop off avoidance is considered experimental/investigational as there is insufficient published clinical literature demonstrating effectiveness or that it improves clinical outcomes.

MVP Medicaid Managed Care and MVP Child Health Plus Variation

The following applies to MVP Medicaid Managed Care and MVP Child Health Plus:

Please see the New York State Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Procedure Codes and Coverage Guidelines for full details located at: https://www.emedny.org/ProviderManuals/DME/index.aspx

Transit option/Transport brackets are included in the reimbursement for any power wheelchair base and are not separately reimbursable.

References (Updated 2023)

- Centers for Medicare & Medicaid Services National Coverage Determination (Effective Date 7/5/2005); NCD for Mobility Assistive Equipment (MAE) 280.3; Available: www.cms.gov
- 2. Centers for Medicare & Medicaid Services National Coverage Database Determination (07/26/2006); Independence iBOT 4000 Mobility System 280.15. Available: www.cms.gov
- 3. Noridian, Durable Medical Equipment Medicare Administrative Contractor, LCD for Wheelchair Options/Accessories (L33792), Revision Effective Date 01/01/2020. Available: https://med.noridianmedicare.com/web/jadme/policies/lcd/active
- 4. Noridian, Durable Medical Equipment Medicare Administrative Contractor, LCD for Wheelchair Seating (L33312), Revision Effective Date 01/01/2020. Available: https://med.noridianmedicare.com/web/jadme/policies/lcd/active

- 5. Noridian, Durable Medical Equipment Medicare Administrative Contractor, LCD for Power Mobility Devices (L33789), Revision Effective Date 01/01/2020. Available: https://med.noridianmedicare.com/web/jadme/policies/lcd/active
- 6. New York State Medicaid Program Durable Medical Equipment, Orthotics, Prosthetics, and Supplies Procedure Codes and Coverage Guidelines. Available: https://www.emedny.org/ProviderManuals/DME/index.aspx
- 7. Noridian, Durable Medical Equipment Medicare Administrative Contractor Article:
 Power Seat Elevation Equipment on Power Wheelchairs: Coverage, Coding, and
 Payment. May 26, 2023. Available:
 https://med.noridianmedicare.com/web/jadme/article-detail/-/view/6547796/power-seat-elevation-equipment-on-power-wheelchairs-coverage-coding-and-payment

Customer Product	Medical Management Requirements*
New York Products	
НМО	Prior Auth
PPO in Plan	Prior Auth
PPO OOP	Prior Auth
POS in Plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Prior Auth
MVP Child Health Plus	Prior Auth
MVP Medicare Complete Wellness	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP Medicare WellSelect PPO	Prior Auth
MVP Medicare WellSelect Plus PPO	Prior Auth
MVP Medicare Patriot Plan PPO	Prior Auth
MVP DualAccess D-SNP HMO	Prior Auth
MVP DualAccess Complete D-SNP HMO	Prior Auth
MVP DualAccess Plus D-SNP HMO	Prior Auth
UVM Health Advantage Select PPO	Prior Auth
USA Care	Prior Auth
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	3cc 3i D
POS in Plan	Prior Auth
POS OOP	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Freiened Gold Timo FOS MVP Medicare Secure Plus HMO POS	Prior Auth
MVP VT HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD
ASU	I 266 2አስ

[♦] Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review.

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Revision History:

02/01/2022 – Added an exclusion for the LUCI power mobility add-on for collision, object, and drop off avoidance.

06/09/2023 – Added indications for Power seat elevation equipment (E2300) and power wheelchair with built in seat elevation (K0830, K0831) effective 5/16/2023.

04/01/2024 - Wheelchair Seat elevation section has been updated with new HCPCS code E2298 for 4/1/24 that only applies to Group 3 PWC's. E2300 is now a deleted code for 4/1/24.



Preimplantation Genetic Testing - PGT

Type of Policy: Medical

Prior Approval Date: n/a

Approval Date: 08/05/2024

Effective Date: 10/01/2024

Related Polices: Advanced Infertility Services and In

Vitro Fertilization (IVF)

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

89290 – Biopsy, oocyte polar body or embryo blastomere, microtechnique (for preimplantation genetic diagnosis); less than or equal to 5 embryos

89291 - Biopsy, oocyte polar body or embryo blastomere, microtechnique (for preimplantation genetic diagnosis); greater than 5 embryos

Codes Requiring Retrospective Review: N/A

Experimental/Investigational

0254U - Reproductive medicine (preimplantation genetic assessment), analysis of 24 chromosomes using embryonic DNA genomic sequence analysis for aneuploidy, and a mitochondrial DNA score in euploid embryos, results reported as normal (euploidy), monosomy, trisomy, or partial deletion/duplication, mosaicism, and segmental aneuploidy, per embryo tested

0396U - Obstetrics (pre-implantation genetic testing), evaluation of 300000 DNA single-nucleotide polymorphisms (SNPs) by microarray, embryonic tissue, algorithm reported as a probability for single-gene germline conditions

Common Diagnosis Codes: N/A

Common Diagnosis Codes associated with this policy have been provided for informational purposes only. The list of codes may not be all-inclusive and may be updated to reflect any applicable revisions to the ICD-10 code set and/or medical necessity quidelines applied in this policy.

ICD-10 Diagnosis Codes:

Common Procedure Codes: N/A

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

Preimplantation genetic testing (PGT) is used as an adjunct to assisted reproductive technology. This testing is performed but removing cells from an embryo. PGT testing can be used for the purpose of testing for aneuploidy (PGT-A), monogenic disorder (PGT-M), polygenic disease risk (PGT-P) and structural rearrangement (PGT-SR).

Preimplantation genetic testing for an euploidy (PGT-A) is used to test for an euploidy in parents with no known chromosomal anomaly, variant for genetic abnormality. It is often used for history of recurrent early pregnancy loss or repeated IVF failure.

Preimplantation genetic testing for monogenic disorders (PGT-M) is used to test for a known single-gene disorder (eg, autosomal recessive, autosomal dominant, X-linked) carried by one or both biological parents.

Preimplantation genetic testing for polygenic disease risk (PGT-P) is proposed testing to aid in embryo selection by using polygenic scoring to estimate the risk of an embryo developing an adult-onset, multifocal condition such as cancer, coronary disease or diabetes.

Preimplantation genetic testing for structural rearrangements (PGT-SR) is used to detect structural chromosomal rearrangements. Rearrangements can be balance or unbalanced and most carriers are unaware of their status until they try to have children. Unbalanced rearrangements can result in trisomy or monosomy and cause congenital abnormalities or developmental delays.

Coverage for Pre-implantation genetic testing does not guarantee coverage for IVF or related services. For coverage of in vitro fertilization and related advanced infertility services, see the MVP Health Care Advanced Infertility Services Medical Policy.

Indications/Criteria

Preimplantation genetic testing for monogenic disorders (PGT-M) or for chromosomal structural rearrangements (PGT-SR) are considered medically necessary with all of the following are met:

- Customer has had pre- and will have post genetic counseling; AND
- the genetic condition is associated with severe disability or has a lethal natural history; AND
- the results of the genetic test will impact clinical decision-making and clinical outcome when ANY of the following criteria is met:
 - both biologic parents are carriers of a single autosomal gene that is a recessively-inherited disorder; OR

- o one biologic parent is a known carrier of a single autosomal gene that is dominantly-inherited disorder or a single x-linked disorder; OR
- o one biologic parent is a translocation carrier; OR
- testing for unbalanced chromosome rearrangements when at least one parent is a known carrier of a structural chromosomal rearrangement.

The following list is examples (list is not all inclusive) of covered genetic conditions:

- Nuclear mitochondrial genes
- Sickle cell disease
- Muscular dystrophies (DMD, BMD, EDMD, DM1, DM2, SM)
- Alpha and beta thalassemia
- Fragile X syndrome
- Gaucher disease
- Rett syndrome
- Niemann-Pick disease
- PTEN-related disorders
- Canavan disease
- Von Hippel-Lindau disease
- Tay-Sachs disease
- Long QT syndrome
- DFNB1 non syndromic hearing loss and deafness
- Retinoblastoma
- Huntington disease
- 21-hydroxylase deficiency
- Cystic fibrosis

Exclusions

Preimplantation genetic testing for aneuploidy (PGT-A) is considered experimental and investigational for all indications, including optimization of IVF outcomes, history of failed IVF cycles, or recurrent miscarriages.

Preimplantation genetic testing for polygenic disease risk (PGT-P) is considered experimental and investigational for all indications.

PGT testing for any other indication is considered experimental and investigational for the following, but not limited to:

- human leukocyte antigen (HLA) typing of an embryo to identify a future suitable stem-cell tissue or organ transplantation donor;
- testing solely to determine if an embryo is a carrier of an autosomal recessively-inherited disorder;
- testing for a multifactorial condition;

testing for variants of unknown significance;

References (2024)

- American College of Medical Genetics and Genomics (ACMG). ©2023 American College of Medical Genetics and Genomics. Available at URL address: <u>Medical Genetics Practice Resources (acmg.net)</u>
- 2. American College of Obstetricians and Gynecologists (ACOG). ©2023. Committee Opinion No. 690 (Mar 2017, reaffirmed 2023). Carrier screening in the age of genomic medicine. Available at URL address: Carrier Screening in the Age of Genomic Medicine | ACOG
- 3. American Society of Reproductive Medicine (ASRM). Preimplantation genetic testing: a Practice Committee opinion. Practice Committee of the Society for Assisted Reproductive Technology; Practice Committee of the American Society for Reproductive Medicine. Fertil Steril. ©2008 American Society for Reproductive Medicine. Fertil Steril. 2008j Nov;90(5 Suppl):S136-43
- 4. Brezina PR, Kutteh WH. Clinical applications of preimplantation genetic testing. BMJ. 2015 Feb 19;350:g7611. doi: 10.1136/bmj.g7611. PMID: 25697663.
- 5. Debrock S, Melotte C, Spiessens C, Peeraer K, Vanneste E, Meeuwis L, Meuleman C, Frijns JP, Vermeesch JR, D'Hooghe TM. Preimplantation genetic screening for aneuploidy of embryos after in vitro fertilization in women aged at least 35 years: a prospective randomized trial. Fertil Steril. 2010 Feb;93(2):364-73. doi: 10.1016/j.fertnstert.2008.10.072. Epub 2009 Feb 26. PMID: 19249029.
- 6. Meyer LR, Klipstein S, Hazlett WD, Nasta T, Mangan P, Karande VC. A prospective randomized controlled trial of preimplantation genetic screening in the "good prognosis" patient. Fertil Steril. 2009;91(5):1731-1738.
- 7. Staessen C, Platteau P, Van Assche E, et al. Comparison of blastocyst transfer with or without preimplantation genetic diagnosis for aneuploidy screening in couples with advanced maternal age: a prospective randomized controlled trial. Hum Reprod. 2004;19(12):2849-2858.

Customer Product	Medical Management Requirements*
New York Products	
HMO	Prior Auth
PPO in Plan	Prior Auth
PPO OOP	Prior Auth
POS in Plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Prior Auth
MVP Child Health Plus	Prior Auth
MVP Harmonious Health Care Plan	Prior Auth
MVP Medicare Complete Wellness	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP Medicare WellSelect PPO	Prior Auth
MVP Medicare WellSelect Plus PPO	Prior Auth
MVP Medicare Patriot Plan (PPO)	Prior Auth
MVP DualAccess D-SNP HMO	Prior Auth
MVP DualAccess Complete D-SNP HMO	Prior Auth
MVP DualAccess Plus D-SNP HMO	Prior Auth
UVM Health Advantage Select PPO	Prior Auth
USA Care	Potential for Retrospective Review
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	300 3. 3
POS in Plan	Prior Auth
POS OOP	Prior Auth
MVP Medicare Preferred Gold HMO POS POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP VT HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD
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♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review.

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Revision History:

10/01/2024 – New policy created.



MVP Health Care

Private Duty Nursing

Type of Policy: Medical

Prior Approval Date: 05/02/2022

Approval Date: 08/05/2024

Effective Date: 10/01/2024

Related Polices: Home Care

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

HCPCS Codes:

S9123 - Nursing care, in the home; by registered nurse, per hour

S9124 - Nursing care, in the home; by licensed practical nurse, per hour

T1000- Private duty/independent nursing service(s), licensed, up to 15 minutes

T1001- Nursing assessment/evaluation

T1002- RN services, up to 15 minutes

T1003 – LPN/LVN services, up to 15 minutes

Codes Subject to Retrospective Review

N/A

Experimental/Investigational

N/A

Common Diagnosis Codes

ICD-10- CM Diagnosis Codes: Z74.2

Common Procedure Codes

N/A

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Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy.

Overview

Private duty nursing services are nursing services for customers who require more individual and continuous skilled nursing care than is available from a certified home health agency (CHHA).

Private duty nursing services can be provided for the critically ill through an approved home nursing registry, licensed home care agency or a private practitioner.

Private duty nursing services may be performed on a continuous, intermittent or parttime visiting basis, according to the defined treatment plan and under the direction of a physician in order to ensure safety of the customer and to achieve the medically desired result.

The location of nursing services may be in the customer's home (or other designated temporary residence) when the care is required for conditions that, without the support, would require the customer to receive services at a higher level of care (e.g., skilled nursing facility, hospital observation, or inpatient).

The intention of private duty nursing (PDN) services is to support – not replace – the skilled care provided to a customer by parents, family, and other responsible caregivers. Commitment by the family and community are necessary to meet the customer's needs and to ensure the customer can remain safely at home.

Backup care givers will need to be identified for use when a nurse is not available. Family and other caregivers should routinely provide hands on care to maintain their general care skills, and assure they are competent in providing backup care when the nurse is unavailable.

Most MVP Health Care Plans exclude coverage for private duty nursing services, refer to the member specific plan documents for details.

Indications/Criteria

Coverage of continuous, intermittent, or part-time private duty nursing services may be limited by contract benefits.

Prior approval for all private duty nursing services is required before the start of providing services and the request must be submitted by the provider. All required documentation must be dated within 6 months of the prior approval start date. The personal centered service plan is reassessed every six months for continued private duty nursing services.

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Documentation Requirements:

1. Physician's Order for Nursing Services:

- a. Private duty nursing services shall be provided by a registered professional nurse (RN) or licensed practical nurse (LPN).
- b. Statement justifying RN level of care.
- c. Documentation must be in the form of generally accepted professional nursing notes, detailing all skilled nursing tasks provided, as well as any assessments, teaching, planning, and evaluations performed of the customer or family needs and their responses to the nursing care.
- d. Number of private duty nursing hours requested (per day or per week) and distribution of hours (daytime, nighttime, flexible use hours).

2. Physician Plan of Care/Skilled Nursing Tasks:

- a. Documentation of the skilled nursing tasks necessary for the care of the member.
- b. Physician plan of care for the customer should be signed, dated and include orders for all skilled nursing tasks.

3. Independent Nurse Contractors:

a. Physician statement that he/she will provide oversight of the LPN(s) providing nursing care to the customer.

4. Assessment from Community Based Organizations or Physician Visit:

- a. Assessment may be performed by a CHHA, LHCSA, or local department of social services OR
- b. Annual history and physical exam including the current medical status performed by a physician or nurse practitioner.
- c. Annual assessment must have been completed within six (6) months of the prior approval start date.

5. Home Evaluation:

- a. Performed by a healthcare professional or Social Worker to include home safety and adequacy for customer's care.
- b. If the member requires invasive mechanical ventilation, a respiratory company must complete the evaluation.

6. Backup Caregiver:

- a. At least one (1) trained backup caregiver must be identified for the customer.
- b. Caregivers must be trained and available to provide care in the home during the absence of the private duty nurse and as required by the members medical status.

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- 7. School Information: (if applicable)
 - a. If the customer is considered school age and does not attend school, submit a statement that the customer does not attend a public or private school outside the home.
 - b. The school district is responsible for providing nursing services to the customer during transportation and school hours.
 - c. If it is determined that school health services and/or school nurse services, including assignment of a full-day (continuous) one-to-one nurse, are required related services for a student with a disability, those services must be provided by the school district at no cost to the parents and are the fiscal and programmatic responsibility of the school district of residence.
- 8. Day Program Information: (if applicable)
 - a. If the customer attends a day program, submit program schedule with transportation times.
 - b. If PDN services are requested to accompany the customer, also submit the name of the program, contact information, and letter from the day program.
- 9. Other Personal Healthcare Services: (CDPAP, PCA, or HHA)
 - a. Submit the approval and plan of care from the authorizing program showing the specific services authorized, and the hours per day, days per week, and times of day these other services are approved for
 - b. If services have been discontinued, submit a statement from the authorizing program indicating the date of service termination
- 10. Private Duty Nursing services requires documentation from the ordering provider of all skilled nursing tasks necessary for the care of the customer. The signed and dated physician plan of care should include the following information, if applicable to the customer:
 - Diagnosis;
 - Orders for all skilled tasks with frequency and time of day performed such as:
 - suctioning: type (nasal, oral, trach) and frequency
 - tube feedings: route (G-tube, J-tube, NG-tube, other), formula, rate, volume, frequency, time of administration
 - Dressing changes/wound care/ostomy care frequency, location, stage, standard dressings or specialized dressings. For extensive wound care, indicate the time frame required for dressing change.
 - scheduled and as needed medication orders: name, does, route, and frequency
 - Intravenous medication: name, dose, frequency, time of administration, length of infusion

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- Ventilator: all settings, PEEP, backup rate, tidal volume or rate, hours per day, time of day, weaning schedule.
- Tracheostomy care: frequency. If removed, decannulation date and care of stoma
- BIPAP/BIPAP-ST/CPAP: all settings, PEEP, backup rate, hours per day, time of day, weaning schedule
- Chest therapy type (physiotherapy, vest, cough assistance), frequency
- Glucose monitoring: frequency
- Seizures: type, number per day, intervention
- Nebulizer treatments: name, dose, and frequency
- Suctioning: type (nasal, oral, trach) and frequency
- Oxygen: rate, schedule (continuous, frequency, pulsed oximetry -based), route (nasal cannula, mask, direct trach), parameters and intervention
- Pulse oximeter monitoring: frequency, parameters and intervention
- Urinary catheter: type; for intermittent catheterizations frequency and time of day
- Bowel regimen: procedure, frequency, duration

Residential Habilitation:

PDN services may not be provided in a Residential Habilitation Program that provides services as part of its routine operation. Residential habilitation services are provided to individuals living in a certified NYS residence.

PDN services of a Registered Nurse or Licensed Practical Nurse, delivered in the residence, may be approved through MVP under the following conditions:

- A. The service is ordered by a physician and the customers care needs of the person cannot be met with residential staffing alone; and
- B. The registered nurse or licensed practical nurse who delivers the approved PDN services are not employed by the agency providing the residential habilitation service to the customer.

Vermont Exchange Product Variation

Private Duty Nursing is covered for Vermont Exchange Products according to the plan contract or certificate of coverage (COC) when the criteria above is met (refer to the Indications/Criteria section of the medical policy). According to the plan contract; Private Duty Nursing (PDN) is covered outside of a hospital subject to these limitations:

- PDN visits are limited up to 4 visits per enrollee, per year.
- PDN services shall be provided by a registered professional nurse (RN) or licensed practical nurse (LPN)
- PDN services are not covered at the same time as home health care nursing services.

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Exclusions

- Private duty nursing services are not a substitute for customers clearly requiring acute inpatient or outpatient on-site services:
- Facility-based private duty nursing is not covered:
- Nursing services provided by an individual nurse cannot exceed working sixteen (16) hours in a 24-hour period;
- Operating a motor vehicle, chauffeuring, or otherwise facilitating transportation of the customer while the nurse is purported to be providing nursing services; a nurse may accompany the customer, but may not drive, chauffeur, or otherwise facilitate transporting the customer;
- Performing tasks that are not skilled nursing in nature including, but not limited to cooking, cleaning and other household chores (washing dishes, laundry).

Medicare

Based on review there is no Medicare National (NCD) or Local (LCD) Coverage Determinations for Private Duty Nursing.

Private duty nursing is not covered for Medicare Advantage Plans.

References (Reviewed 2024)

- Medicare Program Manual: Home Care; available at: www.cms.hhs.gov/manuals/Downloads/bp102c07.pdf
- 2. eMedNY. New York State Medicaid Program. Office of Health Insurance. Department of Health. Provider Manuals. Private Duty Nursing Manual. Policy Guidelines. Version 3.0 Effective April 2023. Available:

https://www.emedny.org/ProviderManuals/index.aspx

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Customer Product	Medical Management Requirements*
New York Products	
НМО	Not Covered
PPO in Plan	Not Covered
PPO OOP	Not Covered
POS in Plan	Not Covered
POS OOP	Not Covered
Essential Plan	Not Covered
MVP Medicaid Managed Care	Prior Auth
MVP Child Health Plus	Not Covered
MVP Harmonious Health Care Plan	Prior Auth
MVP Medicare Gold Giveback	Not Covered
MVP Medicare Preferred Gold HMO POS	Not Covered
MVP Medicare Secure HMO POS	Not Covered
MVP Medicare Secure Plus HMO POS	Not Covered
MVP Medicare WellSelect PPO	Not Covered
MVP Medicare WellSelect Plus PPO	Not Covered
MVP Medicare Patriot Plan PPO	Not Covered
MVP DualAccess D-SNP HMO	Not Covered
MVP DualAccess Complete D-SNP HMO	Not Covered
MVP DualAccess Plus D-SNP HMO	Not Covered
UVM Health Advantage Select PPO	Not Covered
UVM Health Advantage Secure PPO	Not Covered
UVM Health Advantage Preferred PPO	Not Covered
USA Care	Potential for Retrospective Review
Healthy NY	Not Covered
MVP Premier	Not Covered
MVP Premier Plus	Not Covered
MVP Premier Plus HDHP	Not Covered
MVP Secure	Not Covered
MVP EPO	Not Covered
MVP EPO HDHP	Not Covered
MVP PPO	Not Covered
MVP PPO HDHP	Not Covered
Student Health Plans	Not Covered
ASO	See SPD
	See Si D
Vermont Products	
POS in Plan	Not Covered
POS OOP	Not Covered
MVP Medicare Preferred Gold HMO POS	Not Covered
MVP Medicare Secure Plus HMO POS	Not Covered
UVM Health Advantage Select PPO	Not Covered
UVM Health Advantage Secure PPO	Not Covered
UVM Health Advantage Preferred PPO	Not Covered
MVP VT HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

*Medical Management Requirements

Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

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Revision History

08/01/2022 - Reviewed NYS Medicaid program for updates; Documentation requirements expanded and added to requirements for school; updated references and website links.

08/01/2024 – Reviewed NYS Medicaid Private Duty Nursing Provider Policy and Manual for updates and updated policy accordingly.

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Procedures for the Management of Chronic Spinal Pain and Chronic Pain

Type of Policy: Medical

Prior Approval Date: 10/23/2023

Approval Date: 12/04/2023

Effective Date: 02/01/2024

Related Polices: Spinal Cord Stimulator for Intractable Pain

Radiofrequency Ablation (Rhizotomy) for Chronic Pain

Prolotherapy

Investigational Procedures

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

N/A

Codes Requiring Retrospective Review

CPT Codes: 20560, 20561, 64625, 64999, 97139, 97799

Experimental/Investigational

20560, 20561, 64625, 0275T

Common Diagnosis Codes

ICD-10- CM Diagnosis Codes:

M12.9, M47.012, M47.013, M47.014, M47.015, M47.016, M47.019, M47.022, M47.029, M47.10, M47.12, M47.13, M47.14, M47.15, M47.16, M472, M47.20, M47.21, M47.22, M47.23, M47.24, M47.25, M47.26, M47.27, M47.28, M47.81, M47.812, M47.813, M47.814, M47.815, M47.816, M47.817, M47.818, M47.819, M47.89, M47.892, M47.893, M47.894,

M47.895, M47.896, M47.897, M47.898, M47.899, M47.9, M48.0, M48.00, M48.01, M48.02, M48.03, M48.04, M48.05, M48.06, M48.07, M48.08, M48.1, M48.10, M48.11, M48.12, M48.13, M48.14, M48.15, M48.16, M48.17, M48.18, M48.19, M48.2, M48.20, M48.21, M48.22, M48.23, M48.24, M48.25, M48.26, M48.27, M48.3, M48.30, M48.31, M48.32, M48.33, M48.34, M48.35, M48.36, M48.37, M48.38, M48.9

Common Diagnosis Codes associated with this policy have been provided for informational purposes only. The list of codes may not be all-inclusive and may be updated to reflect any applicable revisions to the ICD-10 code set and/or medical necessity guidelines applied in this policy.

Common Procedure Codes

CPT Codes: 20552, 20553, 27096, 62320, 62321, 62322, 62323, 64479, 64480, 64483, 64484, 64490, 64491, 64492, 64777

HCPCS Code: G0260

Non-Covered CPT Codes for MVP Medicaid: 62290, 72295

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

Chronic pain has been defined as "persistent or episodic pain of duration or intensity that adversely affects the function or well-being of the patient, attributable to any non-malignant etiology" ("Practice Guidelines for Chronic Pain Management: A Report by the American Society of Anesthesiologists Task Force on Pain Management, Chronic Pain Section"). In addition, the pain has been refractory to repeated attempts at medical management and usually has been present for at least three to six months.

Spinal pain generates from multiple structures in the spine. Certain conditions may not be detectable using currently available technology or biochemical studies. However, for a structure to be implicated, it should have been shown to be a source of pain in patients using diagnostic techniques of known reliability and validity. The structures responsible for pain in the spine include, but are not limited to, the vertebral bodies, intervertebral discs, spinal cord, nerve roots, facet joints, ligaments, muscles, atlanto-occipital joints, atlanto-axial joints, and sacroiliac joints.

Chronic pain is defined as:

- Lasting 12 weeks or longer;
- nonspecific, in that it has no remediable systemic cause (i.e., not associated with metastatic, inflammatory, infectious, etc. disease);
- not associated with surgery; and,

not associated with pregnancy.

Trigger point injection is one of the many modalities utilized in the management of chronic pain. Myofascial trigger points are self-sustaining hyperirritative foci that may occur in any skeletal muscle in response to strain produced by acute or chronic overload. These trigger points produce a referred pain pattern characteristic for that individual muscle. Production of a referred pain pattern differentiates myofascial pain syndrome from tender points and fibromyalgia. Each pattern becomes part of a single muscle myofascial pain syndrome (MPS); and each of these single muscle syndromes is responsive to appropriate treatment, which includes injection therapy. Injection is achieved with needle insertion and the administration of agents such as local anesthetics.

Lumbar epidural injections are generally performed to treat pain arising from spinal nerve roots. These procedures may be performed via three distinct techniques, each of which involves introducing a needle into the epidural space by a different route of entry. These are termed the interlaminar, caudal, and transforaminal approaches. The procedures involve the injection of a solution containing local anesthetic with or without corticosteroids.

Peripheral nerve blocks are a type of regional anesthesia that are proposed to treat both chronic and peri-operative pain. Peripheral nerve blocks can be either a one-time injection to the target nerve for peri-operative analgesia and/or surgical anesthesia, or continuous insertion of a catheter directly adjacent to the target peripheral nerve. Peripheral nerve blocks allow for shorter discharge times after ambulatory surgery. Indications for peripheral nerve blocks have also been described for the treatment of chronic pain.

Indications/Criteria

Trigger Point Injections (CPT Codes 20552, 20553)

Trigger point injections will be considered as a treatment of myofascial pain syndrome (MPS) using a local anesthetic with or without steroids. The goal is to treat the cause of the pain and not just the symptoms.

Trigger point injections/therapy will be considered for individuals meeting the criteria indicated below:

- when non-invasive medical management such as analgesics, passive physical therapy, ultrasound, range of motion and active exercises were not successful; and
- when the movement of a joint is mechanically blocked resulting in pain and/or functional impairment.

The medical record must contain documentation that fully supports the medical necessity. This documentation includes, but is not limited to, relevant medical history,

physical examination, and results of pertinent diagnostic tests or procedures. The treatment of established trigger point, the medical record must document:

- The evaluation leading to the diagnosis of the trigger point in an individual muscle;
- Identification of the affected muscle(s);
- Reason for selecting the trigger point injection as a therapeutic option, and whether it is being used as an initial or subsequent treatment for myofascial pain.

Repeat trigger point injections may be necessary when there is evidence of persistent pain. Generally, more than three injections of the same trigger point are not indicated. Evidence of partial improvements to the range of motion in any muscle area after an injection, but with persistent significant pain, would justify a repeat injection. The medical record must clearly reflect the medical necessity for repeated injections.

Frequency and Number of Injections or Interventions:

- In the diagnostic phase, a patient may receive injections at intervals of no sooner than one week or preferably, two weeks.
- The number of injections in the diagnostic phase should be limited to no more than two times.
- Once a structure is proven to be negative, no repeat interventions should be directed
 at that structure unless there is a new clinical presentation with symptoms, signs, and
 diagnostic studies of known reliability and validity that implicate the structure.
- The effect of injected corticosteroids may remain for several weeks. The benefit is attributed to a decrease of local inflammation and perhaps some local anesthetic effect. It is usually not necessary to repeat an injection if there has been a satisfactory response to the first injection. Patients who relapse after a satisfactory response may be candidates for another trial after an appropriate interval. Consideration should be given to the cumulative dose injected and limitations made to avoid steroid complications.
- In the therapeutic phase (after the diagnostic phase is completed), the frequency should be two months or longer between each injection, provided that there is initial pain relief with diagnostic injections of greater than or equal to (>/=) 75% 100% with the ability to perform previously painful maneuvers, and a persistent pain relief of greater than or equal to (>/=) 50% with the continued ability to perform previously painful maneuvers is maintained for at least six weeks. The therapeutic frequency must remain at least two months or longer.
- In the treatment or therapeutic phase, the injections should be repeated only as medically necessary. No more than four per patient per year are anticipated for the majority of patients.

 Only sacroiliac joints for which there has been a positive response should be injected for therapeutic reasons.

<u>Lumbar Epidural Injections (interlaminar, caudal, and transforaminal approaches) (CPT codes 62311, 62319, 64483, 64484)</u>

Lumbar epidural injections are covered when all the following indications are met:

- Pain associated with
 - Herpes Zoster; or
 - Suspected radicular pain, based on radiation of pain along the dermatome (sensory distribution) of a nerve; or
 - Neurogenic claudication; or
 - Low back pain (LBP), Numeric Pain Rating Scale (NPRS) ≥ 3/10 (moderate to severe pain) associated with significant impairment of activities of daily living (ADLs) and one of the following:
 - substantial imaging abnormalities such as a central disc herniation
 - severe degenerative disc disease or central spinal stenosis.
- Failure of four weeks* (counting from onset of pain) of non-surgical, non-injection care, which includes appropriate oral medication(s) and physical therapy to the extent tolerated.
- * Exceptions to the four-week wait may include:
 - o pain from Herpes Zoster.
 - o at least moderate pain with significant functional loss at work or home.
 - o severe pain unresponsive to outpatient medical management.
 - inability to tolerate non-surgical, non-injection care due to co-existing medical condition(s)
 - o prior successful injections for same specific condition with relief of at least three months' duration.

If a prior epidural provided no relief, a second epidural is allowed following reassessment of the patient and injection technique.

Local anesthesia or minimal conscious sedation may be appropriate. Use of moderate sedation and Monitored Anesthesia Care (MAC) is usually unnecessary. Documentation must clearly establish the need for such sedation in the specific patient.

The medical record must contain documentation that fully supports the medical necessity. This documentation includes, but is not limited to, relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures.

<u>Indications for Sacroiliac (SI) Joint Injections – Diagnostic and Therapeutic (CPT Codes 27096, G0260)</u>

Sacroiliac (SI) joint injections are considered medically necessary for the diagnosis and/or treatment of chronic low back pain that is considered to be secondary to suspected sacroiliac joint dysfunction.

Diagnostic and therapeutic injections of the SI joint are performed when the following criteria have been met:

- conservative therapy and non-invasive treatments (i.e., rest, physical therapy, NSAIDs, analgesics etc.) for three months or longer failed to relieve the pain;
- a diagnostic block of a sacroiliac joint may be performed to determine whether it is
 the source of low back pain. Arthropathy (joint disease) is diagnosed through a
 double-comparative local anesthetic blockade of the joint by the intra-articular
 injection of a small volume of local anesthetics (2 to 3 ml) of different durations of
 actions. A positive response should demonstrate initial pain relief ≥ 75%-100% and
 the ability to perform previously painful maneuvers; and
- therapeutic sacroiliac (SI) joint injections of an anesthetic and/or steroid to block the
 joint for immediate, and potentially long lasting, pain relief are considered medically
 reasonable and necessary if it is determined that the SI joint is the source of pain in
 the lower back.

If previous diagnostic or therapeutic SI injections of an anesthetic and/or steroid to block the joint for immediate, and potentially long lasting, pain relief have not effectively relieved the pain, further injections would be considered not medically necessary.

Nerve Blocks

The following nerve blocks are considered necessary for peri-operative analgesia and/or surgical anesthesia including but not limited to:

- Cervical plexus block (superficial and deep) after anterior cervical discectomy fusion
- Femoral nerve blocks immediately after knee replacement surgery
- IPACK (infiltration between popliteal artery and capsule of the knee) block for pain control following ankle arthroplasty, anterior cruciate ligament repair, knee arthroscopy, medial meniscectomy, or total knee arthroplasty
- Lumbar plexus block after total hip arthroplasty
- Pericapsular nerve group (PENG) block for hip procedures
- Erector spinae plane (ESP) block for the management of peri-operative pain

Exclusions

- Requests not meeting criteria listed under Indications/Criteria of this policy.
- Percutaneous image-guided lumbar decompression, to include, but not limited to, the Minimally invasive lumbar Decompression (MILD) (0275T) are considered experimental/investigational because there is insufficient evidence in peer-reviewed medical literature.

Trigger Point Injections

- Trigger point injections used on a routine basis, e.g., on a regular periodic and continuous basis, for patients with chronic non-malignant pain syndromes are considered not medically necessary.
- Trigger point Injections consisting of only saline and/or botanical substances are not supported in the peer-reviewed literature and are considered not medically necessary.
- Dry needling is considered investigational because there is insufficient evidence to provide definitive conclusions regarding its effectiveness.

Lumbar Epidural Injections

- Levels per session
 - No more than two transforaminal injections may be performed at a single setting (e.g., single level bilaterally or two levels unilaterally).
 - One caudal or lumbar interlaminar injection per session and not in conjunction with a lumbar transforaminal injection.
- No more than three epidurals may be performed in a six-month period of time.
- No more than six epidural injection sessions (therapeutic epidurals and/or diagnostic transforaminal injections) may be performed in a 12-month period of time regardless of the number of levels involved.
- For a patient with low back pain only, a simple disc bulge or annular tear/fissure is insufficient to justify performance of an epidural.
- Patient must not have major risk factors for spinal cancer (e.g., LBP with fever) or, if cancer is present, but the pain is clearly unrelated, an epidural may be indicated if one of the indications listed in the Indications/Criteria section is present.
- A co-existing medical or other condition that precludes the safe performance of the procedure precludes coverage of the procedure, e.g., new onset of LBP with fever, risk factors for, or signs of, cauda equina syndrome, rapidly progressing (or other) neurological deficits.
- Numbness and/or weakness without paresthesiae/dysesthesiae or pain precludes coverage.

- There is no role for "series of three" epidurals. Response to each epidural should be determined prior to determining the value of a repeat epidural and the specific methods used for subsequent epidurals.
- Radiofrequency ablation used for sacro-iliac joint pain is considered investigational whether performed using traditional, cooled, or pulsed radiofrequency (64625).
- The following treatments for chronic non-specific low back pain (LBP) are not covered because they are considered ineffective or investigational:
 - o prolotherapy;
 - o systemic corticosteroids;
 - therapeutic facet joint steroid injections in the lumbar and sacral regions with or without CT or fluoroscopic image guidance;
 - o injections of steroids into intervertebral discs; and
 - o continuous or intermittent mechanical traction for chronic LBP.

Medicare Variation

There is currently a Local Coverage Determination (LCD) for Pain Management (L33622). Medicare full coverage details are available at: Medicare Coverage Database (MCD)
Search (cms.gov).

There is currently a Local Coverage Article for Pain Management (A52863). Medicare full coverage details are available at: Medicare Coverage Database (MCD) Search (cms.gov).

There is currently a Local Coverage Determination (LCD) for Epidural Steroid Injections for Pain Management (L39036). Medicare full coverage details are available at: <u>Medicare Coverage Database (MCD) Search (cms.gov)</u>.

Effective for services performed on or after January 21, 2020, CMS will cover acupuncture including dry needling for Medicare patients with chronic Lower Back Pain (cLBP).

All types of acupuncture including dry needling for any condition other than cLBP are non-covered by Medicare.

Full details on coverage are available in the National Coverage Determination (NCD) Acupuncture for Chronic Lower Back Pain (cLBP) 30.3.3 Effective 01/21/2020 available: Medicare Coverage Database (MCD) Search (cms.gov)

Percutaneous Image-guided Lumbar Decompression (PILD) (procedure code 0275T) will be covered under an evidence development (CED) clinical trial for Medicare customers with lumbar spinal stenosis (LSS) who are enrolled in a CMS-approved prospective longitudinal study for PILD procedures using a FDA-approved/cleared device that

completed a CMS-approved randomized, controlled clinical trial (RCT) that met the criteria listed in the National Coverage Determination (NCD).

Full details on coverage criteria are available in the National Coverage Determination (NCD) Percutaneous Image-Guided Lumbar Decompression for Lumbar Spinal Stenosis

150.13 Effective 12/07/2016. Available: Medicare Coverage Database

MVP Medicaid Managed Care Variation

The following treatments and procedures for chronic non-specific low back pain (LBP) are not covered because they are considered ineffective or investigational: [7,8,9,10]

- prolotherapy;
- systemic corticosteroids;
- therapeutic facet joint steroid injections in the lumbar and sacral regions with or without CT or fluoroscopic image guidance;
- injections of steroids into intervertebral discs; and
- continuous or intermittent mechanical traction for chronic LBP; and

Lumbar discography (62290, 72295) for chronic low back pain (LBP) or non-specific LBP (ICD-10 Codes M54.5, M54.89 and M549) is not covered for the diagnosis of lumbago, LBP syndrome, lumbalgia, unspecified backache and vertebrogenic syndrome. Claims with one of these diagnoses will deny administratively.

References (Updated 2023)

- National Government Services, Inc. Local Coverage Determination (LCD). LCD for pain management (L33622). Revision Effective Date 10/01/2019. Available: https://www.cms.gov.
- 2. National Government Services, Inc. Local Coverage Determination (LCD). LCD for Epidural Steroid Injections for Pain Management (L39036). Revision Effective Date: 08/10/2023. Available: https://www.cms.gov.
- 3. Boswell, MV, Trescot, AM, Datta, S, Schultz, DM, et al. Interventional techniques: Evidence-based practice guidelines in the management of chronic spinal pain. Guideline. *Pain Physician* 2007; 10:7-111 ISSN 1533-3159.
- 4. Gorbach, C, Schmid, MR, Elfering, A, et al. Therapeutic efficacy of facet joint blocks. AJR Am J Roentgenol.
- 5. Fukusaki, M, Kobayashi, I, Hara, T, Sumikawa, K. Symptoms of spinal stenosis do not improve after epidural steroid injection. Clin J Pain. 1998 14(2):148-451. 2006; 186(5):1228-1233.

- 6. HAYES Medical Technology Directory[™]. Epidural steroid injections for low back pain and sciatica. Lansdale, PA: HAYES, Inc.; © 2008 Winifred S. Hayes, Inc. Jan. 30, 2013. ARCHIVED March 1, 2018. Available to subscribers: www.hayesinc.
- 7. New York State Medicaid Update. Low Back Pain Coverage Guidelines. Vol 28. No 5. April 2012. Available: www.medicaidupdate@health.state.ny.us.
- 8. Practice Guidelines for Chronic Pain Management. An Updated Report by the American Society of Anesthesiologists Task Force on Chronic Pain Management and the American Society of Regional Anesthesia and Pain Medicine. Anesthesiology. April 2010.
- 9. Clinical Guideline for the Evaluation and Management of Low Back Pain. Evidence Review. American Pain Society 2009.
- 10. Deyo, RA, M.D., M.P.H, Mirza SK. M.D., M.P.H., Turner, JA, PhD, and Martin, BI, M.P.H. Over treating Chronic Back Pain: Time to Back Off? JABFM January-February 2009. Vol. 22 No. 1. Available: https://www.jabfm.org/content/22/1/62.
- 11. New York State Medicaid Update. Low Back Pain Coverage Guidelines Discography. Vol 29. No 10. September 2013. Available: www.medicaidupdate@health.state.ny.us.
- 12. National Government Services, Inc. Local Coverage Determination (LCD). LCD Facet Joint Injections, Medical Branch Blocks, and Facet Joint radiofrequency Neurotomy (L35936). Revision Effective Date 12/05/2019. Available: https://www.cms.gov.
- 13. National Government Services, Inc. Article. Pain Management Supplemental Instructions Article. (A52863). Revision Effective Date 01/01/2020. Available: https://www.cms.gov.
- 14. National Government Services, Inc. Lumbar Epidural Injections (L35937). Retired 12/04/2021. Available: https://www.cms.gov.
- 15. HAYES Comparative Effectiveness Review. Comparative Effectiveness Review Of Dry Needling For Indications Other Than Neck Or Trapezius Muscle Pain In Adults. Lansdale, PA: HAYES, Inc.; ©2020 TractManager, Inc. June 22, 2017; Annual Review July 8, 2019.
- 16. Aydin SM, Gharibo CG, Mehnert M, Stitik TP. The role of radiofrequency ablation for sacroiliac joint pain: a meta-analysis. *PM R*. 2010 Sep;2(9):842-851.
- 17. Cheng J, Pope JE, Dalton JE, Cheng O Bensitel A. Comparative Outcomes of Cooled Versus Traditional Radiofrequency Ablation of the Lateral Branches for Sacroiliac Joint Pain. *Clin J Pain*. 2013 Feb:29(2):132-137.
- 18. Cohen SP, Strassels SA, Kurihara C, et al. Outcome predictors for sacroiliac joint (lateral branch) radiofrequency denervation. *Reg Anesth Pain Med.* 2009 May-Jun;34(3):206-214.

- 19. Ho KY, Hadi MA, Pasutharnchat K, Tan KH. Cooled radiofrequency denervation for treatment of sacroiliac joint pain: two-year results from 20 cases. *J Pain Res.* 2013 Jul 4;6:505-511.
- 20. Muhlner SB. Review article: radiofrequency neurotomy for the treatment of sacroiliac joint syndrome. *Curr Rev Musculoskelet Med.* 2009;2:10–14.
- 21. Stelzer W, Aiglesberger M, Stelzer D, Stelzer V. Use of cooled radiofrequency lateral branch neurotomy for the treatment of sacroiliac joint-mediated low back pain: A large case series. *Pain Medicine*. 2013 Jan;14(1):29-35.

Customer Product	Medical Management Requirements*
New York Products	
НМО	Retrospective Review
PPO in Plan	Retrospective Review
PPO OOP	Retrospective Review
POS in Plan	Retrospective Review
POS OOP	Retrospective Review
Essential Plan	Retrospective Review
MVP Medicaid Managed Care	Retrospective Review
MVP Child Health Plus	Retrospective Review
MVP Harmonious Health Care Plan	Retrospective Review
MVP Medicare Complete Wellness	Retrospective Review
MVP Medicare Preferred Gold HMO POS	Retrospective Review
MVP Medicare Secure HMO POS	Retrospective Review
MVP Medicare Secure Plus HMO POS	Retrospective Review
MVP Medicare WellSelect PPO	Retrospective Review
MVP Medicare WellSelect Plus PPO	Retrospective Review
MVP Medicare Patriot Plan PPO	Retrospective Review
MVP DualAccess D-SNP HMO	Retrospective Review
MVP DualAccess Complete D-SNP HMO	Retrospective Review
MVP DualAccess Plus D-SNP HMO	Retrospective Review
UVM Health Advantage Select PPO	Retrospective Review
USA Care PPO	Potential for Retrospective Review
Healthy NY	Retrospective Review
MVP Premier	Retrospective Review
MVP Premier Plus	Retrospective Review
MVP Premier Plus HDHP	Retrospective Review
MVP Secure	Retrospective Review
MVP EPO	Retrospective Review
MVP EPO HDHP	Retrospective Review
MVP PPO	Retrospective Review
MVP PPO HDHP	Retrospective Review
Student Health Plans	Retrospective Review
ASO	See SPD
Vermont Products	366 6. 2
POS in Plan	Retrospective Review
POS OOP	Retrospective Review
MVP Medicare Preferred Gold HMO POS	Retrospective Review
MVP Medicare Secure Plus HMO POS	Retrospective Review
MVP VT HMO	Retrospective Review
MVP VT Plus HMO	Retrospective Review
MVP VT HDHP HMO	Retrospective Review
MVP VT Plus HDHP HMO	Retrospective Review
MVP Secure	Retrospective Review
ASO	See SPD
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♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit
See SPD See Specific Plan Design

Revision History:

08/01/2022 - Added coverage to dry needling (20560, 20561) to Medicare plans only.

08/17/2022 - Added MILD procedure to Exclusions, (0275T).

10/01/2022 - Added limited coverage for nerve blocks.

02/01/2024 –Annual review with no changes to indications or criteria.



Prophylactic Mastectomy and Prophylactic Oophorectomy

Type of Policy: Surgical

Prior Approval Date: 04/04/2022

Approval Date: 03/04/2024

Effective Date: 06/01/2024

Related Polices: N/A

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

For MVP Medicaid Managed Care Products Only:

CPT Codes:

19301 - Mastectomy, partial (e.g., lumpectomy, tylectomy, quadrantectomy, segmentectomy);

19302 -Mastectomy, partial (e.g., lumpectomy, tylectomy, quadrantectomy, segmentectomy); with axillary lymphadenectomy

19303 - Mastectomy, simple, complete

19305 - Mastectomy, radical, including pectoral muscles, axillary lymph nodes

19306 -Mastectomy, radical, including pectoral muscles, axillary and internal mammary lymph nodes (Urban type operation)

19307 -Mastectomy, modified radical, including axillary lymph nodes, with or without pectoralis minor muscle, but excluding pectoralis major muscle

Codes Requiring Retrospective Review

N/A

Experimental/Investigational

N/A

Common Diagnosis Codes

N/A

Common Procedure Codes

CPT Codes: 19301, 19302, 19303, 19305, 19306, 19307, 58661, 58720, 58940

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

Prophylactic mastectomy is the surgical removal of one or both non-diseased breasts to prevent the occurrence of carcinoma in individuals who are at high-risk for developing carcinoma in that breast.

Prophylactic oophorectomy is the preventive, surgical removal of the ovaries. Removal of the ovaries is to prevent the development of ovarian cancer and/or reduce the risk of breast cancer in women who are at high-risk for these diseases.

Indications/Criteria

Documentation requirements:

 Documentation of the patient's medical history should be submitted along with a second opinion examination and consultation report. The second opinion must be performed by a physician who is not in the same practice as the requesting physician.

Documentation must also include all of the following:

- the customer has the ability to make informed consent; and
- the customer has an understanding and acceptance of body image change issues;
 and
- the customer understands that some breast tissue remains following a prophylactic mastectomy and the cancer risk is not totally eliminated; and
- the customer has received genetic counseling to be advised of personal risk of cancer; and
- the customer has received a copy of the surgical evaluation which includes risk/ benefit discussion.

MVP follows the National Comprehensive Cancer Network® Clinical Practice Guidelines in Oncology.TM

Risk reduction mastectomy or bilateral salpingo-oophorectomy should generally be considered only in women with BRCA1/2, or other strongly pre-disposing gene, compelling family history, or possibly women with atypical hyperplasia or lobular carcinoma in situ.

Women considering risk reduction mastectomy or bilateral salpingo-oophorectomy should receive multidisciplinary counseling including consultation with genetics, if not already done. Addressing psychosocial, social, and quality-of-life aspects is recommended.

Exclusions

Requests not meeting criteria.

Medicare

Based on review there is no Medicare Local Coverage Determination (LCD) or Medicare National Coverage Determination (NCD) for Prophylactic Mastectomy and Prophylactic Oophorectomy.

References (Reviewed 2024)

- 1. HAYES Health Technology Assessment. Risk-Reducing (Prophylactic) Mastectomy. HAYES, Inc..Dec, 2013.
- 2. HAYES Health Technology Assessment. Prophylactic Oophorectomy for the Prevention of Ovarian Cancer. HAYES, Inc Dec, 2013.
- 3. The American College of Obstetricians. ACOG Committee Opinion. No. 578. November 2013. Surgery and patient choice. Available: www.acog.org/.
- 4. American Congress of Obstetricians and Gynecologists (ACOG). ACOG Practice Bulletin No. 89. Elective and risk-reducing salpingo-oophorectomy. Obstet Gynecol. 2008; 111(1):231-241. Reaffirmed 2014.
 - 5. American Congress of Obstetricians and Gynecologists (ACOG). ACOG Practice Bulletin Elective and risk-reducing salpingo-oophorectomy. Obstet Gynecol. 2008; 111(1):231-241. Reaffirmed 2014.
- 6. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines)®. Genetic/ Familial High-Risk Assessment: Breast and Ovarian and Pancreatic Version 2.2024. Available: www.nccn.com.
- 7. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) ®. Breast Cancer Risk Reduction Version 1.2024. Available: www.nccn.com.

- 8. Society of Surgical Oncology. Position statement on prophylactic mastectomy. Approved 2001 Mar; Updated 2007 Mar.
- 9. American Cancer Society® Learn about cancer. Breast Cancer. Detailed guide. Can breast cancer be prevented? Last revised: 10/16/2021. Available: About Breast Cancer | Breast Cancer Overview and Basics | American Cancer Society

Customer Product	Medical Management Requirements*
New York Products	
HMO	Potential for Retrospective Review
PPO in Plan	Potential for Retrospective Review
PPO OOP	Potential for Retrospective Review
POS in Plan	Potential for Retrospective Review
POS OOP	Potential for Retrospective Review
Essential Plan	Potential for Retrospective Review
MVP Medicaid Managed Care	Prior Auth
MVP Child Health Plus	Prior Auth
MVP Harmonious Health Care Plan	Prior Auth
MVP Medicare Complete Wellness	Potential for Retrospective Review
MVP Medicare Preferred Gold HMO POS	Potential for Retrospective Review
MVP Medicare Secure HMO POS	Potential for Retrospective Review
MVP Medicare Secure Plus HMO POS	Potential for Retrospective Review
MVP Medicare WellSelect PPO	Potential for Retrospective Review
MVP Medicare WellSelect Plus PPO	Potential for Retrospective Review
MVP Medicare Patriot Plan PPO	Potential for Retrospective Review
MVP DualAccess D-SNP HMO	Potential for Retrospective Review
MVP DualAccess Complete D-SNP HMO	Potential for Retrospective Review
MVP DualAccess Plus D-SNP HMO	Potential for Retrospective Review
UVM Health Advantage Select PPO	Potential for Retrospective Review
USA Care	Potential for Retrospective Review
Healthy NY	Potential for Retrospective Review
MVP Premier	Potential for Retrospective Review
MVP Premier Plus	Potential for Retrospective Review
MVP Premier Plus HDHP	Potential for Retrospective Review
MVP Secure	Potential for Retrospective Review
MVP EPO	Potential for Retrospective Review
MVP EPO HDHP	Potential for Retrospective Review
MVP PPO	Potential for Retrospective Review
MVP PPO HDHP	Potential for Retrospective Review
Student Health Plans	Potential for Retrospective Review
ASO	See SPD
Vermont Products	566 51.5
POS in Plan	Potential for Retrospective Review
POS OOP	Potential for Retrospective Review
MVP Medicare Preferred Gold HMO POS	Potential for Retrospective Review
MVP Medicare Secure Plus HMO POS	Potential for Retrospective Review
MVP VT HMO	Potential for Retrospective Review
MVP VT HDHP HMO	Potential for Retrospective Review
MVP VT Plus HMO	Potential for Retrospective Review
MVP VT Plus HDHP HMO	Potential for Retrospective Review
MVP Secure	Potential for Retrospective Review
ASO	See SPD

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Auth
Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Revision History:

06/01/2022 – Annual review; format updated with code descriptions, no changes to the indications or criteria, websites and references updated.

MVP Health Care Medical Policy
06/01/2024 – Annual review: references updated.



Prostate Cancer Interventions

Type of Policy: Surgical

Prior Approval Date: 12/02/2024

Approval Date: 03/28/2025

Effective Date: 06/01/2025

Related Polices: N/A

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

55880 - Ablation of malignant prostate tissue, transrectal, with high intensity-focused ultrasound (HIFU), including ultrasound guidance

55873 - Cryosurgical ablation of the prostate (includes ultrasonic guidance and monitoring)

Codes Requiring Retrospective Review

None

Experimental/Investigational

51721 – Insertion of transurethral ablation transducer for delivery of thermal ultrasound for prostate tissue ablation, including suprapubic tube placement during the same session and placement of an endorectal cooling device, when performed

55881- Ablation of prostate tissue, transurethral, using thermal ultrasound, including magnetic resonance imaging guidance for, and monitoring of, tissue ablation;

55882- Ablation of prostate tissue, transurethral, using thermal ultrasound, including magnetic resonance imaging guidance for, and monitoring of, tissue ablation; with insertion of transurethral ultrasound transducer for delivery of thermal ultrasound, including suprapubic tube placement and placement of an endorectal cooling device, when performed

Common Diagnosis Codes

C61 - Malignant neoplasm of prostate

Common Diagnosis Codes associated with this policy have been provided for informational purposes only. The list of codes may not be all-inclusive and may be updated to reflect any applicable revisions to the ICD-10 code set and/or medical necessity quidelines applied in this policy.

Common Procedure Codes

CPT Codes: 55874 - Transperineal placement of biodegradable material, perihyphenprostatic, single or multiple injection(s), including image guidance, when performed [For SpaceOAR]

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

External beam radiation therapy is a standard treatment option for clinically localized PCa (NCCN, 2018), commonly delivered using image-guided conformal radiation therapy, stereotactic body radiotherapy, intensity-modulated radiation therapy, and image-guided radiation therapy. Despite the improved ability to focus radiation therapy (RT) to specific areas, radiation can still pass around and through the target area, exposing healthy tissue to cytotoxic radiation. Since the prostate gland sits in front of the rectum, any RT directed at the prostate puts the rectum at risk of radiation exposure.

Prostate rectal spacers are various materials or devices placed between the prostate and anterior wall of the rectum for use in men receiving radiation therapy for prostate cancer. The anterior wall of the rectum is considered a major dose-limiting factor in radiation therapy of prostate cancer. Physical separation is proposed to allow reduced toxicity and treatment intensification.

The SpaceOAR absorbable perirectal spacer (APS) is a polyethylene glycol (PEG) hydrogel that is injected under anesthesia with transrectal ultrasound guidance into a space between the prostate and rectum.

High-intensity focused ultrasound (HIFU) is a minimally invasive treatment that uses high intensity convergent ultrasound delivered via an endorectal probe to treat recurrent prostate cancer.

Cryosurgical ablation of the prostate, also known as cryotherapy or cryoablation, is a minimally invasive procedure used to treat prostate cancer. It involves freezing and destroying cancerous cells in the prostate gland. This method is less invasive compared to traditional surgery with the benefits of shorter surgical procedure times and minimal blood loss.

Transurethral Ultrasound Ablation (TULSA; TULSA-Pro) uses ultrasound to produce a high temperature to ablate the prostate via a catheter through the urethra. The TULSA-Pro also combines the use of Magnetic Resonance Imaging (MRI) to direct the robot driven ultrasound.

Indications/Criteria

Polyethylene-glycol (PEG) hydrogel (SpaceOAR)

Transperineal periprostatic placement of biodegradable material (SpacOAR) is medically necessary for reducing rectal toxicity in men undergoing radiotherapy, which includes IMRT, for prostate cancer.

High intensity focused ultrasound (HIFU)

High intensity focused ultrasound (HIFU) is covered when the following criteria are met:

- Diagnosed with recurrent post-radiation prostate cancer, and
- there is no evidence of metastatic disease.

Cryosurgery of Prostate

Cryosurgery as primary treatment is covered when the following criteria are met:

- Have no evidence of metastatic disease; and
- Stage T1 to T3.

Cryosurgery of the prostate for recurrent cancer is covered when the following criteria are met:

- Have no evidence of metastatic disease; and
- Have failed a trial of radiation therapy as their primary treatment; and
- Meet one of the following conditions:
 - Stage T2B or below, or
 - Gleason score <9, or
 - o PSA <8 ng/mL.

Exclusions

Transperineal periprostatic placement of biodegradable material (SpacOAR) is excluded from coverage for customers with obvious rectal invasion or posterior extension.

Transperineal periprostatic placement of biodegradable material (SpacOAR) is excluded from coverage for all other indications.

Transurethral Ultrasound Ablation (TULSA; TULSA-Pro) Procedure proposed for the treatment of prostate cancer is considered investigational because there is a low-quality

body of evidence regarding the safety and effectiveness of the procedure compared with other treatments.

Medicare

Based on review, there is no active Medicare National Coverage Decision (NCD) or Medicare Local Coverage Decision (LCD) for High intensity focused ultrasound (HIFU) for prostate cancer or SpaceOAR.

For full CMS/Medicare coverage and limitation details refer to the following Medicare National Coverage Decision (NCD), Cryosurgery of Prostate (230.9) Effective Date 07/01/2001. Available: MCD Search (cms.gov)

References (Updated 2025)

- 1. Song DY, Herfarth KK, Uhl M, et al. A multi-institutional clinical trial of rectal dose reduction via injected polyethylene-glycol hydrogel during intensity modulated radiation therapy for prostate cancer: analysis of dosimetric outcomes. International journal of radiation oncology, biology, physics. 2013;87(1):81-87.
- 2. Pinkawa M, Piroth MD, Holy R, et al. Spacer stability and prostate position variability during radiotherapy for prostate cancer applying a hydrogel to protect the rectal wall. Radiother Oncol. 2013;106(2):220-224.
- 3. Uhl M, Herfarth K, Eble MJ, et al. Absorbable hydrogel spacer use in men undergoing prostate cancer radiotherapy: 12 month toxicity and proctoscopy results of a prospective multicenter phase II trial. Radiat Oncol. 2014;9:96.
- 4. Hamstra DA, Mariados N, Sylvester J, et al. Continued Benefit to Rectal Separation for Prostate Radiation Therapy: Final Results of a Phase III Trial. International journal of radiation oncology, biology, physics. 2017;97(5):976-985.
- 5. Padmanabhan R, Pinkawa M, Song DY. Hydrogel spacers in prostate radiotherapy: a promising approach to decrease rectal toxicity. Future Oncol. 2017;13(29):2697-2708.
- 6. Clinically Localized Prostate Cancer: AUA/ASTRO/SUO Guideline. 2017; http://www.auanet.org/guidelines/prostate-cancer-clinically-localized-(2017).
- 7. National Comprehensive Cancer Network® (NCCN). NCCN GUIDELINES™ Clinical Guidelines in Oncology™. © National Comprehensive Cancer Network, Inc. 2021a. All Rights Reserved. Prostate cancer v 2. 2022. Accessed December 1, 2021. Available at URL address: https://www.nccn.org/professionals/physician_gls/default.aspxMuller AC, Mischinger J, Klotz T, et al. Interdisciplinary consensus statement on indication and application of a hydrogel spacer for prostate radiotherapy based on experience in more than 250 patients. Radiol Oncol. 2016;50(3):329-336.

- 8. Mok G, Benz E, Vallee JP, Miralbell R, Zilli T. Optimization of radiation therapy techniques for prostate cancer with prostate-rectum spacers: a systematic review. International journal of radiation oncology, biology, physics. 2014;90(2):278-288.
- 9. Chennupati SK, Pelizzari CA, Kunnavakkam R, Liauw SL. Late toxicity and quality of life after definitive treatment of prostate cancer: redefining optimal rectal sparing constraints for intensity-modulated radiation therapy. Cancer Med. 2014;3(4):954-961.
- 10. Hamstra DA, Stenmark MH, Ritter T, et al. Age and comorbid illness are associated with late rectal toxicity following dose-escalated radiation therapy for prostate cancer. International journal of radiation oncology, biology, physics. 2013;85(5):1246-1253.
- 11. Choe KS, Jani AB, Liauw SL. External beam radiotherapy for prostate cancer patients on anticoagulation therapy: how significant is the bleeding toxicity? International journal of radiation oncology, biology, physics. 2010;76(3):755-760.
- 12. Health Technology Assessment Information Service SpaceOAR® System (Augmenix, Inc.) Hydrogel Spacer for Reducing Exposure during Radiation Therapy for Prostate Cancer. ECRI Institute. May 2017, pages 1-13.
- 13. Morgan SC, Hoffman K, Loblaw DA, et al. Hypofractionated Radiation Therapy for Localized Prostate Cancer: An ASTRO, ASCO, and AUA Evidence-Based Guideline. *J Clin Oncol.* 2018;JCO1801097.
- 14. UpToDate: External beam radiation therapy for localized prostate cancer. 2018; <u>UpToDate</u>
- 15. Hayes Health Technology Assessment. Absorbable Perirectal Spacer (SpaceOAR System; Augmenix Inc.) During Radiation Therapy For Prostate Cancer. April 10, 2018. Annual Review: April 30,2020. ARCHIVED May 10, 2021 ©2021 Hayes, a sympir company.
- 16. Medicare Local Coverage Determination National Government Services Inc. (LCD): Prostate Rectal Spacers (L37485). Original Effective Date: 07/02/2018. Retired and no longer in effect: 05/01/2024. Available: MCD Search (cms.gov)
- Aetna: Transperineal Placement of Biodegradeable Material (SpaceOAR) for Prostate Cancer Policy number:
 0926. http://www.aetna.com/cpb/medical/data/900_999/0926.html. Accessed 10/2/19.
- 18. Humana: Intensity Modulated Radiation Therapy (IMRT) # HCS-0322-019. http://apps.humana.com/tad/tad_new/home.aspx. Accessed 10/2/19.
- 19. Cigna: Omnibus Codes #0504. CIGNA Medical Policy. Accessed 10/2/19.

- 20. Hayes Inc. Health Technology Assessment. Ultrasound-Guided High-Intensity Focused Ultrasound for Primary Treatment of Localized Prostate Cancer. Hayes, Inc. Published: November 22, 2022.
- 21. Centers for Medicare & Medicaid Services. Local Coverage Determination National Government Services Inc. (LCD): Salvage High-intensity Focused Ultrasound (HIFU) Treatment in Prostate Cancer (PCa). Retired 10/20/2022.

Customer Product	Medical Management Requirements*
New York Products	
НМО	Prior Auth
PPO in Plan	Prior Auth
PPO OOP	Prior Auth
POS in Plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Prior Auth
MVP Child Health Plus	Prior Auth
MVP Harmonious Health Care Plan	Prior Auth
MVP Medicare Complete Wellness	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP Medicare WellSelect PPO	Prior Auth
MVP Medicare WellSelect Plus PPO	Prior Auth
MVP Medicare Patriot Plan PPO	Prior Auth
MVP DualAccess D-SNP HMO	Prior Auth
MVP DualAccess Complete D-SNP HMO	Prior Auth
MVP DualAccess Plus D-SNP HMO	Prior Auth
UVM Health Advantage Select PPO	Prior Auth
USA Care	Potential for Retrospective Review
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	
POS in Plan	Prior Auth
POS OOP	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP VT HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
	See SPD

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review.

Retro ReviewRetrospective Review RequiredNot CoveredService is not a covered benefit.See SPDSee Specific Plan Design

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MVP Health Care Medical Policy Revision History:

12/01/2021 – new policy effective.

04/01/2023 - update name of policy to Prostate Cancer Interventions, added Medicare language and added coverage for HIFU treatment.

10/01/2024 –added criteria for cryosurgery and CPT Code 55873 to prior authorization.

04/01/2025 –added criteria for SpaceOAR.

06/01/2025 - TULSA (CPT Codes: 51721, 55881, 55882) added to exclusions.



Prosthetic Devices (External): Eye and Facial and Scleral Shells

Type of Policy: DME

Prior Approval Date: 03/10/2023

Approval Date: 03/28/2025 **Effective Date:** 06/01/2025

Related Polices: Cosmetic and Reconstructive Services

Durable Medical Equipment

Hearing Aid Services

Lenses for Medical Conditions of the Eye Prosthetic Devices Upper & Lower Limb

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

For Durable Medical Equipment (DME) that requires Prior Authorization, refer to https://www.mvphealthcare.com/providers/reference-library/#utilization-management

V2629 - Prosthetic eye, other type

Codes Subject to Retrospective Review

N/A

Experimental/Investigational

N/A

Common Diagnosis Codes

N/A

Common Procedure Codes

HCPCS Code:

- V2624 Polishing/resurfacing of ocular prosthesis
- L8040 Nasal prosthesis, provided by a nonphysician
- L8041- Midfacial prosthesis, provided by a nonphysician
- L8042 Orbital prosthesis, provided by a nonphysician
- L8043 Upper facial prosthesis, provided by a nonphysician
- L8044- Hemi-facial prosthesis, provided by a nonphysician
- L8045- Auricular prosthesis, provided by a nonphysician
- L8046 Partial facial prosthesis, provided by a nonphysician
- L8047 Nasal septal prosthesis, provided by a nonphysician
- L8048 Unspecified maxillofacial prosthesis, by report, provided by a nonphysician
- L8049 Repair or modification of maxillofacial prosthesis, labor component, 15-minute increments, provided by a nonphysician

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive.

Overview

A prosthetic device is an artificial substitute for a missing body part. This policy addresses eye prosthesis, facial prosthesis, and scleral shells.

Documentation Requirements

The medical record must contain information which supports medical necessity. An order for each item billed must be signed and dated by the treating physician and kept on file by the supplier. For coverage for non-standard prosthetic devices, documentation must include detailed information supporting medical necessity.

Indications/Criteria

General

Coverage will be for an appropriate prosthetic device consistent with the customer's medical necessity requirements to allow for occupational and/or general activities of daily living requirements.

All external prosthetic devices must be supplied by a qualified vendor.

Eye Prosthesis

An eye prosthesis is covered for a customer with absence or shrinkage of an eye due to birth defect, trauma, or surgical removal.

Polishing and resurfacing (V2624) is covered on a twice-per-year basis.

One enlargement (V2625) or reduction (V2626) of the prosthesis is covered without documentation. Additional enlargements or reductions are rarely medically necessary and are, therefore, covered only when there is information in the medical record which supports medical necessity.

Repairs are covered when there has been accidental damage or extensive wear to the prosthesis that can be repaired. If the expense for repairs exceeds the estimated expense for replacement prosthesis, no payments can be made for the amount of the excess.

Replacement of an ocular prosthesis because of loss or irreparable damage may be reimbursed without a physician's order when it is determined that the prosthesis as originally ordered still fits the customer's medical needs.

Facial Prosthesis

A facial prosthesis is covered when there is loss or absence of facial tissue due to disease, trauma, surgery, or a congenital defect.

Modifications to a prosthesis are separately payable when they occur more than 90 days after delivery of the prosthesis and they are required because of a change in the customer's condition.

Repairs are covered when there has been accidental damage or extensive wear to the prosthesis that can be repaired. If the expense for repairs exceeds the estimated expense for replacement prosthesis, no payments can be made for the amount of excess.

Replacement of a facial prosthesis is covered in cases of loss or irreparable damage or wear or when required because of a change in the customer's condition that cannot be accommodated by modification of the existing prosthesis. When replacement involves a new impression/moulage rather than the use of a previous master model, the reason for the new impression/moulage must be clearly documented in the supplier's records and available upon request.

Scleral Shell (V2627)

Scleral shell (or shield) is covered for the following:

 A scleral shell fits over the entire exposed surface of the eye as opposed to a corneal contact lens which covers only the central non-white area encompassing the pupil and iris. Where an eye has been rendered sightless and shrunken by inflammatory disease, a scleral shell may, among other things, obviate the need for surgical enucleation and prosthetic implant and act to support the surrounding orbital tissue. In such a case, the device serves essentially as an artificial eye.

• Scleral shells are occasionally used in combination with artificial tears in the treatment of "dry eye" of diverse etiology. Tears ordinarily dry at a rapid rate and are continually replaced by the lacrimal gland. When the lacrimal gland fails, the half-life of artificial tears may be greatly prolonged by the use of the scleral contact lens as a protective barrier against the drying action of the atmosphere. Thus, the difficult and sometimes hazardous process of frequent installation of artificial tears may be avoided. The lens acts in this instance to substitute, in part, for the functioning of the diseased lacrimal gland and would be covered as a prosthetic device in the rare case when it is used in the treatment of "dry eye."

Exclusions

The following may be exclusions to the customer's contract. (Always refer to the specific Customer's Contract when determining benefits).

- replacement of equipment to improve appearance, for convenience or for comfort.
 Refer to the MVP Cosmetic and Reconstructive Surgery policy.
- dentures are not a covered benefit.
- eyeglasses are not a covered benefit.
- hearing aids are not covered (except for the MVP Medicaid Managed Care and MVP Child Health Plus contracts). Refer to MVP's Hearing Aid Services policy.
- duplicate items, (e.g., for use in more than one location; one at home and one at school to participate in sports).

Coverage and coverage exclusion for DME is specific to the individual plan's coverage.

Medicare

For full Medicare detail coverage and limitations for eye prostheses refer to the following: Nordian Healthcare Solutions. Local Coverage Determination (LCD) Eye Prosthesis (L33737) Effective 01/01/2020. Available:

https://med.noridianmedicare.com/web/jadme/policies/lcd/active

For full Medicare detail coverage and limitations for facial prosthesis refer to the following: Nordian Healthcare Solutions. LCD Facial Prostheses (L33737) Effective 01/01/2020. Available: https://med.noridianmedicare.com/web/jadme/policies/lcd/active

For full Medicare detail coverage and limitations for Scleral Shell refer to the following: Centers for Medicare & Medicaid Services (CMS) Medicare Coverage Database NCD for Scleral Shell (80.5). Available: www.cms.hhs.gov/

References (Updated 2025)

- Nordian Healthcare Solutions. LCD Eye Prosthesis (L33737) Effective 01/01/20. Reviewed 01/20/2022 Available: https://med.noridianmedicare.com/web/jadme/policies/lcd/active.
- 2. Nordian Healthcare Solutions. LCD Facial Prosthesis (L33738) Effective 01/01/20. Reviewed 01/20/2022 Available: https://med.noridianmedicare.com/web/jadme/policies/lcd/active
- 3. CMS Medicare Coverage Database NCD for Scleral Shell (80.5). Reviewed 01/20/2022. Available: www.cms.hhs.gov/.
- 4. Nordian Healthcare Solutions. Local Coverage Article. Eye Prosthesis (A52462) Effective 01/01/20. Available: https://med.noridianmedicare.com/web/jadme/policies/lcd/active.
- 5. Nordian Healthcare Solutions. Local Coverage Article. Facial Prosthesis (A52463) Effective 01/01/20. Available: https://med.noridianmedicare.com/web/jadme/policies/lcd/active.

Customer Product	Medical Management Requirements*
New York Products	
HMO	Prior Auth
PPO in Plan	Prior Auth
PPO OOP	Prior Auth
POS in Plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Prior Auth
MVP Child Health Plus	Prior Auth
MVP Harmonious Health Care Plan	Prior Auth
MVP Medicare Complete Wellness	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
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MVP DualAccess Complete D-SNP HMO	Prior Auth
MVP DualAccess Plus D-SNP HMO	Prior Auth
UVM Health Advantage Select PPO	Prior Auth
USA Care PPO	Potential for Retrospective Review
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
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MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	See SFD
	D: A II
POS in Plan	Prior Auth
POS OOP	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP VT HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD

[♦] Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit

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Revision History:

06/01/2022 – Annual Review with no changes to the indications or criteria. References and weblinks were updated.

04/01/2023 – Removed prior authorization from CPT/HCPCS Codes: V2624, L8040, L8041, L8042, L8043, L8044, L8045, L8046, L8047, L8048, L8049.

06/01/2025 – Annual review. No changes to criteria.



Prosthetic Devices (Upper Limb and Lower Limb)

Type of Policy: DME

Prior Approval Date: 03/06/2023

Approval Date: 01/06/2025

Effective Date: 04/01/2025

Related Polices: Prosthetic Devices (External) Eye, Facial

Durable Medical Equipment

Cosmetic and Reconstructive Surgery

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

MVP Durable Medical Equipment (DME) that requires Prior Authorization, refer to the list available on the <u>Provider Online Resources</u> page.

Most prostheses require prior authorization.

Codes Subject to Retrospective Review

HCPCS Code: L7600

Experimental/Investigational

N/A

Common Diagnosis Codes

N/A

Common Procedure Codes

N/A

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-

authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive.

Overview

A prosthetic device is an artificial substitute for a missing body part. This policy addresses upper limb and lower limb prostheses.

Documentation Requirements

General

The medical record must contain information regarding the medical necessity of the requested device.

An order for the prosthesis, including each separately billed component, must be signed and dated by the treating practitioner and kept on file by the supplier. Requests for coverage of prosthetic devices must contain documentation that includes detailed information supporting medical necessity.

The prosthetist's records must be corroborated by the patient's information in the physician's medical record.

Lower Limb Devices

The medical record must document the following:

- the patient's functional capabilities and their expected functional potential, including an explanation for the differences, if applicable;
- functional assessment objective findings using validated testing protocols (Amputee Mobility Predictor, Orthotics and Prosthetics Research Study-Prosthetic Evaluation Questionnaire) either with or without a prosthesis, by a health care professional other than the prosthetic device supplier, to include but not limited to, such observations of functional capabilities such as ability to transfer, distance, speed, ability for ambulation with variable cadence, and ability to navigate barriers. It is recognized, within the functional classification hierarchy, that bilateral amputees often cannot be strictly bound by functional level classification

Links to testing protocols and tools:

Amputee Mobility Predictor – this objective testing protocol would typically be completed by a Physiatrist or Physical Therapist and has 2 formats: AMPnoPRO – for first time amputees who do not have a prosthetic or amputees whose prosthetic is not functional; AMPPRO – for amputees who have a functioning prosthetic. Note: This test protocol does not apply to bilateral lower extremity amputees. general - le amputation.pdf (oandp.com)

Orthotics and Prosthetics Research Study-Prosthetic Evaluation Questionnaire – this is a subjective self-reporting tool and can be used by an amputee to document their

prosthetic use and issues. Please note that this is not an objective tool and does not replace the required medical record documentation noted above but can be used to supplement it.

<u>Microsoft Word - Prosthesis Evaluation Questionnaire PEQ .doc</u> (orthocareinnovations.com)

This policy addresses conventional lower limb devices for the feet, ankles, knees, and hip. The policy also addresses microprocessor-controlled prostheses systems for the feet, ankle and knee. Upper limb prostheses such as standard hook and cable operated upper limb prostheses and myoelectric upper arm prosthetic components are also addressed.

Indications/Criteria

General

External prosthetic devices are covered for customers when medically necessary as a result of an accident, congenital absence, or illness.

Coverage will be for an appropriate prosthetic device consistent with the customer's medical necessity requirements to allow for occupational and/or general activities of daily living requirements.

If a prosthesis is denied as not medically necessary, related additions will also be denied as not medically necessary.

Adjustments to a prosthesis required by wear or by a change in the patient's condition are covered under the initial physician's order for the prosthesis for the life of the prosthesis.

Repairs to a prosthesis are covered when necessary to make the prosthesis functional.

Replacement of a limb prosthesis or prosthetic component is covered if the treating practitioner orders a replacement device or part because of any of the following:

- a change in the physiological condition of the patient; or
- irreparable wear of the device or a part of the device; or
- the condition of the device, or part of the device, requires repairs and the cost of such repairs would be more than 60% of the cost of a replacement device, or of the part being replaced.

Replacement of a prosthesis or prosthetic components required because of loss or irreparable damage may be reimbursed without a physician's order when it is determined that the prosthesis, as originally ordered, still fills the patient's medical needs.

Replacement and repair are covered only when medically necessary AND if it is not covered under a manufacturer's warranty or purchase agreement.

Lower Limb Prosthesis

- A lower limb prosthesis is covered when the patient:
 - o will reach or maintain a defined functional state within a reasonable time consistent with their medical needs; and
 - o is motivated to ambulate as documented by a health care provider(s) other than the prosthetist.

Functional Levels

A determination of the medical necessity for certain components/additions to the prosthesis is based on the patient's potential functional abilities. Potential functional ability is based on the reasonable expectations of the therapist and treating practitioner considering factors including, but not limited to:

- the patient's past history (including prior prosthetic use, if applicable); and
- the patient's current condition including the status of the residual limb and the nature of other medical problems; and
- the patient's desire to ambulate.

Clinical assessments of patient rehabilitation potential must be based on the following classification levels:

- Level 0: does not have the ability or potential to ambulate or transfer safely with or without assistance and a prosthesis does not enhance their quality of life or mobility;
 - The individual does not have sufficient cognitive ability to safely use a prosthesis with or without assistance.
 - The individual requires assistance from equipment or a caregiver in order to transfer and use of a prosthesis does not improve mobility or independence with transfers.
 - The individual is wheelchair dependent for mobility and use of a prosthesis does not improve transfer abilities.
 - The individual is bedridden and has no need or capacity to ambulate or transfer.
- Level 1: has the ability or potential to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence. Typical of the limited and unlimited household ambulator:
 - The individual has sufficient cognitive ability to safely use a prosthesis with or without an assistive device and/or the assistance/supervision of one person.

- The individual is capable of safe but limited ambulation within the home or on a similar flat surface like a home, with or without an assistive device and/or with or without the assistance/supervision of one person.
- The individual requires the use of a wheelchair for most activities outside of their residence.
- The individual is not capable of most of the functional activities designated in Level 2 Level 2: has
 the ability or potential for ambulation with the ability to traverse low level
 environmental barriers such as curbs, stairs or uneven surfaces. Typical of the limited
 community ambulator;
 - The individual can, with or without an assistive device (which may include one or two handrails) and/or with or without the assistance/supervision of one person:
 - Perform the Level 1 tasks designated above
 - Ambulate on a flat, smooth surface (e.g., concrete, asphalt) such as might be found outside the home. (e.g., porch, deck, patio garage, driveway)
 - Negotiate a curb
 - Access public or private transportation
 - Negotiate 1-2 stairs
 - Negotiate a ramp built to ADA specifications.
 - The individual may require a wheelchair for distances that are beyond the perimeters of the yard/driveway, apartment building, etc.
 - The individual is only able to increase their generally observed speed of walking for short distances or with great effort.
- The individual is generally not capable of accomplishing most of the tasks at Level 3 (or does so infrequently with great effort). Level 3: has the ability or potential for ambulation with variable cadence. Typical of the community ambulator who has the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion; and
 - With or without an assistive device (which may include one or two handrails), the individual is independently capable (i.e. requires no personal assistance or supervision) of performing the Level 2 tasks above and can:
 - Walk on terrain that varies in texture and level (e.g., grass, gravel, uneven concrete)
 - Negotiate 3-7 consecutive stairs
 - Walk up/down ramps built to ADA specifications
 - Open and close doors
 - Ambulate through a crowded area (e.g., grocery store, big box store, restaurant)
 - Cross a controlled intersection within their community within the time limit provided (varies by location)
 - Access public or private transportation

- Perform dual ambulation tasks (e.g. carry an item or meaningfully converse while ambulating)
- The individual does not perform the activities of Level 4.
- Level 4: has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy level typical of the prosthetic demands of the child, active adult, or athlete.

With or without an assistive device (which may include one or two handrails), this individual is independently capable (i.e. requires no personal assistance or supervision) of performing high impact domestic, vocational or recreational activities such as:

- Running
- Repetitive stair climbing
- Climbing of steep hills
- Being a caregiver for another individual
- Home maintenance (e.g. repairs, cleaning)

The records must document the patient's current functional capabilities and his/her expected functional potential, including an explanation for the difference, if that is the case.

It is recognized, within the functional classification hierarchy, that bilateral amputees often cannot be strictly bound by functional level classifications. If the patient is a bilateral amputee, or their functional capabilities have been assigned based not on their current capabilities but on their potential capabilities, then the documentation must be clear and compelling as to what medical conditions are limiting their current capabilities and how the proposed course of treatment will mitigate or overcome these medical conditions.

When an initial below-the-knee prosthesis (L5500) or a preparatory below-the-knee prosthesis (L5510, L5520, L5530, L5540) is provided, prosthetic substitutions and/or additions of procedures and components are covered in accordance with the functional level assessment except for codes L5629, L5638, L5639, L5646, L5647, L5704, L5785, L5962, and L5980 which will be denied as not medically necessary. When a below-the-knee preparatory prefabricated prosthesis (L5535) is provided, prosthetic substitutions and/or additions of procedures are covered in accordance with the functional level assessment except for codes L5620, L5629, L5645, L5646, L5670, L5676, L5704, and L5962 which will be denied as not medically necessary.

When an above-the-knee initial prosthesis (L5505) or an above-the-knee preparatory (L5560, L5570, L5580, L5590, L5595, L5600) prosthesis is provided, prosthetic substitution and/or additions of procedures and components are covered in accordance with the functional level assessment except for codes L5610, L5631, L5640, L5642, L5644,

L5648, L5705, L5706, L5964, L5980, and L5710, L5711, L5712, L5714, L5716, L5718, L5722, L5724, L5726, L5728, L5780, L5790, L5795 which will be denied as not medically necessary.

When an above-the-knee preparatory prefabricated prosthesis (L5585) is provided, prosthetic substitution and/or additions of procedures and components are covered in accordance with the functional level assessment except for codes L5624, L5631, L5648, L5651, L5652, L5705, L5706, L5964, and L5966 which will be denied as not medically necessary.

The determination of coverage for selected prostheses and components with respect to potential functional levels represents the usual case. Exceptions will be considered on an individual case if additional documentation is included that justifies the medical necessity.

Feet

A determination of the type of foot for the prosthesis will be made by the treating practitioner and/or the prosthetist based upon the functional needs of the patient. Lower extremity prostheses include a SACH foot. Other prosthetic feet are considered for coverage based upon functional classification.

An external keel SACH foot (L5970) or single axis ankle/foot (L5974) is covered for patients whose functional level is 1 or above.

A flexible-keel foot (L5972) or multiaxial ankle/foot (L5978) is covered for patients whose functional level is 2 or above.

A microprocessor-controlled ankle foot system (L5973), energy storing foot (L5976), dynamic response foot with multi-axial ankle (L5979), flex foot system (L5980), flex-walk system or equal (L5981), or shank foot system with vertical loading pylon (L5987) is covered for customers whose functional level is 3 or above.

Coverage is extended only if there is sufficient clinical documentation of functional need for the technologic or design feature of a given type of foot or foot addition (such as L5968 Multiaxial ankle with active dorsiflexion).

Foot covers are included in the codes for a prosthetic foot component and are not separately covered upon initial issue of a new prosthetic.

Knees

A determination of the type of knee for the prosthesis will be made by the treating practitioner and/or the prosthetist based upon the functional needs of the patient. Lower extremity prostheses include a single axis or constant friction knee. Other prosthetic knees are considered for coverage based upon functional classification.

A high activity knee control frame (L5930) is covered for patients whose functional level is 4.

A fluid, pneumatic, or electronic knee (L5610, L5613, L5614, L5615, L5722, L5724, L5726, L5728, L5780, L5814, L5822, L5824, L5826, L5828, L5830, L5840, L5841, L5848, L5856, L5857, and L5858) is covered for patients whose functional level is 3 or above.

Other knee systems (L5611, L5616, L5710, L5711, L5712, L5714, L5716, L5718, L5810, L5811, L5812, L5816, and L5818) are covered for patients whose functional level is 1 or above.

Coverage is extended only if there is sufficient clinical documentation of functional need for the technological or design feature of a given type of knee (see Documentation Requirements section above).

Microprocessor controlled knee (L5856, L5858) may be considered medically appropriate for Level 3 or above transfemoral or knee disarticulation amputees when all of the following criteria are met:

- documentation of Functional Level 3 or above as determined by Amputee Mobility Predictor test score; and
- the patient has received additional training for use of this technology and has demonstrated adequate cognitive ability to master use and care requirements.

Microprocessor controlled knee addition (L5859) may be considered medically appropriate when all the following criteria are met:

- has a microprocessor (swing and stance phase type (L5856) controlled (electronic) knee:
- functional Level 3 only;
- has a documented co-morbidity of the spine and/or sound limb affecting hip extension and/or quadriceps function that impairs Functional Level 3 with the use of a microprocessor-controlled knee alone;
- is able to make use of a product that requires daily charging; and
- is able to understand and respond to error alerts and alarms indicating problems with the function of the unit.

Ankles

An axial rotation unit (L5982, L5984, L5985, L5986) is covered for patients whose functional level is 2 or above.

<u>Hips</u>

A pneumatic or hydraulic hip joint (L5961) is covered for patients whose functional level is 3 or above.

Rotation Units

A Positional rotation unit L5926 is covered for patients whose functional level is 2 or above.

Sockets

Non-vacuum sockets: one test socket is initially covered when providing a new prosthesis or socket replacement. A second test socket is covered only if there is a documented medical need such as, but not limited to, limb volume change or surgical revision that has altered the shape and volume of the limb that could not be accommodated for in the initial test socket by making socket volume adjustments. For vacuum sockets: (L5645, L5625 in association with L5781, L5782) two test sockets will initially be allowed.

More than two test (diagnostic) sockets (L5618, L5620, L5622, L5624, L5626, L5628) for an individual prosthesis are not medically necessary unless there is documentation in the medical record which justifies the need. Exception: A test socket is not medically necessary for an immediate prosthesis (L5400, L5410, L5420, L5430, L5450, L5460).

No more than two of the same socket inserts (L5654, L5655, L5656, L5658, L5661, L5665, L5673, L5679, L5681, L5683) are allowed per individual prosthesis at the same time.

Socket replacements are considered medically necessary if there is adequate documentation of functional and/or physiological need. It is recognized that there are situations where the explanation includes, but is not limited to, changes in the residual limb; functional need changes; or irreparable damage or wear/tear due to excessive patient weight or prosthetic demands of very active amputees.

Codes L5940, L5950, L5960 for ultra-light materials may only be used when materials such as carbon fiber, fiberglass, Kevlar®, or other advanced composite lamination materials are used in the fabrication of a socket for an endoskeletal prosthesis. They are not used for ultralight materials used in other components of a prosthesis – e.g., knee/shin system, pylon, ankle, or foot. For codes L5940, L5950, L5960, the unit of service is per limb.

Vacuum Pumps

Vacuum pump systems (L5781, L5782) are covered when there is a need for suspension and the following conditions apply:

- the patient has a documented clinical condition of volume variation with objective measurements of the residual limb provided over a period of time (excluding any volume change due to weight gain, weight loss, the normal atrophy process, growth, or systemic issues such as vascular or cardiac issues which would cause volume changes despite the use of vacuum technology); and
- documented clinical condition of moisture retention with evidence of dermatological issues caused by the excessive perspiration; and

- a history of slow or non-healing wounds; and
- reduced proprioceptive capabilities.

Adjustable socket (BOA, Revofit, etc.)

Adjustable socket (L5783) is covered when all of the following are met:

- The patient has a documented clinical condition of volume variation with objective measurements of the residual limb provided over a period of time (excluding any volume change due to weight gain, weight loss, the normal atrophy process, growth, or systemic issues such as vascular or cardiac issues which would cause volume changes);
- Not part of initial prosthesis or preparatory prosthesis;
- Documented functional level 3 or above;

Use is not for member convenience due to adjustments needed during the day. <u>Prosthetic Covers and Covering Systems</u>

Protective outer surface covering systems (L5962, L5964, and L5966) are specialized covers intended to be worn over an existing prosthesis. They are used by a beneficiary who has special needs for protection against unusually harsh environmental situations where it is necessary to protect the lower limb prosthesis beyond the level of that which is afforded by L5704, L5705, L5706, L5707. They are not covered for cosmetic or convenience reasons, or for everyday usage in a typical environment. Documentation to support medical necessity of a protective outer surface covering system (L5962, L5964, and L5966) must indicate the type of extraordinary activities that would justify the need for extra protection afforded by this highly durable item.

Partial Foot

The L5000 – Partial foot, shoe insert with longitudinal arch, toe filler is covered when customer has partial foot or toe amputations.

<u>Upper Limb</u>

Upper limb prostheses that replace all or part of a body organ or that replace all or some of the functions of a permanently inoperative and/or malfunctioning body organ are covered.

Standard body powered operated upper limb prostheses which provide functional manipulation of the elbow and hand are covered.

Myoelectric upper arm prosthetic components may be considered medically necessary when all the following are met as determined by a rehabilitation specialist other than the prosthetist:

- body-powered prosthetic devices cannot be used or are insufficient to meet the functional needs of the individual in performing activities of daily living after adequate training with use through Physical and/or Occupational Therapy; and
- evaluation indicates that a myoelectric prosthesis meets the functional needs of the individual in performing activities of daily living; and
- the patient has demonstrated sufficient physiological and cognitive function to allow effective operation of a myoelectric prosthetic device.

Prosthetic Finger Digits

Coverage will be for an appropriate prosthetic device consistent with the customer's medical necessity requirements to allow for occupational and/or general activities of daily living requirements.

The use of a prosthetic finger digit to improve appearance, for convenience, or for comfort is an exclusion.

Exclusions

- Prostheses will be denied as not medically necessary if the patient's potential functional level is 0.
- A user-adjustable heel height feature (L5990) is considered not medically necessary.
- A prosthetic donning sleeve (L7600) is considered not medically necessary.
- A microprocessor foot or ankle system addition with power assist which includes any type of motor (L5969) is considered not medically necessary.
- The LUKE Arm (DEKA Arm; Mobius Bionics) is an upper limb prosthesis controlled by a micro-electromechanical system intended to restore limb function. The LUKE Arm is considered an investigational prosthetic device because there is limited and insufficient evidence regarding its safety and effectiveness.
- An osseointegrated/osseoanchored L5991 (OPRA anchor for the prosthesis is implanted into bone during a 2-stage surgery) surgical procedure and prosthetic device are considered investigational because there is insufficient evidence regarding its safety and effectiveness.
- There is insufficient evidence to support the use of lower limb sensory prostheses (i.e. Walkasins) (HCPCS Code: L8720). Additional studies, including those with comparative interventions and larger sample sizes, are needed to determine the benefit and safety of the treatments. Furthermore, there are no clinical guidelines with recommendations to support sensory prostheses for the lower limb. Therefore, lower limb sensory prostheses (i.e. Walkasins) is considered experimental and investigational.

- Prosthetic devices for use in recreation and sporting events are not covered.
- Repair or replacement of a prosthetic device which becomes unusable or non-functioning because of individual misuse, abuse, or neglect is not covered.

The following may be exclusions to the customer's contract. (Always refer to the specific Customer's Contract when determining benefits).

- the use of or replacement of equipment to improve appearance, for convenience, or for comfort;
- routine maintenance is not covered. Routine periodic servicing, such as testing, cleaning, regulating, and checking of the equipment is not covered;
- duplicate items, (e.g., for use in more than one location; one at home and one at school to participate in sports).

Coverage and coverage exclusion for DME is specific to the individual plan's coverage.

New York Exchange (Standard): MVP Premium, MVP Premium Plus, MVP Premium Plus HDHP, MVP Secure, MVP Liberty Variation

Only one (1) prosthetic device, per limb, per lifetime is covered.

Medicare Variation

KNEES:

A determination of the type of knee for the prosthesis will be made by the treating practitioner and/or the prosthetist based upon the functional needs of the beneficiary. Basic lower extremity prostheses include a single axis, constant friction knee. Other prosthetic knees are considered for coverage based upon functional classification.

A high activity knee control frame (L5930) is covered for beneficiaries whose functional level is 4.

A fluid or pneumatic knee unit (L5610, L5613, L5614, L5615, L5722, L5724, L5726, L5728, L5780, L5814, L5822, L5824, L5826, L5828, L5830, L5840, and L5841), or control addition, fluid (L5848), or electronic/microprocessor (L5856, L5857, L5858) is covered for beneficiaries whose functional level is 3 or above.

A fluid or pneumatic knee unit (L5610, L5613, L5614, L5615, L5722, L5724, L5726, L5728, L5780, L5814, L5822, L5824, L5826, L5828, L5830, L5840, and L5841), or control addition, fluid (L5848), or electronic/microprocessor (L5856, L5857, L5858) is also covered under limited circumstances for beneficiaries whose functional level is 2, when all of the following criteria (1-3) are met (see the POLICY SPECIFIC DOCUMENTATION REQUIREMENTS section in the LCD related Policy Article):

- 1. The beneficiary has had a clinical evaluation to determine their functional level (see FUNCTIONAL LEVELS section above); and,
- 2. Supporting documentation in the medical record outlines, in the context of the beneficiary's overall medical health, the rationale for selection of a fluid, pneumatic, or electronic/microprocessor-controlled knee, including (at minimum) how the selected knee will:
 - a. Improve the beneficiary's functional health outcomes (e.g., fall reduction, injury prevention, lower energy expenditure); and,
 - b. Help the beneficiary accomplish their activities of daily living (ADLs); and,
- 3. Lower-level knee systems (e.g., knee systems which exclude use of fluid, pneumatic, or microprocessor) have been considered and ruled out based on the beneficiary's specific functional and medical needs.
 - The medical record must include the following when the functional level is 2:
- 1. Documentation of a clinical evaluation of the beneficiary's potential functional abilities by a treating practitioner or the prosthetist which designates a functional level of 2 (If completed by a prosthetist, the treating practitioner's medical records must support the functional level assigned); and,
- 2. Discussion of the beneficiary's overall medical health and the rationale for selection of a fluid, pneumatic, or electronic/microprocessor-control addition to a prosthetic knee system. Taking into consideration potential safety concerns of the advanced knee technology, the following must be included (at minimum):
 - a. Which functional health outcomes (e.g., fall reduction, injury prevention, lower energy expenditure) are expected to be improved with the selected knee; and,
 - b. Specifically which activities of daily living (e.g., transferring, climbing stairs, grocery shopping, housekeeping, working) are expected to be improved with the use of the selected knee; and,
- 3. Documentation to support that lower-level knee systems (e.g., knee systems which exclude use of fluid, pneumatic, or microprocessor) have been considered and ruled out, including the rationale for why a lower-level knee system would not be sufficient to meet the beneficiary's specific functional and medical needs.

In addition, for coverage of an electronic/microprocessor-controlled knee system (L5856, L5857, or L5858 plus associated components) for beneficiaries whose functional level is 2, all of the following criteria (1-4) must also be met (see the POLICY SPECIFIC DOCUMENTATION REQUIREMENTS section in the LCD related Policy Article):

- 1. The electronic/microprocessor knee is indicated for functional level 2; and,
- 2. The electronic/microprocessor knee has integrated technology that allows the knee to detect when the user trips or stumbles and can automatically adjust to stabilize the knee unit (e.g., stumble recovery); and,
- 3. The beneficiary is able to make use of a product that requires daily charging; and,

4. The beneficiary is able to understand and respond to error alerts and alarms indicating problems with the function of the unit.

The medical record must include the following when the functional level is 2:

- Documentation that the electronic/microprocessor knee is indicated for functional level 2 and has integrated technology that allows the knee to detect when the user trips or stumbles and can automatically adjust to stabilize the knee unit (e.g., stumble recovery); and,
- 2. Documentation indicating the beneficiary is able to make use of a product that requires daily charging and has the capacity to understand and respond to error alerts and alarms indicating problems with the function of the unit.

L5859 (ADDITION TO LOWER EXTREMITY PROSTHESIS, ENDOSKELETAL KNEE-SHIN SYSTEM, POWERED AND PROGRAMMABLE FLEXION/EXTENSION ASSIST CONTROL, INCLUDES ANY TYPE MOTOR(S)) is only covered when the beneficiary meets all of the criteria below:

- 1. Has a microprocessor (swing and stance phase type (L5856)) controlled (electronic) knee
- 2. K3 functional level only
- 3. Has a documented comorbidity of the spine and/or sound limb affecting hip extension and/or quadriceps function that impairs K3 level function with the use of a microprocessor-controlled knee alone
- 4. Is able to make use of a product that requires daily charging
- 5. Is able to understand and respond to error alerts and alarms indicating problems with the function of the unit

For L5859, the medical records should describe the nature and extent of the comorbidity of the spine or the sound limb which is what is limiting this beneficiary to a household ambulator, and clearly document how this feature will enable the beneficiary to function as a community ambulator.

If these coverage criteria for the knee component are not met, L5859 will be denied as not reasonable and necessary.

Other knee systems (L5611, L5616, L5710, L5711, L5712, L5714, L5716, L5718, L5810, L5811, L5812, L5816, L5818) are covered for beneficiaries whose functional level is 1 or above.

Coverage is extended only if there is sufficient clinical documentation of functional need

for the technologic or design feature of a given type of knee. This information must be retained in the treating practitioner's or prosthetist's files.

FEET

An external keel SACH foot (L5970) or single axis ankle/foot (L5974) is covered for beneficiaries whose functional level is 1 or above.

A flexible-keel foot (L5972) or multiaxial ankle/foot (L5978) is covered for beneficiaries whose functional level is 2 or above.

A microprocessor-controlled ankle foot system (L5973), energy storing foot (L5976), dynamic response foot with multi-axial ankle (L5979), flex foot system (L5980), flex-walk system or equal (L5981), or shank foot system with vertical loading pylon (L5987) is covered when one of the following criteria is met:

- 1. The beneficiary's functional level is 3 or above; or,
- 2. The beneficiary's functional level is 2; and,
 - a. Meets the functional level 2 coverage criteria for a fluid, pneumatic, or electronic/microprocessor control addition for a prosthetic knee; and,
 - b. A higher-level (i.e., functional level 3) foot is required for the safe and proper use of the prescribed knee system.

The microprocessor foot or ankle system addition with power assist which includes any type of motor (L5969) is not covered because there is insufficient information to demonstrate that the item meets the Medicare standard to be considered reasonable and necessary as per PIM Chapter 13. Claims for L5969 will be denied as not reasonable and necessary.

Coverage is extended only if there is sufficient clinical documentation of functional need for the technologic or design feature of a given type of foot. This information must be retained in the treating practitioner's or prosthetist's files.

A user-adjustable heel height feature (L5990) will be denied as not reasonable and necessary.

References (Updated 2025)

 Noridian Healthcare Solutions, LLC. Local Coverage Determination (LCD) for Lower Limb Prostheses (L33787). Revision Effective Date:01/01/2020. Available: https://med.noridianmedicare.com/web/jadme.

- 2. <u>Centers for Medicare & Medicaid Services Local Coverage Article Lower Limb Prosthesis Policy Article (A52496). Revision Effective Date: 08/01/2020. Available: https://www.cms.gov/medicare-coverage-database/search.aspx</u>.
- 3. Chin, et al. Comparison of different microprocessor controlled knee joints on the energy consumption during walking in trans-femoral amputees: intelligent knee prosthesis (IP) versus C-Leg. Prosth Orthot Internatio 2006. April; 30(1):73-80.
- 4. Hafner BJ, et al. Evaluation of function, performance, and preference as transfemoral amputee's transition from mechanical to microprocessor control of the prosthetic knee. Arch Phys Med Rehabbil 2007; 88:207-17.
- 5. Orenduff, MS, et al. Gait efficiency using the C-leg. JRRD 2006; 43(2):239-46.
- 6. Seymour R., et al. Comparison between the C-leg® microprocessor-controlled prosthetic knee and non-microprocessor control prosthetic knees: A preliminary study of energy expenditure, obstacle course performance, and quality of life survey. Prosthetic Orthot International 2007 Mar; 31(1):51-61.
- 7. HAYES brief™. C-Leg Prosthesis (Otto Bock HealthCare LP). Lansdale, PA: HAYES, Inc.; ©Winifred S. Hayes, Inc. August 3, 2011. ARCHIVED March 1, 2016.
- 8. Gailey, RS., et al. The Amputee Mobility Predictor: An instrument to assess determinants of the lower-limb amputee's ability to ambulate. May 2002 Arch Phys Med Rehabil. (83) 613-627.
- 9. Rehab Measures: Orthotics and Prosthetics User's Survey (OPUS). Available: https://www.sralab.org/rehabilitation-measures/orthotics-prosthetics-users-survey.
- 10. Heinemann, A., et al. Development of the Orthotics and Prosthetics User Survey: Applications and opportunities for health care quality improvement. American Academy of Orthotists and Prosthetists. 2006 (18) 1S 80-85. Available: http://www.oandp.org/jpo/library/2006_01S_080.asp.
- 11. Guide for the Use of the Prosthesis Evaluation Questionnaire. © 1998, Prosthetics Research Study, Seattle Washington. Available: http://analisedemarcha.com/papers/o-p/peq/EN/peq-Evaluation Guide.pdf.
- 12. Koller A, Wetz HH. Management of upper limb deformities. Treatment concepts through the years. Orthopade 2006 Nov; 35(11):1137-8, 1140-2, 1144-5.
- 13. Parker P, Englehart K, Hudgins B. Myoelectric signal processing for control of powered limb prostheses. Electromyogr Kinesiol 2006 Dec; 16(6):541-8.
- 14. Lake C. Experience with electric prostheses for the partial hand presentation: An eight-year retrospective. J Prosthet Orthot. 2009; 21(2):125-130.
- 15. Kelly, BM, et al., Upper limb prosthetics. January 14, 2009.

- 16. HAYES Health Technology brief™. The LUKE Arm (DEKA Arm; Mobius Bionics) for Upper Extremity Amputation. © 2020 TractManager Co. 5/10/18. Annual Review: June 3, 2019.
- 17. Hayes Clinical Research Response. Osseointegrated Prosthetic Implants for Lower Leg Amputation. HAYES, Inc.; © 2022 Hayes, a symplr company. September 14, 2022.
- 18. Hayes Evidence Analysis Research Brief External Lower Extremity Sensory Prostheses for Treatment of Sensory Peripheral Neuropathy. © 2024 Hayes, a symplr company. October 18, 2024.

Customer Product	Medical Management Requirements*
New York Products	
НМО	Prior Auth
PPO in Plan	Prior Auth
PPO OOP	Prior Auth
POS in Plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Prior Auth
MVP Child Health Plus	Prior Auth
MVP Harmonious Health Care Plan	Prior Auth
MVP Medicare Complete Wellness	Prior Auth
MVP Medicare Preferred Gold HMO	Prior Auth
MVP Medicare Secure HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP Medicare WellSelect PPO	Prior Auth
MVP Medicare WellSelect Plus PPO	Prior Auth
MVP Medicare Patriot Plan PPO	Prior Auth
MVP DualAccess D-SNP HMO	Prior Auth
MVP DualAccess Complete D-SNP HMO	Prior Auth
MVP DualAccess Plus D-SNP HMO	Prior Auth
UVM Health Advantage Select PPO	Prior Auth
USA Care	Prior Auth
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	
POS in Plan	Prior Auth
POS OOP	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP VT HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Revision History:

08/01/2022 – Annual Review; Removed: "etc." from the not all-inclusive list of other components of a prosthesis; vacuum pump added "and" to indicate that all criteria must be met for coverage, updated and verified references.

06/01/2023 –Added exclusions for osseointegrated/osseoanchored prosthesis (OPRA) and coverage criteria for RevoFit adjustable socket.

04/01/2024 - Added 5 new codes that have been introduced in last 6 months and were not added previous. L5991 – osseointegration code, 2 new knee codes (L5841, L5615), positional rotation code L5926, and new code L5783 for adjustable sockets.

04/01/2025 - Added lower limb sensory prostheses to exclusions.



Radiofrequency Neuroablation (Rhizotomy) Facet Joint Injections, Medial Branch Blocks, Procedures for Chronic Pain

Type of Policy: Surgical

Prior Approval Date: 03/10/2023

Approval Date: 12/04/2023

Provisional Effective

02/01/2024

Date:

Related Polices: Procedures for the

Management of Chronic Spinal Pain, Chronic Pain

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

N/A

Codes Requiring Retrospective Review

CPT Code: 64625, 64628, 64629, 64999

Experimental/Investigational

64625, 64628, 64629, 64999

Common Diagnosis Codes

ICD-10- CM Diagnosis Codes

G50.0, G50.1, G50.8, G50.9, G57.6, G57.60, G57.61, G57.62, M47.16, M47.25, M47.26, M47.816, M47.896

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Common Diagnosis Codes associated with this policy have been provided for informational purposes only. The list of codes may not be all-inclusive and may be updated to reflect any applicable revisions to the ICD-10 code set and/or medical necessity guidelines applied in this policy.

Common Procedure Codes

CPT Codes: 64455, 64632, 64490, 64491, 64492, 64600, 64605, 64610, 64620, 64680, 64681

64600 – Destruction by neurolytic agent, trigeminal nerve; supraorbital, infraorbital, mental, or inferior alveolar branch

64605 - Destruction by neurolytic agent, trigeminal nerve; second and third division branches at foramen ovale

64610 - Destruction by neurolytic agent, trigeminal nerve; second and third division branches at foramen ovale under radiologic monitoring

64620 - Destruction by neurolytic agent, intercostal nerve

64680 – Destruction by neurolytic agent, with or without radiologic monitoring; celiac plexus

64681 - Destruction by neurolytic agent, with or without radiologic monitoring; superior hypogastric plexus

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

Rhizotomy is the surgical severance of spinal nerve roots to relieve back pain. The facet joints, also called paravertebral joints, are often the primary source of pain for many back pain sufferers. Depending on where the problematic facet joints are located, they can cause pain in the mid-back, chest (thoracic facet joints) or lower back. Rhizotomy is achieved by use of radiofrequency energy (heat) passed through a needle to the sensory nerves. The heat is used to create a lesion in the spinal nerves and reduces pain by interrupting the transmission of pain signals for the sensory nerves to the brain. This procedure is also known as radiofrequency neurotomy, radiofrequency rhizotomy, or radiofrequency neuroablation.

Radiofrequency neuroablation can also be applied to other areas of the body for the relief of pain due to cancer, trigeminal neuralgia (facial pain) and a condition known as Morton's neuroma (foot pain). When this procedure is used for the treatment of non-spinal pain, it is known as radiofrequency ablation or radiofrequency thermoneurolysis.

Radiofrequency Neuroablation (Rhizotomy), Facet Joint Injections, Medial Branch Blocks, Procedures for Chronic Pain

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Facet joints are paired diarthrodial articulations of the superior and inferior articular processes of adjacent vertebrae. The medial branches (MB) of the dorsal rami of the segmental nerves innervate facet joints and the MB nerves from the two adjacent dorsal rami innervate each joint. Either intraarticular injections or medial branch blocks may provide temporary or long-lasting or permanent relief of facet-mediated pain.

Cooled radiofrequency denervation is a modification of conventional RFA, in that it maintains the tissue temperature immediately adjacent to the electrode at 60°C while the target tissue (nerve) is heated to 75°C or higher. This purportedly allows for a larger volume of treated tissue without the risk of damage to the adjacent tissue.

Indications/Criteria

The medical record must contain documentation that fully supports the medical necessity. This documentation includes, but is not limited to, relevant medical history, an appropriately focused musculoskeletal and neurological physical examination. There should be a summary of pertinent diagnostic tests or procedures justifying the possible presence of facet joint pain. Patient must have history of at least 3 months of moderate to severe pain with functional impairment and pain is inadequately responsive to conservative care such as NSAIDs, acetaminophen, physical therapy (as tolerated).

Pain is predominantly axial and, with the possible exception of facet joint cysts, not associated with radiculopathy or neurogenic claudication.

There is no non-facet pathology that could explain the source of the patient's pain, such as fracture, tumor, infection, or significant deformity.

Clinical assessment implicates the facet joint as the putative source of pain.

Facet joint interventions (diagnostic and/or therapeutic) must be performed under fluoroscopic or computed tomographic (CT) guidance. Facet joint interventions performed under ultrasound guidance are not covered.

Coverage for radiofrequency ablation for spinal pain (cervical, thoracic and lumbar) is indicated for the following:

Diagnostic Facet Joint Injections

- Dual medial branch blocks (MBB)* are necessary to diagnose facet pain due to the unacceptably high false positive rate of single MBB injections.
- * A second confirmatory MBB is allowed if documentation indicates the first MBB produced > 80% relief of primary (index) pain and duration of relief is consistent with the agent employed.

Intraarticular facet block should not be performed as a diagnostic test unless medial branch blocks cannot be performed due to specific documented anatomic restrictions.

Therapeutic Injections

Radiofrequency Neuroablation (Rhizotomy), Facet Joint Injections, Medial Branch Blocks, Procedures for Chronic Pain

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Either intraarticular injections or medial branch blocks may be repeated if the first injection results in significant pain relief (>50%) for at least 3 months.

Recurrent pain at the site of previously treated facet joint may be treated without additional diagnostic blocks if >50% pain relief from the previous block(s) lasted at least 3 months.

<u>Thermal Medial Branch Radiofrequency Neurotomy (includes RF and microwave technologies)</u>

Radiofrequency neurotomy is covered when dual medial branch blocks (MBBs) provide > 80% relief of the primary or index pain and duration of relief is consistent with the agent.

Repeat denervation procedures involving the same joint will only be considered medically necessary if the patient experienced > 50% improvement of pain and improvement in patient specific activities of daily living (ADLs) documented for at least 6 months.

Trigeminal Neuralgia

Radiofrequency neuroablation for trigeminal neuralgia will be considered medically necessary when all of the following have been met:

- sharp/stabbing pain in trigeminal nerve distribution;
- continued pain after a trial of one of the following:
 - o anticonvulsant > 4 weeks; or
 - o baclofen > 4 weeks.

Pancreatic Cancer

Radiofrequency neuroablation for pancreatic cancer will be considered medically necessary when all of the following have been met:

- severe abdominal/back pain;
- continued pain after a trial of two of the following opiates:
 - o oral/rectal/transdermal > 2 weeks;
 - parenteral > 1 week;
 - epidural infusion > 1 week; and
- positive response to sympathetic nerve block.

Severe Cancer Pain

The medical documentation submitted must identify each of the following:

treatment of underlying cancer attempted or not indicated;

Radiofrequency Neuroablation (Rhizotomy), Facet Joint Injections, Medial Branch Blocks, Procedures for Chronic Pain

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- pain persists even after optimized conservative treatment directed by a physician, including the use of parenteral or epidural analgesics;
- a positive response from a previous diagnostic nerve block in relieving pain.

Morton's Neuroma

Radiofrequency neuroablation for Morton's Neuroma will be covered when a three-month trial of all of the following conservative measures has failed:

- changes in footwear:
 - o avoid wearing shoes with high heels or shoes that are tight;
 - o padding techniques, including metatarsal pads or toe crest pads;
 - o shoe inserts (orthotics) to help correct any mechanical imbalance in the foot;
- medications unless otherwise contraindicated (e.g., non-steroidal anti-inflammatory drugs [NSAIDs] which help reduce inflammation);
- a local injection(s) of anesthetic and corticosteroid medication into the affected area;
- percutaneous alcohol nerve sclerosing (PANS) injections will be considered medically necessary when the customer has failed all of the conservative therapies listed above and the following protocol is followed:
 - two injections administered at 5–10-day intervals. If the patient is unable to tolerate a second injection, PANS treatment would be terminated;
 - if there is a clinically significant positive response symptoms reduced reported and documented after two injections, up to five additional (or less if the patient reports elimination of neuroma symptoms) injections at 5–10-day intervals may be administered if symptoms persist;
 - if, however, two consecutive PANS injections fail to achieve continued and clinically significant symptom improvement, subsequent PANS injections would be considered not medically necessary;
 - documentation failing to report interval status improvements prior to the administration of the next injection will be considered to be evidence of a lack of symptom improvement.

Radiofrequency neuroablation procedures must be performed by one of the following specialists:

- Pain Management;
- Radiologist;
- Orthopedist;
- Anesthesiologist;

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- Physical Med and Rehab;
- Neurosurgeon; or
- Podiatrist

Exclusions

- Requests for radiofrequency ablation procedures not listed under Indications/Criteria
 of this policy, including plantar fasciitis.
- A maximum of five (5) facet joint injection sessions inclusive of medial branch blocks, intraarticular injections, facet cyst rupture and RF ablations may be performed per year in the cervical/thoracic spine and five (5) in the lumbar spine.
- For each covered spinal region (cervical/thoracic or lumbar), no more than two (2) thermal RF sessions will be reimbursed in any calendar year, involving no more than four (4) joints per session, e.g., two (2) bilateral levels or four (4) unilateral levels.
- Neither conscious sedation nor Monitored Anesthesia Care (MAC) is routinely
 necessary for intraarticular facet joint injections or medial branch blocks and are not
 routinely reimbursable. Individual consideration may be given for coverage in rare
 unique circumstances if the medical necessity of sedation is unequivocal and clearly
 documented.
- Non-thermal RF modalities (64999) for facet joint denervation including chemical and low-grade thermal energy (<80 degrees Celsius) (cooled radiofrequency) are considered investigational and therefore not covered. The efficacy of non-thermal RF modalities for facet joint denervation including chemical and low-grade thermal energy (<80 degrees Celsius) (cooled radiofrequency) has not been established in the published medical literature.
- Intraarticular and/or extraarticular facet joint prolotherapy are not covered. The efficacy of intraarticular and/or extraarticular facet joint prolotherapy has not been established in the published medical literature.
- Pulsed radiofrequency for denervation is considered experimental/investigational and is not covered. The efficacy of pulsed radiofrequency for denervation has not been established in the published medical literature.
- Radiofrequency ablation used for sacroiliac joint pain is considered investigational whether performed using traditional, cooled, or pulsed radiofrequency (64625).
- Intracept System (CPT codes: 64628, 64629) using intra-osseous basivertebral nerve ablation for the treatment of low back pain is considered investigational due to the lack of evidence in peer-reviewed literature.

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MVP Medicare Variation

There is currently a Local Coverage Determination (LCD) for Facet Joint Injections, Medial Branch Blocks, and Facet Joint Radiofrequency Neurotomy (L35936). Medicare full coverage details are available: https://www.cms.gov

There is currently a Local Article for Pain Management-Supplemental Instructions Article (A52863). Medicare full coverage details are available: https://www.cms.gov

Thermal ablation of the intraosseous Basivertebral Nerve (BVN) (CPT Code: 64628, 64629) is considered medically reasonable and necessary for the treatment of Chronic Low Back Pain (CLBP) in the proposed Local Coverage Determination (LCD) Intraosseous Basivertebral Nerve Ablation (DL39642) with Noridian Healthcare Solutions, LLC that is available at: Medicare Coverage Database (MCD) Search (cms.gov).

MVP Medicaid Managed Care Variation

The following treatments and procedures for chronic non-specific low back pain (LBP) are not covered because they are considered ineffective or investigational:

Therapeutic facet joint steroid injections in the lumbar and sacral regions with or without CT or fluoroscopic image guidance.

References (Reviewed 2023)

- Centers for Medicare and Medicaid Services. National Government Services (NGS). Local Coverage Determination (LCD): Facet Joint Injections, Medial Branch Blocks, and Facet Joint Radiofrequency Neurotomy (L35936). Revision Effective Date 10/01/2016. Available: https://www.cms.gov.
- National Government Services, Inc. Local Coverage Determination (LCD). LCD for pain management (L33622). Revision Effective Date 10/01/2019. Available: https://www.cms.gov.
- 3. Niemisto, L., Kalso, E.A., Malmivaara, A., Seitsalo, S., Hurri, H. Radiofrequency denervation for neck and back pain. *Cochrane Database of Systematic Reviews* 2003, Issue 1. Art. No.: CD004058. DOI: 10.1002/14651858.CD004058.
- 4. Malik, K., Benzon, H.T. Radiofrequency applications to dorsal root ganglia: A literature review. Copyright © 2008, the American Society of Anesthesiologists, Inc. Lippincott Williams & Wilkins, Inc. Anesthesiology 2008; 109:527–42.
- 5. National Government Services, Inc. Article. Pain Management Supplemental Instructions Article. (A52863). Revision Effective Date 10/01/2016. Available: https://www.cms.gov.
- 6. American Academy of Orthopedic Surgeons. Morton's Neuroma. September 2012. Available: http:\\orthoinfo.aaos.org/topic.cfm?topic=a00158.

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- 7. American Podiatric Medical Association (APMA). Neuromas. ©2013 American Podiatric Medical Association. Available: https://www.apma.org/neuromas.
- 8. Thomas JL, Blitch EL, Chaney DM et al. Diagnosis and Treatment of Forefoot Disorders. Section 3. Morton's Intermetatarsal Neuroma. Clinical Practice Guideline Forefoot Disorders. The Journal of Foot and Ankle Surgery. Vol 48, No 2, March/April 2009. ©2009 by the American College of Foot and Ankle Surgeons.
- 9. Pribut SM. Morton's Neuroma: Cause and Treatment. ©2013 by American Academy of Podiatric Sports Medicine. Available: www.aapsm.org/neuroma.html.
- 10. Dockery, Gary, DPM. Is Injection Therapy the Best Solution for Foot Neuromas? Podiatry Today. Vol 15, Issue 1, January 2002.
- 11. Schoene LM, DPM, ATC, FACFAS. A Closer Look at Injection Therapy for Athletes. Podiatry Today. Vol 26, Issue 10, October 2013. Available: https://www.podiatrytoday.com/closer-look-injection-therapy-athletes.
- 12. American College of Foot and Ankle Surgeons (ACFAS). The Diagnosis and Treatment of Heel Pain. A Clinical Practice Guideline Revision 2010. The Journal of Foot & Ankle Surgery 49 (2010) S1-S19. Available: www.jfas.org.
- 13. HAYES Medical Technology Directory™. Percutaneous Radiofrequency Ablation for Cervical and Thoracic Spinal Indications. Lansdale, PA: HAYES, Inc.; ©Winifred S. Hayes, Inc. Nov 3, 2016. Available: www.hayesinc.com/.
- 14. Kim WM, Lee HG, Jeong CW, et al. A randomized controlled trial of intra-articular prolotherapy versus steroid injection for sacroiliac joint pain. J Altern Complement Med. 2010;16(12):1285-1290.
- 15. HAYES Medical Technology Directory™. Radiofrequency Ablation for Sacroiliac Joint Pain Lansdale, PA: HAYES, Inc.; ©Winifred S. Hayes, Inc. August 21, 2012. Available: www.hayesinc.com/.
- 16. Hayes Evolving Evidence Review: Intracept Intraosseous Nerve Ablation System (Relievant Medsystems Inc.) for Treatment of Adults With Low Back Pain . HAYES, Inc.; © 2021 Hayes, a symplr company. July 30, 2021.
- 17. New York State Medicaid Update. Low Back Pain Coverage Guidelines. Vol 28. No 5. April 2012. Available: https://www.health.ny.gov/health-care/medicaid/program/update/2012/2012-04.htm.
- 18. Aydin SM, Gharibo CG, Mehnert M, Stitik TP. The role of radiofrequency ablation for sacroiliac joint pain: a meta-analysis. PM R. 2010 Sep;2(9):842-851.
- 19. Cheng J, Pope JE, Dalton JE, Cheng O Bensitel A. Comparative Outcomes of Cooled Versus Traditional Radiofrequency Ablation of the Lateral Branches for Sacroiliac Joint Pain. Clin J Pain. 2013 Feb:29(2):132-137.

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- 20. Cohen SP, Strassels SA, Kurihara C, et al. Outcome predictors for sacroiliac joint (lateral branch) radiofrequency denervation. Reg Anesth Pain Med. 2009 May-Jun;34(3):206-214.
- 21. Ho KY, Hadi MA, Pasutharnchat K, Tan KH. Cooled radiofrequency denervation for treatment of sacroiliac joint pain: two-year results from 20 cases. J Pain Res. 2013 Jul 4;6:505-511.
- 22. Muhlner SB. Review article: radiofrequency neurotomy for the treatment of sacroiliac joint syndrome. Curr Rev Musculoskelet Med. 2009;2:10–14.
- 23. Stelzer W, Aiglesberger M, Stelzer D, Stelzer V. Use of cooled radiofrequency lateral branch neurotomy for the treatment of sacroiliac joint-mediated low back pain: A large case series. Pain Medicine. 2013 Jan;14(1):29-35.

Customer Product	Medical Management Requirements*
New York Products	-
HMO	Retrospective Review
PPO in Plan	Retrospective Review
PPO OOP	Retrospective Review
POS in Plan	Retrospective Review
POS OOP	Retrospective Review
Essential Plan	Retrospective Review
MVP Medicaid Managed Care	Retrospective Review
MVP Child Health Plus	Retrospective Review
MVP Harmonious Health Care Plan	Retrospective Review
MVP Medicare Complete Wellness	Retrospective Review
MVP Medicare Preferred Gold HMO POS	Retrospective Review
MVP Medicare Secure HMO POS	Retrospective Review
MVP Medicare Secure Plus HMO POS	Retrospective Review
MVP Medicare WellSelect PPO	Retrospective Review
MVP Medicare WellSelect Plus PPO	Retrospective Review
MVP Medicare Patriot Plan PPO	Retrospective Review
MVP DualAccess D-SNP HMO	Retrospective Review
MVP DualAccess Complete D-SNP HMO	Retrospective Review
MVP DualAccess Plus D-SNP HMO	Retrospective Review
UVM Health Advantage Select PPO	Retrospective Review
USA Care PPO	Potential for Retrospective Review
Healthy NY	Retrospective Review
MVP Premier	Retrospective Review
MVP Premier Plus	Retrospective Review
MVP Premier Plus HDHP	Retrospective Review
MVP Secure	Retrospective Review
MVP EPO	Retrospective Review
MVP EPO HDHP	Retrospective Review
MVP PPO	Retrospective Review
MVP PPO HDHP	Retrospective Review
Student Health Plans	Retrospective Review
ASO	See SPD
Vermont Products	
POS in Plan	Retrospective Review
POS OOP	Retrospective Review
MVP Medicare Preferred Gold HMO POS	Retrospective Review
MVP Medicare Secure Plus HMO POS	Retrospective Review
MVP VT HMO	Retrospective Review
MVP VT HDHP HMO	Retrospective Review
MVP VT Plus HMO	Retrospective Review
MVP VT Plus HDHP HMO	Retrospective Review
MVP Secure	Retrospective Review
ASO	See SPD

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Radiofrequency Neuroablation (Rhizotomy), Facet Joint Injections, Medial Branch Blocks, Procedures for Chronic Pain Page 10 of 11





Rhinoplasty

Type of Policy: Surgical

Prior Approval Date: 06/06/2022

Approval Date: 06/03/2024

Effective Date: 08/01/2024

Related Polices: N/A

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

CPT Code:	Description:
30420	Rhinoplasty, primary; including major septal repair
30435	Rhinoplasty, secondary; intermediate revision (bony work with osteotomies)
30450	Rhinoplasty, secondary; major revision (nasal tip work and osteotomies)

Codes Requiring Retrospective Review

N/A

Experimental/Investigational/Cosmetic

CPT Code:	Description:
30400	Rhinoplasty, primary; lateral and alar cartilages and/or elevation of nasal tip

30410	Rhinoplasty, primary; complete, external parts including bony pyramid, lateral and alar cartilages, and/or elevation of nasal tip
30430	Rhinoplasty, secondary; minor revision (small amount of nasal tip work)
30468	Repair of nasal valve collapse with subcutaneous/submucosal lateral wall implant(s)
30469	Repair of nasal valve collapse with low energy, temperature- controlled (ie, radiofrequency) subcutaneous/submucosal remodeling

Common Diagnosis Codes

N/A

Common Procedure Codes

N/A

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

Rhinoplasty is a surgical procedure which is usually performed in order to improve the function or the appearance of a person's nose. It can change the shape of the tip or the bridge, narrow the span of the nostrils, or change the angle between your nose and your upper lip. Rhinoplasty may also correct an aesthetically unpleasing nose, birth defects, injury caused by an accident, or some breathing problems.

When performed solely to enhance the appearance of the nose, rhinoplasty is considered to be cosmetic in nature. It is sometimes performed in conjunction with a septoplasty to correct nasal structures when there is a deformity of the nose that may be affecting breathing.

Indications/Criteria

Rhinoplasty is covered under the following conditions:

- 1. Correction or repair of a nasal deformity secondary to a cleft lip/palate or other congenital craniofacial deformity in a child five years of age or younger.
- 2. Correction or repair of a nasal deformity secondary to a cleft lip/palate or other congenital deformity in a child that is six years of age or older with photographic evidence and functional impairment with documentation noted below.
- 3. Correction or repair of a nasal deformity secondary to trauma that is causing a functional impairment with documentation noted below:

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Documentation Requirements

Submitted documentation, as a primary procedure, should include all of the following:

- the date the trauma was sustained; and
- a description of the trauma and related complications; and
- failure of a six-week trial of conservative medical management (e.g., topical/nasal corticosteroids, antihistamines); and
- the request for the surgery is being made within the one-year time frame, if there has been trauma, or when medically advisable; and
- photographs of the nose have been taken within two (2) months of the proposed surgery.

Requests for a rhinoplasty to be performed as a secondary procedure must include medical documentation demonstrating all of the following:

- the primary procedure will not result in a good outcome without the rhinoplasty; and
- the rhinoplasty must be performed at the same time as the primary procedure.

The Medical Director must review requests not meeting criteria.

Exclusions

Rhinoplasty, when done as a primary procedure, is considered not medically necessary for the following:

- solely for cosmetic reasons;
- in cases when the trauma occurred prior to one (1) year before the proposed surgery; or
- when the trauma cannot be substantiated by medical record documentation.
- repair of nasal valve collapse with absorbable nasal implants.
- Vivaer procedure is considered to be investigational because there is a low-quality body of evidence regarding the safety and effectiveness of the procedure compared with other treatments.

References (Reviewed 2024)

- 1. American Society of Plastic Surgeons (ASPS) (Feb 2000) Position Paper: Nasal surgery. Available: www.plasticsurgery.org.
- 2. American Academy of Otolaryngology Head and Neck Surgery. Clinical Indicator: Rhinoplasty (2019). Available: https://www.entnet.org/?q=node/522.
- 3. Cannon DE, Rhee JS. Evidence-based practice: functional rhinoplasty. Otolaryngol Clin North Am. 2012 Oct;45(5):1033-43.

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- 4. Fraser L, Kelly G. An evidence-based approach to the management of the adult with nasal obstruction. Clin Otolaryngol. 2009 Apr;34(2):151-5.
- 5. Kantas I, Balatsouras DG, Papadakis CE, Marangos N, Korres SG, Danielides V. Aesthetic reconstruction of a crooked nose via extracorporeal septoplasty. J Otolaryngol Head Neck Surg. 2008 Apr;37(2):154-9.
- 6. Tasman, Abel-Jan. "Rhinoplasty indications and techniques." *GMS current topics in otorhinolaryngology, head and neck surgery* vol. 6 (): Doc09. Epub 2008 Mar 14.
- 7. Hayes Evolving Evidence Review Absorbable Nasal Implants for the Treatment of Nasal Valve Collapse. Hayes Inc. March 10, 2022. Annual Review March 13, 2024.
- 8. Hayes Evolving Evidence Review VivAer (Aerin Medical Inc.) for Nasal Airway Remodeling to Treat Nasal Obstruction. Hayes Inc. January 13, 2023. Annual Review January 26, 2024.

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Customer Product	Medical Management Requirements*
New York Products	
HMO	Prior Auth
PPO in Plan	Prior Auth
PPO OOP	Prior Auth
POS in Plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Prior Auth
MVP Harmonious Health Care Plan	Prior Auth
MVP Child Health Plus	Prior Auth
MVP Medicare Complete Wellness	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP Medicare WellSelect PPO	Prior Auth
MVP Medicare WellSelect Plus PPO	Prior Auth
MVP Medicare Patriot Plan PPO	Prior Auth
MVP DualAccess D-SNP HMO	Prior Auth
MVP DualAccess Complete D-SNP HMO	Prior Auth
MVP DualAccess Plus D-SNP HMO	Prior Auth
UVM Health Advantage Select PPO	Prior Auth
USA Care	Potential for Retrospective Review
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	
POS In Plan	Prior Auth
POS OOP	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP VT HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

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Revision History:

10/01/2021 – Added coverage indications for Rhinoplasty, added criteria for coverage to include failure of conservative medical management, added exclusion for coverage of absorbable nasal implants.

10/01/2022 – Added VivAer procedure as an exclusion.

08/01/2024 – Annual review, no changes to criteria.

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Sacral Nerve Stimulation and Percutaneous Nerve Stimulation

Type of Policy: Surgical

Prior Approval Date: 05/01/2023

Approval Date: 10/03/2023

Effective Date: 12/01/2023

Related Polices: Durable Medical Equipment

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

CPT Codes:

64561 - Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed

64566 - Posterior tibial neurostimulation, percutaneous needle electrode, single treatment, includes programming

Codes Subject to Retrospective Review

N/A

Experimental/Investigational

N/A

Common Diagnosis Codes

ICD-10 Diagnosis Codes: N39.3, N39.41, N39.42, R15.0, R15.1, R15.2, R15.9, R.33.8, R.33.9, R35.0 R39.14

Common Procedure Codes

N/A

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Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy.

Overview

This policy addresses both sacral nerve stimulation and percutaneous nerve stimulation.

Sacral nerve stimulation involves the implantation of a permanent device used to modulate the sacral nerve, which influences the behavior of the bladder, bowel, sphincter, and pelvic floor. There are two stages to the procedure: test stimulation and implant. Patients keep diaries of their voiding or bowel behavior prior to and during the test stimulation period. The test stimulation period is usually 5-7 days. A trial stimulation should be performed in the practitioner's office to test patient response prior to the actual implantation of the neurostimulator. The success of the test stimulation is based on a comparison of the diary at baseline, during the test period, and following stimulation. Only patients with successful test stimulation are considered candidates for surgical implantation.

Sacral nerve stimulation is an alternative treatment modality for patients with significant symptoms of urge incontinence, frequency-urgency syndrome, non-obstructive urinary retention, or fecal incontinence who have failed conventional therapies. Sacral nerve stimulation has also been proposed as treatment for constipation and pain.

Percutaneous (posterior) nerve stimulation is a technique of electrical stimulation of the tibial nerve which has been proposed as a treatment option for urinary incontinence. Altering the function of the posterior tibial nerve with percutaneous tibial nerve stimulation is believed to improve voiding function and control. Percutaneous nerve stimulation consists of a battery powered, external pulse generator that delivers a low voltage electrical impulse using a needle electrode placed near the ankle as an entry point. The stimulator's impulses travel along the tibial nerve to the nerves in the spine that control pelvic floor function.

Documentation Requirements

Documentation of the medical necessity for an implantable neuroprosthesis must be submitted upon request. Documentation must include, but is not limited to, the following:

- clinical history of urinary incontinence/urinary retention or fecal incontinence;
- medical therapies attempted and results of such therapies; or
- test stimulation results.

Sacral Nerve Stimulation Page 2 of 13

Sacral nerve stimulation for urinary incontinence or fecal incontinence with an implantable neuroprosthesis (InterStim) is covered on a case-by-case basis, subject to the criteria listed below.

Indications/Criteria

Urinary Incontinence

Percutaneous screening trial of a Sacral Nerve Stimulator for urinary incontinence is considered medically necessary when all of the following criteria are met:

- customer must have urge incontinence, frequency-urgency syndrome, or nonobstructive urinary retention for at least 12 months;
- customer must be refractory to all conventional therapies; failed a four-to-eight week trial of pharmacological therapy to include at least two different agents. (See below)
 - Over Active Bladder (darifenacin, oxybutynin, solifenacin, tolterodine, trospium, mirabegron, fesoterodine), Urinary Retention: (bethanechol chloride, neostigmine)
 - Urinary Retention: (bethanechol chloride, neostigmine)
- Customer must maintain a voiding diary. The diary must contain the date, description of incontinence episodes, and the response to conservative therapies.
- Customer must be able to demonstrate adequate ability to record voiding diary data such that the clinical results of the implant procedure can be properly evaluated; and

Permanent sacral nerve stimulation implantation for urinary incontinence as medically necessary when all of the following criteria are met:

- customer has met the criteria for a screening trial of sacral nerve stimulation; customer must have had successful test stimulation in order to support subsequent implantation. Test stimulation duration is three-to-seven days. Before a customer is eligible for permanent implantation, the customer must demonstrate a minimum of a 50% or greater improvement in baseline symptoms through test stimulation.
- Improvement is measured through a voiding diary;
- customer must provide a urinary voiding diary for the duration of the screening trail of sacral nerve stimulation. The urinary voiding diary must contain the date, description of incontinence episodes, and the response to sacral nerve stimulation.
- customer must be able to operate the implantable pulse generator; and
- the sacral nerve stimulator implanted must be an FDA approved device.

Fecal Incontinence

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Percutaneous screening trial of SNS for fecal incontinence is considered medically necessary when all of the following criteria are met:

- customer has severe, chronic fecal incontinence (fecal incontinent episodes of frank fecal incontinence of fecal material > 2 times per week for a duration of > 6 months [1 year-post vaginal birth], with a Wexner's incontinence score of > 12);
- the severity of the fecal incontinence result in significant disability which interfere
 with the ability to perform activities of daily living (e.g., the frequency and/or severity
 of leakages restrict the customer's ability to work or participate in activities outside
 the home);
- failure of conservative medical management performed for ≥ 12 months:
 - o pelvic floor exercises and biofeedback;
 - o dietary management:
 - avoid foods that may cause loose or more frequent stools (e.g., spicy foods, fatty or greasy foods, caffeinated beverages, diet foods or drinks, sugar-free gum or candy, and alcohol)
 - eat smaller frequent meals;
 - increase fiber in the diet;
 - o pharmacotherapy:
 - bulking substances such methylcellulose;
 - anti-diarrhea medications such as loperamide and diphenoxylate;
 - anticholinergic medications;
- customer must maintain a bowel diary. The bowel diary must contain the date, description of incontinence episodes, and the response to conservative therapies;
- sphincter surgery is either not indicated or is contraindicated (defect in the external anal sphincter muscle);
- absence of a significant anorectal malformation or chronic inflammatory bowel disease involving the anus; and
- fecal incontinence is not secondary to another neurological condition such as peripheral neuropathy or complete spinal cord injury.

Permanent sacral nerve stimulation implantation for fecal incontinence as medically necessary when all of the following criteria are met:

- customer has met the criteria for a screening trial of sacral nerve stimulation;
- customer has experienced a beneficial clinical response to a percutaneous screening trial of SNS as evidenced by at least a 50% improvement in reported symptoms; and

Sacral Nerve Stimulation Page 4 of 13

• customer must provide a bowel diary for the duration of the screening trail of sacral nerve stimulation. The bowel diary must contain the date, description of incontinence episodes, and the response to sacral nerve stimulation.

Replacement of Sacral Nerve Stimulator

Replacement of a sacral nerve stimulator for urinary or fecal management is covered with the following criteria are met:

- documentation includes initial date of implantation, that customer has been compliant with device and is expected to continue to benefit from device, and
- documentation that device is no longer functioning adequately, cannot be repaired, and is no longer covered by warranty.

Percutaneous Tibial Nerve Stimulation (CPT Code 64566)

Medical Record Documentation

Compliance and voiding diaries for a minimum of three days must be kept and provided to document the patient has been compliant with first- and second-line therapies without sufficient improvement prior to receiving PTNS.

Compliance and voiding diaries for a minimum of three days must be kept and provided during PTNS treatment and to document any symptoms of relapse.

Indications/Criteria

Percutaneous tibial nerve stimulation is covered for customers with a diagnosis of overactive bladder (OAB) as a third-line treatment when all the following criteria are met:

- an evaluation by a urologist or urogynecologist has been performed and the specialist has determined that the patient is diagnosed with overactive bladder (OAB) and a candidate for PTNS; and
- the medical record documents both of the following:
 - the customer has been compliant with and failed a trial of symptom-appropriate behavioral therapy of sufficient length to evaluate potential efficacy (a six month trial of diet and fluid intake modification, behavioral therapy, or pelvic exercises);
 and
 - the customer has been compliant with and has failed or been unable to tolerate a trial of at least two appropriate medications administered for four to eight weeks;
 and
- the voiding diary shows continued findings of overactive bladder syndrome (OBS);
 and

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- the customer has documented a willingness to attend in-office treatment sessions, to comply with the behavioral therapies and to continue to keep voiding diaries including documentation of behavioral therapy compliance; and
- treatment will consist of an initial course of one 30-minute session per week for 12 weeks.

Treatments for relapse shall only be allowed for those patients who achieve a >50% decrease in OBS symptoms with the initial treatment and then relapse. Treatments for relapse would not be expected to occur more often than one to two sessions every one to two months.

Exclusions

Customers with stress or neurogenic incontinence.

Replacement desired due to advanced technology is considered not medically necessary.

MVP Medicaid Managed Care, MVP Child Health Plus Variation for Fecal Incontinence

MVP Medicaid Managed Care, MVP Child Health Plus products must meet all the requirements for sacral nerve stimulation for fecal incontinence listed in the indications/criteria section with the exception of the biofeedback requirement.

Medicare Variation

For full coverage details, indications, and exclusions for Sacral Nerve Stimulation refer to the Centers for Medicare & Medicaid Services (CMS), National Coverage Determination (NCD) for Sacral Nerve Stimulation for Urinary Incontinence. Pub.100-3, Manual section Number 230.18 Transmittal #144. 01/01/02 Available at: https://www.cms.gov

For full coverage details, indications, and exclusions for Posterior Tibial Nerve Stimulation refer to the following Medicare Local Coverage Determination: Centers for Medicare & Medicaid Services, CMS National Government Services Local Coverage Determination (LCD) for Posterior Tibial Nerve Stimulation for Voiding Dysfunction. L33396. Revision Effective Date:10/24/2019. [On-line] Available at: https://www.cms.gov

Exclusions

Sacral nerve stimulation is not indicated for the treatment of the following: Urinary Control

- stress incontinence;
- urge incontinence due to a neurological condition such as, but not limited to, Multiple Sclerosis, or spinal cord injury, or diabetes;

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- mechanical urethral obstruction, such as benign prostatic hypertrophy, cancer, or urethral stricture;
- pregnancy;
- customer less than 16 years of age;
- other types of chronic voiding dysfunction;
- customer who has not demonstrated a minimum of 50% or greater improvement through test stimulation;
- customer is unable to operate the implantable pulse generator.

Bowel Control

- pregnancy;
- customer less than 18 years of age;
- customers with progressive, systemic neurological diseases;
- customer who has not demonstrated a minimum of 50% or greater improvement through test stimulation; or
- customer is unable to operate the implantable pulse generator;
- the condition is not related to an anorectal malformation (e.g., congenital anorectal malformation; defects of the external sphincter over 60 degrees, visible sequelae of pelvic radiation; active anal abscesses or fistulae), or chronic inflammatory bowel disease.

Other

- chronic constipation;
- pain, including chronic pelvic pain;
- interstitial cystitis; or
- any indication or condition not listed in the Indications/Criteria section above.

Electrical Percutaneous Tibial Nerve Stimulation

Exclusions

Customers with stress or neurogenic incontinence.

References (Updated 2023)

1. CMS NCD for Sacral Nerve Stimulation for Urinary Incontinence. Pub.100-3, Manual section Number 230.18 Transmittal #144. 01/01/02 Available: https://www.cms.gov

Sacral Nerve Stimulation Page 7 of 13

- 2. Food & Drug Administration (FDA) (1999) Summary of safety and effectiveness: Medtronic Interstim System for Urinary Control. PMA Supplement #P970004/S4. Approval date: April 15, 1999.
- 3. Hahn, I., Milsom, I., Fall, M., Ekelund, P. (1993). Long-term results of pelvic floor training in female stress urinary incontinence. British Journal of Urology. 72:421-427.
- 4. Hassouna, MM, Siegal, SW, Lycklama, AA, Nyeholt, A, Elhilali, MM, van Kerrebroeck, PE, Das, AK, Gajewski, JB, Janknegt, RA, Rivas, DA, Dijkema, H, Milam, DF, Olwson, KA, & Schmidt, RA (2000). Sacral neuromodulation in the treatment of urgency-frequency symptoms: a multicenter study on efficacy and safety. Journal of Urology. Jun; 163:1-6.
- 5. American Urological Association (AUA). Position Statement Regarding Sacral Nerve Stimulation for Urinary Incontinence. October 18, 2000.
- 6. National Institute for Clinical Excellence (NICE). Sacral nerve stimulation for urge incontinence and urgency frequency. Interventional Procedure Guidance No. 64. June 2004. Available: www.nice.org.uk/nicemedia/pdf/ip/IPG064guidance.pdf.
- 7. Jolleys, JV (1989). Diagnosis and management of female urinary incontinence in general practice. Journal of Royal College of General Practitioners. 39:277-79.
- 8. Jonas, U., Fowler, C.J., Chancellor, M.B., et al. (2001). Efficacy of nerve stimulation for urinary retention: results 18 months after implantation. Journal of Urology: 165: 15-19.
- 9. Largo-Janssen, TLM, Debruyne, FM., Smits, AJ, van Weel, C (1991). Controlled trial of pelvic floor exercises in the treatment of urinary stress incontinence in general practice. British Journal of General Practice. 41:445-449.
- 10. Medtronic Sacral Neuromodulation. Available: http://professional.medtronic.com/pt/uro/snm/
- 11. Schmidt, RA, Jonas, U, Oleson, KA, Janknegt, RA, Hassouna, MM, Sigel, SW, van Kerrebroeck, PE (1999). Sacral nerve stimulation for treatment of refractory urinary urge incontinence. Journal of Urology. Aug; 162(2): 352-357.
- 12. Siegel, SW, Catanzaro, F, Dijkema, HE, Elhilali, MM, Fowlrwe, CJ, Gajewski, J.B., Hassouna, M.M., Janknegt, R.A., Jonas, U., van Kerrebroeck, P.E., Nijeholt, AA, Oleson, KA, Schmidt, RA (2000). Long-term results of a multi-center study on sacral nerve stimulation for treatment of urinary urge incontinence, urgency-frequency, and retention. Urology. Dec: 56 (6 Suppl 1): 87-91.
- 13. Stewart, WF, Van Rooyen, JB, Cundiff, GW, Abrmas, P, Herzog, AR, Corey, R, Hunt, TL, Wein, AJ (2003) Prevalence and burden of overactive bladder in the United States. World Journal of Urology. 20:327-336.

Sacral Nerve Stimulation Page 8 of 13

- 14. Comiter, CV Sacral neuromodulation for the symptomatic treatment of refractory interstitial cystitis, a prospective study. Journal of Urology 2003; 169(4):1369-73.
- 15. Leroi, AM, et al. Efficacy of sacral nerve stimulation for fecal incontinence; results of a multicenter double-blind crossover study. Annals of Surgery. 2005; 242(5); 662-9.
- 16. Kenefick, NJ, et al. Permanent sacral nerve stimulation for treatment of idiopathic constipation. British Journal of Surgery 2002; 89(7):882-88.
- 17. Tjandra JJ, Dykes SL, Kumar RR, Ellis CN, Gregorcyk SG, Hyman NH, et al. Practice parameters for the treatment of fecal incontinence. Dis Colon Rectum. 2007 Oct; 50(20):1497-507.
- 18. Siegal, S, et al. Sacral nerve stimulation in patients with chronic intractable pelvic pain. Journal of Urology. 2001; 166(5):1742-45.
- 19. Mowatt, G, et al. Sacral nerve stimulation for fecal incontinence and constipation in adults; a short version Cochrane review. Neurourology and Urodynamics. 2008; 27(3):155-61.
- 20. Herbison GP, et al. Sacral neuromodulation with implanted devices for urinary storage and voiding dysfunction in adults. *Cochrane Database Syst Rev.* 2009; (2):CD004202.
- 21. van Kerrebroeck PE, et al. Results of sacral neuromodulation therapy for urinary voiding dysfunction: outcomes of a prospective, worldwide clinical study. *J Urol.* 2007; 178(5):2029-2034.
- 22. Finazzi-Agrò E, Petta F, Sciobica F, Pasqualetti P, Musco S, Bove P. Percutaneous tibial nerve stimulation effects on detrusor overactivity incontinence are not due to a placebo effect: a randomized, double-blind, placebo controlled trial. J Urol. 2010 Nov; 184(5):2001-6.
- 23. Peters KM, Carrico DJ, Perez-Marrero RA, Khan AU, Wooldridge LS, Davis GL, et al. Randomized trial of percutaneous tibial nerve stimulation versus Sham efficacy in the treatment of overactive bladder syndrome: results from the SUmiT trial. J Urol. 2010 Apr; 183(4):1438-43.
- 24. Peters KM, Macdiarmid SA, Wooldridge LS, Leong FC, Shobeiri SA, Rovner ES, et al. Randomized trial of percutaneous tibial nerve stimulation versus extended-release tolterodine: results from the overactive bladder innovative therapy trial. J Urol. 2009 Sep; 182(3):1055-61.
- 25. CMS, National Government Services Local Coverage Determination (LCD) for Posterior Tibial Nerve Stimulation for Voiding Dysfunction. L33396. Revision Effective Date:10/24/2019. Available: https://www.cms.gov.

Sacral Nerve Stimulation Page 9 of 13

- 26. Mellgren A, Wexner SD, Coller JA, et al. Long-term efficacy and safety of sacral nerve stimulation for fecal incontinence. Dis Colon Rectum. 2011; 54(9):1065-1075.
- 27. Wexner SD, Coller JA, Devroede G, et al. Sacral nerve stimulation for fecal incontinence: results of a 120-patient prospective multicenter study. Ann Surg. 2010; 251(3):441-449.
- 28. Michelsen, HB., Thompson-Fawcett, M., Lundby, L., Krigh, K., Laurberg, S., Buntzens, S. Six years of experience with sacral nerve stimulation for fecal incontinence. Dis Colon Rectum. 2010; 53(4): 414-21.
- 29. Tan E, Ngo NT, Darzi A, Shenouda M, Tekkis PP. Meta-analysis: sacral nerve stimulation versus conservative therapy in the treatment of fecal incontinence. Int J Colorectal Dis. 2011 Mar;26(3):275-94.
- 30. George AT, Kalmar K, Panerese A, Dudding TC, Nicholls RJ, Vaizey CJ. Long-term outcomes of sacral nerve stimulation for fecal incontinence. Dis Colon Rectum. 2012 March;55(3):302-6.
- 31. FDA Summary of safety and effectiveness: Medtronic® Interstim® Therapy System for Fecal Incontinence. PMA Supplement #P080025. Approval date: March 14, 2011. Available: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cftopic/pma/pma.cfm?num=p080025.
- 32. Gormley EA, Lightner DJ, Burgio KL, et al. Diagnosis and treatment of overactive bladder (non-neurogenic) in adults: AUA/SUFU Guideline. American Urological Association (AUA) Guideline. May 2014.
- 33. Blue Cross Blue Shield Association Technology Evaluation Center (TEC).
 Percutaneous Tibial Nerve Stimulation for the Treatment of Voiding Dysfunction.
 January 2014. Available:
 http://www.bcbs.com/blueresources/tec/vols/28/percutaneous-tibial-nerve.html
- 34. Peters, KM., Carrico, DJ., Wooldridge, LS., Miller, CJ., MacDiarmid, SA. Percutaneous tibial nerve stimulation for the long-term treatment of overactive bladder: 3-year results of the STEP study. J Urol. 189(6): 2194-201.
- 35. Schreiner, L., Dos Santos, TG., de Souza, AB., et al. Electrical stimulation for urinary incontinence in women: a systematic review. Int Braz J Urol. 2013; 39(4): 454-64.
- 36. Burton, C., Sajja, A., Latthe, PM. Effectiveness of percutaneous posterior tibial nerve stimulation for overactive bladder: a systematic review and meta-analysis.
- 37. HAYES Medical Technology Directory™. Staged Approach to Sacral Nerve Stimulation for Treatment of Fecal Incontinence. Lansdale, PA: HAYES, Inc.; ©Winifred S. Hayes, Inc. December 29, 2015. Annual Review: December 13, 2018.

Sacral Nerve Stimulation Page 10 of 13

- 38. HAYES Medical Technology Directory™. Percutaneous Tibial Nerve Stimulation for the Treatment of Lower Urinary Tract Dysfunction. Lansdale, PA: HAYES, Inc.; ©Winifred S. Hayes, Inc. December 9, 2014. ARCHIVED: April 15, 2019.
- 39. Hayes Health Technology Assessment. Percutaneous Tibial Nerve Stimulation For The Treatment Of Symptomatic Neurogenic Lower Urinary Tract Dysfunction. ©2020 TractManager, Inc. April 15, 2019.

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Customer Product	Medical Management Requirements*
New York Products	-
HMO	Prior Auth
PPO in Plan	Prior Auth
PPO OOP	Prior Auth
POS in Plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Prior Auth
MVP Harmonious Health Care Plan	Prior Auth
MVP Medicaid Managed Care	Prior Auth
MVP Child Health Plus	Prior Auth
MVP Medicare Complete Wellness	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP Medicare WellSelect PPO	Prior Auth
MVP Medicare WellSelect Plus PPO	Prior Auth
MVP Medicare Patriot Plan PPO	Prior Auth
MVP DualAccess D-SNP HMO	Prior Auth
MVP DualAccess Complete D-SNP HMO	Prior Auth
MVP DualAccess Plus D-SNP HMO	Prior Auth
UVM Health Advantage Select PPO	Prior Auth
USA Care PPO	Potential for Retrospective Review
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	See SFD
POS in Plan	Prior Auth
POS OOP	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Preferred Gold HMO POS MVP Medicare Secure Plus HMO POS	Prior Auth
MVP VT HMO	Prior Auth
MVP VT HMO MVP VT HDHP HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT Plus HIMO MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit
See SPD See Specific Plan Design

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Revision History:

04/01/2022 – Added requirement for voiding diary for both the trial and permanent placement of the sacral nerve stimulator for urinary incontinence.

04/01/2023 – Removed 64581, 64590, and L8684 from Prior Authorization.

12/01/2023 – added criteria for replacement of sacral nerve stimulator.

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Sacroiliac Joint Fusion

Type of Policy: Surgical

 Prior Approval Date:
 11/17/2022

 Approval Date:
 10/07/2024

 Effective Date:
 12/01/2024

Related Polices: n/a

Codes Requiring Prior Authorization:

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

CPT/HCPCS Code:	Description:
27279	Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device

Experimental/Investigational Codes Requiring Retrospective Review

27278	Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualizations), with image guidance	
27299	Unlisted procedure, pelvis or hip joint	
22899	Unlisted procedure, spine	

Common Procedure Codes:

27280	Arthrodesis, open, sacroiliac joint, including obtaining bone graft,
27200	including instrumentation, when performed

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has

Sacroiliac Joint Fusion Page 1 of 6

been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

Sacroiliac joint (SIJ) fusion has been suggested as a possible treatment option for individuals with low back pain due to sacroiliac joint dysfunction or syndrome. This procedure may be performed by an open surgical approach or as a minimally invasive procedure in order to place plates and/or screws to develop a bony fusion across the SIJ for stabilization. The iFuse Implant System consists of small titanium implants placed across the sacroiliac joint to stabilize and fuse it via a minimally invasive (percutaneous) approach with use of fluoroscopy to visualize proper placement of the implants. Other minimally invasive systems for SIJ fusion include the SIJFuse Sacroiliac Joint Fusion Device System, Silex Sacroiliac Joint System and Simmetry Sacroiliac Joint Fusion System.

Indications/Criteria

Minimally invasive arthrodesis of the sacroiliac joint using iFuse Implant System is considered medically necessary when all of the following criteria are met:

- 1. Only the iFuse Implant System by SI-Bone Inc. is considered for coverage;
- 2. Adults 18 years of age or older with sacroiliac joint (SIJ) pain for greater than 6 months;
- 3. Presence of pain over the posterior sacroiliac joint or the posterior superior iliac spine (PSIS);
- 4. Statement from a licensed behavioral and/or medical health care provider other than the requesting surgeon regarding the absence of all of the following:
 - a. Absence of generalized pain behavior (eg, somatoform disorder) or;
 - b. Absence of generalized pain disorders (eg, fibromyalgia) or;
 - c. untreated, underlying mental health conditions/issues (e.g. depression, drug, alcohol abuse) that contribute to chronic back pain
- 5. The customer has a positive response to three (3) of the following provocative tests:
 - a. Compression test;
 - b. Posterior Pelvic Pain Provocation test P4 (Thigh thrust test);
 - c. Gaenslen's test:
 - d. Sacroiliac distraction test; or
 - e. Patrick's test (Fabere)

- 6. At least 75 percent reduction of pain for the expected duration of two anesthetics (on separate visits **EACH WITH A DIFFERENT DURATION OF ACTION**);
- 7. failure of six (6) consecutive months of physician-supervised conservative management which includes exercise, medications (unless contraindicated), physical therapy and activity lifestyle modification;
- 8. diagnostic imaging studies confirm ALL of the following:
 - a. imaging of the SI joint excludes the presence of destructive lesions (e.g., tumor, infection) or inflammatory arthropathy
 - b. imaging of the ipsilateral hip that excludes the presence of osteoarthritis
 - c. imaging of the lumbar spine (that excludes neural compression or other degenerative conditions that can be causing low back or buttock pain

Exclusions

Sacroiliac joint fusions are considered experimental and investigational for all other indications because their effectiveness for indications other than the ones listed above has not been established.

Other minimally invasive systems for Sacroiliac Joint (SIJ) fusion including, but not limited to, SILEX sacroiliac Joint fusion system, Simmetry Sacroiliac Joint Fusion System, FIREBIRD SI Fusion System, and/or Si-Fix sacroiliac joint fusion system and are considered investigational.

Implants and posterior stabilization devices, other than those which as placed across the joint (transfixing) to promote fusion (e.g., allograft, synthetic, nonmetallic implants [e.g., CornerLoc™ (Foundation Fusion Solutions, TransFasten™ (Captiva Spine), LinQ™ (PainTEQ), and PsiF™ (Omnia Medical) (CPT Code 22899, 27299, 27278)].

Posterior or posterior dorsal approach to assess the SI joint (CPT codes 22899, 27299, 27278), including use of only bone grafts and no internal fixation.

Percutaneous intra-articular implant (without placement of transfixation device).

Medicare Variation:

Percutaneous sacroiliac joint fusions are covered using an FDA-approved implant. The FDA classifies approved sacroiliac joint fixation devices (use Product Code OUR [sacroiliac joint fixation] here: <u>510(k) Premarket Notification (fda.gov)</u>

For the most current applicable Medicare Local Coverage Determination refer to National Government Services, Inc. Local Coverage Determination (LCD) L36406 Minimally-invasive Surgical (MIS) Fusion of the Sacroiliac (SI) Joint and Billing and (A57431) Coding: Minimally-invasive Surgical (MIS) Fusion of the Sacroiliac (SI) Joint available: MCD Search (cms.gov).

Sacroiliac Joint Fusion Page 3 of 6

References (Updated 2024)

- 1. Hayes Technology Assessment Minimally Invasive Sacroiliac Joint Fusion Using Triangular Titanium Implants (iFuse Implant System, SI-Bone Inc.). September 3, 2020. Hayes, a TractManager Company ©2020.
- 2. Medicare Local Coverage Decision: National Government Services, LLC. Local Coverage Decision, Minimally-invasive Surgical (MIS) Fusion of the Sacroiliac (SI) Joint (L36406) Revision Effective date: 10/10/2019. Available: Medicare Search
- 3. North American Spine Society (NASS) coverage policy recommendation June 1, 2015. NASS Coverage Policy.
- 4. Internationonal Society For The Advancement of Spine Surgery (ISASS) policy statement 2016.
- 5. iFuse Implant System®. SI-Bone, Inc. <u>iFuse: The Triangle-Shaped Implant Designed Specifically for the SI Joint | SI-BONE (si-bone.com).</u>

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Customer Product	Medical Management Requirements*
New York Products	
HMO	Prior Authorization
PPO in Plan	Prior Authorization
PPO OOP	Prior Authorization
POS in Plan	Prior Authorization
POS OOP	Prior Authorization
Essential Plan	Prior Authorization
MVP Medicaid Managed Care	Prior Authorization
MVP Child Health Plus	Prior Authorization
MVP Harmonious Health Care Plan	Prior Authorization
MVP Medicare Complete Wellness	Prior Authorization
NVP Medicare Preferred Gold HMO POS	Prior Authorization
MVP Medicare Secure HMO POS	Prior Authorization
MVP Medicare Secure Plus HMO POS	Prior Authorization
MVP Medicare WellSelect PPO	Prior Authorization
MVP Medicare WellSelect Plus PPO	Prior Authorization
MVP Medicare Patriot Plan PPO	Prior Authorization
MVP DualAccess D-SNP HMO	Prior Authorization
MVP DualAccess Complete D-SNP HMO	Prior Authorization
MVP DualAccess Plus D-SNP HMO	Prior Authorization
UVM Health Advantage Select PPO	Prior Authorization
USA Care PPO	Potential for Retrospective Review
Healthy NY	Prior Authorization
MVP Premier	Prior Authorization
MVP Premier Plus	Prior Authorization
MVP Premier Plus HDHP	Prior Authorization
MVP Secure	Prior Authorization
MVP EPO	Prior Authorization
MVP EPO HDHP	Prior Authorization
MVP PPO	Prior Authorization
MVP PPO HDHP	Prior Authorization
Student Health Plans	Prior Authorization
ASO	See SPD
Vermont Products	
POS in Plan	Prior Authorization
POS OOP	Prior Authorization
MVP Medicare Preferred Gold HMO POS	Prior Authorization
MVP Medicare Secure Plus HMO POS	Prior Authorization
MVP SmartFund MSA	Potential for Retrospective Review
MVP VT HMO	Prior Authorization
MVP VT HDHP HMO	Prior Authorization
MVP VT Plus HMO	Prior Authorization
MVP VT Plus HDHP HMO	Prior Authorization
MVP Secure	Prior Authorization

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

*Medical Management Requirements

Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review.

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

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Revision History:

04/01/2021 - New Policy with prior authorization added to sacroiliac joint fusion procedures (27279).

02/01/2023 – LinQ fusion procedure added to Exclusions.

1/1/2024 – 0809T replaced with CPT code 27278.

12/01/2024 - Added exclusion to show allograft and other minimally invasive surgical (MIS) procedures are excluded, using the same exclusions as Medicare NCD from NGS.

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Sinus Surgery and Related Procedures

Type of Policy: Surgical

Prior Approval Date: 11/17/2022

Approval Date: 05/06/2024

Effective Date: 08/01/2024

Related Polices:

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

CPT Codes:

31295 - Nasal/sinus endoscopy, surgical, with dilation (eg, balloon dilation)

31296 - Nasal/sinus endoscopy, surgical, with dilation (eg, balloon dilation); frontal sinus ostium

31297 - Nasal/sinus endoscopy, surgical, with dilation (eg, balloon dilation); sphenoid sinus ostium

J7402 - Mometasone furoate sinus implant, (Sinuva)

S1091 - Stent, noncoronary, temporary, with delivery system (Propel)

69705 – Nasopharyngoscopy, surgical, with dilation of eustachian tube (ie, balloon dilation); unilateral

69706 - Nasopharyngoscopy, surgical, with dilation of eustachian tube (ie, balloon dilation); bilateral

Experimental/Investigational Codes Requiring Retrospective Review

CPT Codes:

31242- Nasal/sinus endoscopy, surgical; with destruction by radiofrequency ablation, posterior nasal nerve

31243- Nasal/sinus endoscopy, surgical; with destruction by cryoablation, posterior nasal nerve

69799 - Unlisted procedure, middle ear

Common Diagnosis Codes

ICD-10- CM Diagnosis Codes: C31.0, C31.1, C31.2, C31.3, G96.0, J32.0, J32.1, J32.2, J32.3, J32.9, J33.0, J33.1, J33.8, J39.2

Common Procedure Codes

CPT Codes: 31233, 31235, 31240, 31254, 31255, 31256, 31267, 31276, 31287, 31288, 31290, 31291, 31292, 31293, 31294, 31298

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

Rhinosinusitis is a disease which causes thickening and swelling of the linings of the sinuses in the face and forehead region, causing symptoms of congestion, drainage, and post-nasal drip, diminished sense of smell, and headaches or facial pain. Allergic rhinitis is a common precipitating factor in cases of chronic and recurrent rhinosinusitis. *Staphylococcus aureus*, gram-negative organisms, and anaerobes are the most common causes of chronic rhinosinusitis; however, non-infectious inflammation resulting from allergies and nasal obstruction frequently complicates this disease.

Functional endoscopic sinus surgery (FESS) was developed in the 1970's. The procedure requires no incisions on the face but utilizes instrumentation that provides illumination and visualization in the nose and sinus pathways. The purpose of the procedure is to enlarge the drainage pathways of the sinuses thereby preventing the build-up of mucus and pus in the sinuses so common in chronic sinusitis.

Balloon sinuplasty is an office-based procedure that has been proposed as an alternative to endoscopic sinus surgery for the treatment of chronic sinusitis refractory to medical management. The procedure involves placing a balloon using a guide wire in the sinus ostium. The balloon is inflated causing dilation of the blocked ostia and spaces within the paranasal sinus cavities.

Eustachian tube dysfunction (ETD) is the inability of the eustachian tube (ET) to ventilate the middle ear, drain secretions, or protect the middle ear from sounds or pathogens in the nasopharynx. ETD is associated with otologic and rhinology symptoms, including tinnitus (ringing in the ears), aural fullness, a sensation of being underwater, impaired hearing and balance problems. The Eustachian Tube Balloon Dilation (ETBD) System is a

balloon device that consists of a blunt-tipped catheter which is inserted through the nose and advanced to the ET. The balloon is advanced through the guidance catheter to the isthmus of the ET, inflated and then withdrawn.

Sinuva is a steroid releasing sinus implant that is used for the treatment of recurrent nasal polyps who have had previous ethmoid surgery.

Posterior Nasal Nerve destruction has been proposed as a treatment for chronic rhinitis/rhinorrhea. Cryoablation of the nerve (ClariFIX) and radiofrequency ablation (Rhinair) are currently being used.

Indications/Criteria

Functional Endoscopic Sinus Surgery (FESS)

Functional Endoscopic Sinus Surgery (FESS) will be considered medically necessary for the treatment of sinusitis, polyposis, sinus tumor, or other conditions listed below when one or more of the following is present:

- uncomplicated sinusitis (i.e., sinusitis confined to the paranasal sinuses without adjacent involvement of neurologic soft tissue, or bony structures) and <u>all</u> of the following:
 - four or more documented episodes of acute rhinosinusitis in one year, each episode lasting 10 or more days; or chronic sinusitis that interferes with lifestyle; and
 - o optimal medical therapy has been attempted and failed, as indicated by <u>all</u> of the following:
 - antibiotic therapy for four or more weeks of broad-spectrum or culturedirected antibiotics; and
 - trial of inhaled nasal steroids and/or oral steroids; and
 - routine use of nasal saline irrigations; and
 - antihistamines and/or decongestants as clinically indicated;
- multiple or recurrent polyps with airway obstruction and failure of optimal medical management (including assessment for allergy symptoms and allergy evaluation if indicated) with persistent sinus disease on follow up CT scan and/or nasal endoscopy;
- complications of sinusitis, including extension to adjacent structures;
- chronic headache or facial pain caused by an anatomic or pathologic sinus disorder;
- mucocele (excludes benign, asymptomatic mucus retention cysts);
- recurrent sinusitis which exacerbates co-morbid conditions (including but not limited to asthma, recurrent bronchitis or pneumonia, diabetes);

- multi-drug resistant organisms identified by culture;
- sino-nasal benign or malignant tumor (including inverted papilloma);
- cerebrospinal fluid leak (CSF leak);
- dacryocystorhinostomy (DCR) (blockage of tear ducts) for disorders of the lacrimal system;
- orbital decompression; or
- choanal atresia.

Image Guided Endoscopic Sinus Surgery

Image guided surgery may be considered medically necessary when used to assist the surgeon during sinus surgery involving complex anatomy, unusual pathology, or when there is advanced disease in close proximity to a critical structure. There must be documentation supporting medical necessity and indicating one of the following:

- revision sinus surgery;
- distorted sinus anatomy of developmental, postoperative, or traumatic origin;
- extensive sino-nasal polyposis;
- pathology involving the frontal, posterior ethmoid or sphenoid sinuses;
- disease abutting the skull base, orbit, optic nerve or carotid artery;
- cerebral spinal fluid (CSF) rhinorrhea or conditions where there is a skull base defect;
 or
- benign or malignant sino-nasal neoplasms.

Image guided sinus surgery is not covered for any other conditions because it is considered not medically necessary.

Sinus Antrostomy Using Dilation Balloon

Catheter-based inflatable balloon sinuplasty is indicated for the treatment of chronic sinusitis when all the following criteria have been met:

- documentation of persistent sinusitis for greater than three (3) months;
- optimal medical therapy greater than three (3) months has been attempted and failed, as indicated by <u>all</u> of the following:
 - antibiotic therapy for four or more weeks of broad-spectrum or culture-directed antibiotics; and
 - trial of inhaled nasal steroids and/or oral steroids; and
 - o routine use of nasal saline irrigations; and
 - o antihistamines and/or decongestants as clinically indicated;

• radiologic evidence of chronic sinusitis by either air fluid levels, mucosal thickening greater than three (3) millimeters (mm), or opacification).

There is no separate reimbursement for the balloon device. Balloon sinuplasty codes (31295, 31296, 31297, 31298) are inclusive of the balloon catheter cost.

Sinuva is indicated when ALL of the following criteria have been met:

- ≥18 years of age; and
- diagnosis of nasal polyps; and
- previous history of ethmoid sinus surgery; and
- previous treatment, contraindication, or intolerance of at least 2 intranasal products.

Unilateral or Bilateral Eustachian tube balloon dilation (ETBD)

Unilateral or Bilateral Eustachian tube balloon dilation is considered medically necessary for the treatment of chronic obstructive Eustachian tube dysfunction when ALL of the following:

- age 18 or older;
- one of the following symptoms that have been present for six months or longer:
 - o aural fullness; or
 - aural pressure; or
 - hearing loss; or
 - autophony;
- history of chronic ear disease;
- evaluation with nasal endoscopy;
- two abnormal tympanograms (type B or C);
- two abnormal tympanic membrane examinations; and
- failure, intolerance, or contraindication to medical management to include nasal steroid spray.

Exclusions

- Functional endoscopic sinus surgery (FESS) is considered not medically necessary for the treatment of sinusitis or polyposis when the criteria listed in the Indications/Criteria section of this policy have not been met.
- Catheter-based inflatable balloon sinuplasty is not indicated in patients with the following:

- extensive nasal polyps;
- o eosinophilic mucosal membrane disease;
- sino-nasal tumors;
- ethmoid sinus disease;
- fungal rhinosinusitis;
- previous sino-nasal surgery;
- o cystic fibrosis; or
- o sinus disease with significant osteogenesis.
- Eustachian tube balloon dilation (ETBD) is considered experimental, investigational or unproven for all other indications.
- Sinuva is not FDA approved for any other indication and is therefore considered investigational.
- Propel (Propel, Propel Mini, Propel Contour), a drug-eluting device for maintaining
 postoperative sinus ostial patency following endoscopic sinus surgery, is considered
 to be investigational as there is insufficient evidence that supports the safety and
 efficacy of these devices.
- Posterior nasal nerve destruction using radiofrequency ablation (Rhinair) or cryoablation (ClariFIX) to treat chronic rhinitis is considered to be investigational as there is insufficient evidence that supports the safety and efficacy.

Medicare Variation

According to Medicare, the use of the drug or biological must be safe and effective and otherwise reasonable and necessary. Drugs or biologicals approved for marketing by the Food and Drug Administration (FDA) are considered safe and effective for purposes of this requirement when used for indications specified on the labeling.

Propel or Sinuva are indicated when ALL of the following criteria have been met:

- ≥18 years of age; and
- diagnosis of nasal polyps; and
- previous history of ethmoid sinus surgery or frontal sinus surgery.

Internet Only Manual (IOM), Medicare Benefit Policy Manual (Pub. 100-02), Chapter 15, Section 50.4.1 Approved Use of Drugs

References (Reviewed 2024)

1. Rosenfeld RM, Andes D, Bhattacharyya N, et al., Clinical practice guideline: adult sinusitis. Otolaryngol Head Neck Surg, 2007. 137(3 Suppl): S1-31.

- 2. Ahmed J, Pal S, Hopkins C, Jayaraj S. Functional endoscopic balloon dilation of sinus ostia for chronic rhinosinusitis. *Cochrane Database Syst Rev.* 2011; (7):CD008515.
- 3. American Rhinologic Society. Criteria for Image-Guided Surgery. © 2011 American Rhinologic Society. Available: https://www.american-rhinologic.org/index.php?option=com_content&view=article&id=35:criteria-for-image-guided-surgery&catid=26:position-statements&Itemid=197
- 4. Bikhazi N, Light J, Truitt T, et al.; REMODEL Study Investigators. Standalone balloon dilation versus sinus surgery for chronic rhinosinusitis: A prospective, multicenter, randomized, controlled trial with 1-year follow-up. Am J Rhinol Allergy. 2014 Jul;28(4):323-9.
- 5. Centers for Medicare and Medicaid Services Internet Only Manual (IOM), Medicare Benefit Policy Manual (Pub. 100-02), Chapter 15, Section 50.4.1 Approved Use of Drugs. Available: Medicare Benefit Policy Manual (cms.gov)
- 6. Chandra RK, Kern RC, Cutler JL, et al. REMODEL larger cohort with long-term outcomes and meta-analysis of standalone balloon dilation studies. Laryngoscope. 2015 Jul 30.
- 7. Plaza G, Eisenberg G, Montojo J, Onrubia T, Urbasos M, O'Connor C. Balloon dilation of the frontal recess: a randomized clinical trial. *Ann Otol Rhinol Laryngol*. 2011; 120(8):511-518.
- 8. Heimgartner S, Eckardt J, Simmen D, Briner HR, Leunig A, Caversaccio MD. Limitations of balloon sinuplasty in frontal sinus surgery. *Eur Arch Otorhinolaryngol*. 2011; 268(10):1463-1467. Available: https://pubmed.ncbi.nlm.nih.gov/21559809/
- 9. Hopkins C, Noon E, Bray D, Roberts D. Balloon sinuplasty: our first year. *J Laryngol Otol.* 2011; 125(1):43-52.
- 10. Bolger WE, Brown CL, Church CA, et al. Safety and outcomes of balloon catheter sinusotomy: a multicenter 24-week analysis in 115 patients. *Otolaryngol Head Neck Surg.* 2007; 137(1):10-20.
- 11. Ramadan, HH and Terrel, AM. Balloon catheter sinuplasty and adenoidectomy in children with chronic rhinisinusitis. Ann Otol Rhinol Laryngol. 2010; 119(9):578-582.
- 12. Rak KM, Newell JD 2nd, Yakes WF, Damiano MA, Luethke JM. Paranasal sinuses on MR images of the brain: significance of mucosal thickening. AJR Am J Roentgenol. 1991 Feb;156(2):381-4.
- 13. Friedman M, Schalch P, Lin HC, Mazloom N, Neidich M, Joseph NJ. Functional endoscopic dilatation of the sinuses: patient satisfaction, postoperative pain, and cost. *Am J Rhinol*. 2008; 22(2):204-209.

- 14. Kuhn FA, Church CA, Goldberg AN, et al. Balloon catheter sinusotomy: one-year follow-up--outcomes and role in functional endoscopic sinus surgery. *Otolaryngol Head Neck Surg.* 2008; 139(3 Suppl 3):S27-S37.
- 15. Vaughn, W. (2008). Review of balloon sinuplasty. Current Opinion in Otolaryngology and Head and Neck Surgery, 16 (1), 2-9.
- 16. Weiss, R. L., Church, C. A., Kuhn, F. A., Levine, H. L., Sillers, M. J., & Vaughan, W. C. (2008). Long-term outcome analysis of balloon catheter sinusotomy: Two-year follow-up. Otolaryngology Head and Neck Surgery, 139 (3 Suppl 3), S38-S46.
- 17. Hayes Inc. Health Technology Brief, Relieva Balloon Sinuplasty (Acclarent Inc.) for Chronic Sinusitis in Adults. Hayes, a TractManager Company ©2020 TractManager July 13, 2017 [Annual Review]. September 6, 2019. ARCHIVED August 13, 2020 Available: www.hayesinc.com/hayes/.
- 18. Albritton, FD 4th, et al. Feasibility of in-office endoscopic sinus surgery with balloon sinus dilation. Am J Rhinol Alergy. 2012 May-Jun; 26(3):243-8.
- 19. Academy of Otolaryngology Head and Neck Surgery (AAO-HNS). Dilation of sinuses, any method (e.g., balloon, etc.). 2014. Available at: http://www.entnet.org/content/dilation-sinuses-any-method-eg-balloon-etc.
- 20. HAYES Health Technology Brief. Bielefeld Eustachian Tube Balloon Dilation for the Treatment of Chronic Eustachian Tube Dysfunction in Adults. Hayes, a TractManager Company ©2020 TractManager July 20, 2017 Annual Review: September 9, 2019. ARCHIVED: August 20, 2020.
- 21. Hayes Inc. Health Technology Brief, Balloon sinuplasty for Chronic Sinusitis in Pediatric Patients. Hayes, a TractManager Company ©2020 TractManager October 9, 2019. Available: www.hayesinc.com/hayes/.
- 22. Hayes Inc. Health Technology Brief, Balloon Sinuplasty for Treatment of Chronic Rhinosinusitis in Adult Patients. Hayes, a TractManager Company ©2020 TractManager September 26, 2019. Available: www.hayesinc.com/hayes/.
- 23. Bowles PF, Agrawal S, Salam MA. Balloon tuboplasty in patients with Eustachian tube dysfunction: a prospective study in 39 patients (55 ears). *Clin Otolaryngol*. 2016. Epub ahead of print. December 19, 2016. Available: http://onlinelibrary.wiley.com/doi/10.1111/coa.12812/abstract;jsessionid=2F0A8B8479711DA2B22D11B757D778C2.f03t03.
- 24. Catalano PJ, Jonnalagadda S, Yu VM. Balloon catheter dilatation of Eustachian tube: a preliminary study. *Otol Neurotol.* 2012;33(9):1549-1552.
- 25. Di Rienzo Businco L, Di Mario A, Tombolini M, Mattei A, Lauriello M. Eustachian tuboplasty and shrinkage of ostial mucosa with new devices: including a proposal of

- a classification system. *HNO*. 2017. Epub ahead of print. March 30, 2017. Available: https://pubmed.ncbi.nlm.nih.gov/28361174/.
- 26. U.S. Food and Drug Administration (FDA). Sinuva sinus implant. Dec 2017. Accessed Jan 26, 2021. Available: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/209310lbl.pdf.
- 27. Hayes Technology Assessment Sinuva (Intersect ENT Inc.) Steroid-Releasing Sinus Implant for the Treatment of Nasal Polyps After Ethmoid Sinus Surgery. HAYES, Inc.; © 2021 Hayes, a symplr company December 31, 2019. (Annual review April 28, 2021).
- 28. Huang Z, Hwang P, Sun Y, Zhou B. Steroid-eluting sinus stents for improving symptoms in chronic rhinosinusitis patients undergoing functional endoscopic sinus surgery. Cochrane Database Syst Rev. 2015 Jun 10;6:CD010436. doi: 10.1002/14651858.CD010436.pub2.
- 29. Kern RC, Stolovitzky JP, Silvers SL, Singh A, Lee JT, Yen DM, Iloreta AMC Jr., Langford FPJ, Karanfilov B, Matheny KE, Stambaugh JW, Gawlicka AK. RESOLVE II study investigators. A phase 3 trial of mometasone furoate sinus implants for chronic sinusitis with recurrent nasal polyps. Int Forum Allergy Rhinol. 2018 Jan 19. doi: 10.1002/alr.22084.
- 30. Hayes Technology Assessment Propel And Propel Mini Bioabsorbable Steroid-Releasing Sinus Implants For Treatment Of Chronic Rhinosinusitis In Adults. HAYES, Inc.; © 2021 Hayes, a symplr company August 24, 2017. (Annual review October 9, 2019) Archived: September 24, 2020.
- 31. American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS). Position Statement: The use of biomaterials in sinonasal procedures. Sept 2015.
- 32. American Rhinologic Society (ARS). Drug-eluting implants. Sept 14, 2016. Accessed Jan 26, 2021. Taulu R, Bizaki AJ, Numminen J, Rautiainen M. A prospective, randomized clinical study comparing drug eluting stent therapy and intranasal corticoid steroid therapy in the treatment of patients with chronic rhinosinusitis. Rhinology. 2017 Sep 1;55(3):218-226. doi: 10.4193/Rhin16.070.
- 33. Zhao X, Grewal A, Briel M, Lee JM. A systematic review of nonabsorbable, absorbable, and steroid impregnated spacers following endoscopic sinus surgery. Int Forum Allergy Rhinol. 2013 Nov;3(11):896-904.
- 34. Hayes, Inc. Health Technology Assessment. Eustachian Tube Balloon Dilation for the Treatment of Chronic Eustachian Tube Dysfunction in Adults. Hayes, Inc.; Feb 16, 2021. Annual Review January 23, 2022.
- 35. Poe D, Anand V, Dean M, Roberts WH, Stolovitzky JP, Hoffmann K, Nachlas NE, Light JP, Widick MH, Sugrue JP, Elliott CL, Rosenberg SI, Guillory P, Brown N, Syms CA 3rd, Hilton CW, McElveen JT Jr, Singh A, Weiss RL Jr, Arriaga MA, Leopold JP. Balloon

- dilation of the eustachian tube for dilatory dysfunction: A randomized controlled trial. Laryngoscope. 2018 May;128(5):1200-1206. doi: 10.1002/lary.26827. Epub 2017 Sep 20. PMID: 28940574.
- 36. Froehlich MH, Le PT, Nguyen SA, McRackan TR, Rizk HG, Meyer TA. Eustachian Tube Balloon Dilation: A Systematic Review and Meta-analysis of Treatment Outcomes. Otolaryngol Head Neck Surg. 2020 Nov;163(5):870-882. doi: 10.1177/0194599820924322. Epub 2020 Jun 2. PMID: 32482125.
- 37. Huisman JML, Verdam FJ, Stegeman I, de Ru JA. Treatment of Eustachian tube dysfunction with balloon dilation: A systematic review. Laryngoscope. 2018 Jan;128(1):237-247. doi: 10.1002/lary.26800. Epub 2017 Aug 11. PMID: 28799657.
- 38. Tucci DL, McCoul ED, Rosenfeld RM, et al. Clinical Consensus Statement: Balloon Dilation of the Eustachian Tube. Otolaryngology–Head and Neck Surgery. 2019;161(1):6-17. doi:10.1177/0194599819848423.
- 39. Hayes Evolving Evidence Review RhinAer Procedure (Aerin Medical) for Treatment of Chronic Rhinitis. January 13, 2022. Annual Review January 19, 2024.
- 40. Hayes Evolving Evidence Review ClariFix (Arrinex Inc.) for Treatment of Chronic Rhinitis. March 7, 2022. Annual Review May 4, 2023.

Customer Product	Medical Management Requirements*
New York Products	
HMO	Prior Auth
PPO in Plan	Prior Auth
PPO OOP	Prior Auth
POS In plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Prior Auth
MVP Child Health Plus	Prior Auth
MVP Harmonious Health Care Plan	Prior Auth
MVP Medicare Complete Wellness	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure HMO POS	Prior Auth
MVP Medicare Secure HMO Plus POS	Prior Auth
MVP Medicare WellSelect PPO	Prior Auth
MVP Mecicare WellSelect Plus PPO	Prior Auth
MVP Medicare Patriot Plan PPO	Prior Auth
MVP DualAccess D-SNP HMO	Prior Auth
MVP DualAccess Complete D-SNP HMO	Prior Auth
MVP DualAccess Plus D-SNP HMO	Prior Auth
UVM Health Advantage Select PPO	Prior Auth
USA Care	Potential for Retrospective Review
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP HDHP HMO	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	
POS in Plan	Prior Auth
POS OOP	Prior Auth
MVP Medicare Preferred Gold HMO	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP VT HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD
7.50	

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Revision History:

06/01/2021 – Annual Review; Detail added to criteria for FESS and balloon sinuplasty. New codes for the Eustachian Tube Balloon Dilation (ETBD) Systems (69705 and 69706) were added to the policy.

06/01/2022 –Sinuva (J7401, 7402) and Propel (S1091) added to prior authorization according to criteria added to policy.

02/01/2023 – Added coverage to Unilateral or Bilateral Eustachian tube balloon dilation (ETBD) and put procedures 69705 and 69706 on prior authorization.

08/01/2024 -Added Clarifix/Rhinair to exclusions, CPT codes 31242 & 31243 are already configured as E&I.



Skin Endpoint Titration

Type of Policy: Diagnostic Testing

Prior Approval Date: 01/03/2022

Approval Date: 02/05/2024

Effective Date: 04/01/2024

Related Polices: Allergy Testing

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

Codes Requiring Retrospective Review

N/A

Experimental/Investigational

N/A

Common Diagnosis Codes

N/A

Common Procedure Codes

CPT Code: 95017, 95018, 95027

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

Skin endpoint titration (SET) testing, also called serial dilution or threshold dilution testing, is done by administering a specific antigen (allergen) at various strengths to determine how sensitive a patient is to that antigen or what concentration of the antigen is required to produce a reaction. Skin endpoint titration is performed by producing wheals (an elevation in the skin accompanied by itching) of identical size on the superficial layers of the skin. The first wheal is made with a dilution too weak to produce symptoms. Successive wheals are then produced with a dilution five times stronger than the previous one until a positive response is produced. SET tests can identify the species specificity of venom sensitization; however, they do not reliably predict severity of the sting reaction.

Indication/Criteria

Coverage for skin endpoint titration will be considered as indicated below.

- Severe systemic allergic reactions to insect stings, hen's egg based vaccines or drugs including anaphylaxis, angioedema, bronchospasm, or obstructive edema of the upper airway must be documented indicating an anaphylactic or systemic allergic reaction.
- For customers for whom skin endpoint titration is being requested for possible egg
 protein containing vaccine allergic reaction, the purpose of the testing must be used
 to identify the risk of vaccine reaction. In addition, these customers must meet
 medical necessity criteria for the immunization.
- For customers with drug allergic reactions, the purpose of skin endpoint titration
 must be to identify the risk of drug reaction. In addition, these customers must meet
 medical necessity for the drug and documentation must state that there are no
 appropriate drug alternatives.
- Allergens (a substance that causes sensitization) must be approved by the FDA
 Center for Biologics Evaluation and Research. Standardized FDA approved allergens
 can be found at the following site: https://www.fda.gov/vaccines-blood-biologics/allergenics/injectable-allergen-extracts-standardized
- Skin endpoint titration testing may only be performed by a qualified physician
 (Allergist, Clinical and Laboratory Immunologist and Otolaryngologists (ENT)) who
 has the appropriate emergency medication/equipment in their office to manage the
 patient if they experience anaphylaxis during titration testing.

Exclusions

Skin endpoint titration is considered not medically necessary if:

requests for services do not meet criteria under Indications/Criteria of this policy;

Skin Endpoint Titration Page 2 of 5

- a customer has a large local reaction, where swelling occurs at the site of the sting only. This is not usually reason to perform venom testing or to administer venom allergy shots;
- a customer under age 16 has generalized skin symptoms such as hives and swelling after an insect sting;
- skin endpoint titration is used as allergy therapy or as food or environmental allergy testing;
- allergens not approved by the FDA Center for Biologics Evaluation and Research.

References (Reviewed 2023)

- 1. Golden, David B.K. *Insect Sting Anaphylaxis Immunology and Allergy Clinics of North America*, Volume 27, Issue 2, May 2007, Pages 261-272.
- 2. Golden DB, Demaain J, Moffitt J, Freeman T, Graft D, Tankersley M, Tracy J, et al. Stinging insect hypersensitivity: a practice parameter update 2016. J Allergy Clin Immunol. 2017 Jan;118(1):28-54.
- 3. American Academy of Allergy, Asthma and Immunology (AAAAI) and the American College of Allergy, Asthma and Immunology (ACAAI). Allergy Diagnostic Testing: An Updated Practice Parameter. Annals of Allergy, Asthma & Immunology. Volume 100, March 2008.
- 4. American Academy of Allergy, Asthma and Immunology (AAAAI), the American College of Allergy, Asthma and Immunology (ACAAI), and the Joint Council of Allergy, Asthma and Immunology. Stinging Insect Hypersensitivity: A Practice Parameter Update 2011. Allergy Clin Immunol Volume 127, No 4.
- 5. American Academy of Allergy Asthma Immunology, American College of Allergy Asthma Immunology, Joint Council of Allergy Asthma Immunology. Sublingual immunotherapy: A focused allergen immunotherapy practice parameter update. 2017. Available: https://www.aaaai.org/practice-resources/statements-and-practice-parameter-quidelines.

Skin Endpoint Titration Page 3 of 5

Customer Product	Medical Management Requirements*
New York Products	
HMO	Potential for Retrospective Review
PPO in Plan	Potential for Retrospective Review
PPO OOP	Potential for Retrospective Review
POS in Plan	Potential for Retrospective Review
POS OOP	Potential for Retrospective Review
Essential Plan	Potential for Retrospective Review
MVP Medicaid Managed Care	Potential for Retrospective Review
MVP Child Health Plus	Potential for Retrospective Review
MVP Harmonious Health Care Plan	Potential for Retrospective Review
MVP Medicare Complete Wellness	Potential for Retrospective Review
MVP Medicare Preferred Gold HMO POS	Potential for Retrospective Review
MVP Medicare Secure HMO POS	Potential for Retrospective Review
MVP Medicare Secure Plus HMO POS	Potential for Retrospective Review
MVP Medicare WellSelect PPO	Potential for Retrospective Review
MVP Medicare WellSelect Plus PPO	Potential for Retrospective Review
MVP Medicare Patriot Plan PPO	Potential for Retrospective Review
MVP DualAccess D-SNP HMO	Potential for Retrospective Review
MVP DualAccess Complete D-SNP HMO	Potential for Retrospective Review
MVP DualAccess Plus D-SNP HMO	Potential for Retrospective Review
UVM Health Advantage Select PPO	Potential for Retrospective Review
USA Care PPO	Potential for Retrospective Review
Healthy NY	Potential for Retrospective Review
MVP Premier	Potential for Retrospective Review
MVP Premier Plus	Potential for Retrospective Review
MVP Premier Plus HDHP	Potential for Retrospective Review
MVP Secure	Potential for Retrospective Review
MVP EPO	Potential for Retrospective Review
MVP EPO HDHP	Potential for Retrospective Review
MVP PPO	Potential for Retrospective Review
MVP PPO HDHP	Potential for Retrospective Review
Student Health Plans	Potential for Retrospective Review
ASO	See SPD
Vermont Products	
POS in Plan	Potential for Retrospective Review
POS OOP	Potential for Retrospective Review
MVP Medicare Preferred Gold HMO POS	Potential for Retrospective Review
MVP Medicare Secure Plus HMO POS	Potential for Retrospective Review
USACare PPO	Potential for Retrospective Review
MVP VT HMO	Potential for Retrospective Review
MVP VT HDHP HMO	Potential for Retrospective Review
MVP VT Plus HMO	Potential for Retrospective Review
MVP VT Plus HDHP HMO	Potential for Retrospective Review
MVP Secure	Potential for Retrospective Review
ASO	See SPD
<u> </u>	300 31 2

[♦] Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Revision History:

02/01/2022 – Annual review with no changes to the indications or criteria.

04/01/2024 – Annual review with no changes to indications or criteria.



Solid Organ Transplant Rejection Testing

Type of Policy: Surgical

Prior Approval Date: 12/04/2023

Approval Date: 08/05/2024

Effective Date: 10/01/2024

Related Polices: Transplants

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

N/A

Codes Subject to Retrospective Review

CPT Codes:

81479 - Unlisted molecular pathology procedure

81595 - Cardiology (heart transplant), mRNA, gene expression profiling by real-time quantitative PCR of 20 genes (11 content and 9 housekeeping), utilizing subfraction of peripheral blood, algorithm reported as a rejection risk score.

81599 - Unlisted multianalyte assay with algorithmic analysis

86849 - Unlisted immunology procedure

0118U - Transplantation medicine, quantification of donor-derived cell-free DNA using whole genome next-generation sequencing, plasma, reported as percentage of donor-derived cell-free DNA in the total cell-free DNA (Viracor TRAC)

Experimental/Investigational

CPT Codes:

81479 - Unlisted molecular pathology procedure

0118U - Transplantation medicine, quantification of donor-derived cell-free DNA using whole genome next-generation sequencing, plasma, reported as percentage of donor-derived cell-free DNA in the total cell-free DNA (Viracor TRAC)

Common Diagnosis Codes

Z94.0, T86.10, T86.39, Z94.1

Common Procedure Codes

N/A

Please refer to the product grid for detailed authorization requirements for specific plans. Code lists may not be all inclusive. Codes requiring prior-authorization for some products may be retrospectively reviewed for plans that do not require prior-authorization. Common diagnosis and procedure codes are included for informational purposes. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

Transplantation is a widely accepted therapy for the treatment of end-stage organ disease. Allograft rejection (rejection of the transplanted organ) remains a major concern for transplantation patients. Allograft rejection is most frequent within the first several months following transplantation. Patient survival depends on accurate and timely monitoring for allograft rejection and graft dysfunction. Transplant recipients must be tested repeatedly for signs of rejection, typically with an biopsy.

After transplantation, the donor organ (allograft) is susceptible to rejection. Transplant rejection may be assessed by tests, which measure the donor-derived cell-free DNA in peripheral blood and is proposed as an alternative to, or adjunct to, biopsy. Examples of these tests are Allomap^{TM}, AlloSure^{$\mathsf{®}$} and Prospera^{TM}.

Indications/Criteria

AllomapTM Molecular Expression Testing (81595) for detection of heart transplant rejection is medically necessary when the following indications have been met:

- the patient is a clinically stable cardiac transplant recipient i.e., no obvious signs of rejection; and
- > 15 years of age; and
- > 6 months post-transplant; and
- at low risk for moderate/severe cellular rejection;
- ullet AllomapTM testing must have clear purpose and must be used to guide therapy.

Exclusions

AllomapTM Molecular Expression Testing for detection of heart transplant rejection is not indicated for the following:

- acutely symptomatic patients;
- patients with a history of recurrent rejection;
- patients less than six months post transplant;
- patients at high risk for acute rejection or graft failure;
- < 15 years of age;
- pregnant women;
- patients who received blood products or hematopoietic growth factors within the previous 30 days; are on > 20 mg/day of prednisone equivalent or received high-dose steroids within the past 21 days.

Testing simultaneously with an endomyocardial biopsy and Allomap is considered not medically necessary. Endomyocardial biopsy in a patient with a negative Allomap score is considered not medically necessary.

Heartsbreath testing has not been found to contribute to patient outcomes in peer reviewed literature in the detection of grade 3 heart transplant rejection and is investigational.

AlloSure® (CPT 81479) Heart testing is considered experimental, investigational or unproven. There is insufficient evidence to support the accuracy and clinical utility of donor-derived cell free DNA for assessing and monitoring the probability of allograft rejection using AlloSure® Heart in heart transplant patients.

There is insufficient evidence to support the use of peripheral blood measurement of donor-derived cell-free DNA (dd-cfDNA) [e.g., AlloSure, Prospera (CPT 81479), Viracor TRAC (PLU 0118U)] in the management of patients after organ transplantation, including but not limited to the detection of acute transplant rejection or organ transplant graft dysfunction. Therefore, it is considered investigational.

Medicare:

There is a Medicare Local Coverage Determination (LCD) with Palmetto GBA, but no NCD or NGS LCD. MolDX: Molecular Testing for Solid Organ Allograft Rejection (L38568). Original Effective date: 06/06/2021. Available: MCD Search (cms.gov)

There is a Medicare LCD reference Article A58019 that gives guidance on Medicare covered testing and includes:

- Allomap (heart)
- Allosure (kidney, heart, lung)
- HeartCare (heart)
- Prospera (kidney, heart, lung)
- QSant (kidney)
- TruGraf (kidney)

- Viacor Trac (kidney)
- VitaGraft/Allaro Kidney (kidney)

References (Updated 2024)

- 1. U.S.Food and Drug Administration. FDA. Substantial Equivalence Determination Decision Summary Assay and Instrumentation Combination Template 510(k) k073482. AlloMap® Molecular Expression Testing. Available: www.fda.gov/
- 2. CareDX Inc. AlloSure. 2017a. Available at: http://www.allosure.com. Accessed March 26, 2019.
- 3. Centers for Medicare & Medicaid Services. Noridian Healthcare Solutions, LLC. Local Coverage Determination (LCD): MoIDX: AlloSure® Donor-Derived Cell-Free DNA Test (L37358) Original Effective date: 12/11/2017. RETIRED: 12/05/2020 Available: https://www.cms.gov/
- 4. Centers for Medicare & Medicaid Services. Palmetto GBA. Local Coverage Determination Reference Article(LCD): Billing and Coding: MolDX: Molecular Testing for Solid Organ Allograft Rejection (A58019) Original Effective date: 06/06/2021. Revision Effective Date: 01/01/2025 Available: https://www.cms.gov/
- 5. Medicare Local Coverage Article; Noridian Healthcare Solutions, LLC. Palmetto GBA, Local Coverage Determination (LCD): MoIDX: AlloSure ® or Equivalent Cell-Free DNA Testing for Kidney and Heart Allografts (L38380) Original Effective date: 12/06/2020. Retired 06/09/2023
- 6. Prospera[™] donor-derived cell-free DNA test (dd-cfDNA) (Natera, Inc., San Carlos, CA) refer to the following Medicare Local Coverage Determination (LCD): MoIDX: PROSPERA[™] (L38041) Original Effective date: 02/03/2020. Available: https://www.cms.gov/
- 7. Costanzo MR, Costanzo MR, Dipchand A et al. The International Society of Heart and Lung Transplantation guidelines for heart transplant recipients. J Heart Lung Transplant 2010; 29(8):914-56. Centers for Medicare and Medicaid Services. National Coverage Determination (NCD) for Heartsbreath Test for Heart Transplant Rejection (260.10). Available: www.cms.gov
- 8. Pham MX, Teuteberg JJ, Kfoury AG, Starling RC, Deng MC, Cappola TP, Kao A, Anderson AS, Cotts WG, Ewald GA, Baran DA, Bogaev RC, Elashoff B, Baron H, Yee J, Valantine HA; IMAGE Study Group. Gene-expression profiling for rejection surveillance after cardiac transplantation. N Engl J Med. 2010a May 20; 362(20):1890-900.
- 9. Pham MX, PHD, Teuteberg JJ, MD, Kfoury AG, MD, et al. Gene Expression Profiling for Rejection Surveillance after Cardiac Transplantation. The New England Journal of Medicine April 22, 2010, Available: www.NEJM.org

- 10. BlueCross BlueShield Association (BCBSA). Technology Evaluation Center (TEC). Gene expression profiling as a noninvasive method to monitor for cardiac allograft rejection. TEC Assessment Program. Vol 26. No. 8. Chicago, IL. BCBSA. 2011 Nov.
- 11. California Technology Assessment Forum™. Gene Expression Profiling for the Diagnosis of Heart Transplant Rejection. October 2010. Available: http://www.ctaf.org/assessments
- 12. Phillips M, Boehmer JP, Cataneo RN, Cheema T, Eisen HJ, Fallon JT, et al. Heart allograft rejection: detection with breath alkanes in low levels (the HARDBALL study). J Heart Lung Transplant. 2004 Jun; 23(6):701-8.
- 13. Deng MC, et al. Early detection of cardiac allograft vasculopathy through gene expression profiling-Insights of the CARGO study. J Heart Lung Transplant 2006; 25(2), Supplement, S98.
- 14. Crespo-Leiro, et al. Concordance Among Pathologists in the Second Cardiac Allograft Rejection Gene Expression Observational Study (CARGO II). Transplantation 2012;94:1172-1177. Available: http://www.allomap.com/wp-content/uploads/2015/12/1-crespoleiro.pdf
- 15. Kobashigawa J, Patel J, Azarbal B, et al. Randomized Pilot Trial of Gene Expression Profiling Versus Heart Biopsy in the First Year After Heart Transplant: Early Invasive Monitoring Attenuation Through Gene Expression Trial (EIMAGE). Circ Heart Fail. Feb 19 2015.
- 16. Katsuma A, Yamakawa T, Nakada Y, Yamamoto I, Yokoo T. Histopathological findings in transplanted kidneys. *Renal Replacement Therapy*. 2017;3:6.
- 17. AlloMap®: A Non-Invasive, Test Service for Heart Transplant Patients. Available: http://www.allomap.com/.
- 18. U.S.Food and Drug Administration. FDA. Heartsbreath. H030004. Updated March 10, 2004. Available: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cftopic/pma/pma.cfm?num=H030004
- 19. Hayes Genetic Test Evaluation Report AlloSure Kidney (CareDX Inc.). ©2020 Hayes, a TractManager Company. December 7, 2017. Annual Review: May 27, 2021. Available: www.hayesinc.com
- 20. Natera Prospera™ Available at: http://www.natera.com. Accessed October 13, 2020.
- 21. Hayes Molecular Test Assessment AlloMap (CareDx) © 2020 Hayes, a TractManager Company November 22, 2016. Annual Review: July 25, 2020 Available: www.hayesinc.com
- 22. <u>Hayes Precision Medicine Research Brief Prospera (Natera) ©2020 Hayes, a TractManager Company April 13, 2021 Available: www.hayesinc.com</u>

Customer Product	Medical Management Requirements*
New York Products	
HMO	Retrospective Review
PPO In Plan	Retrospective Review
PPO OOP	Retrospective Review
POS In Plan	Retrospective Review
POS OOP	Retrospective Review
Essential Plan	Retrospective Review
MVP Medicaid Managed Care	Retrospective Review
MVP Child Health Plus	Retrospective Review
MVP Harmonious Health Care Plan	Retrospective Review
MVP Medicare Complete Wellness	Retrospective Review
MVP Medicare Preferred Gold HMO POS	Retrospective Review
MVP Medicare Secure HMO POS	Retrospective Review
MVP Medicare Secure Plus HMO POS	Retrospective Review
MVP Medicare WellSelect PPO	Retrospective Review
MVP Medicare WellSelect Plus PPO	Retrospective Review
MVP Medicare Patriot Plan PPO	Retrospective Review
MVP DualAccess D-SNP HMO	Retrospective Review
MVP DualAccess Complete D-SNP HMO	Retrospective Review
MVP DualAccess Plus D-SNP HMO	Retrospective Review
UVM Health Advantage Select PPO	Retrospective Review
USA Care PPO	Potential for Retrospective Review
Healthy NY	Retrospective Review
MVP Premier	Retrospective Review
MVP Premier Plus	Retrospective Review
MVP Premier Plus HDHP	Retrospective Review
MVP Secure	Retrospective Review
MVP EPO	Retrospective Review
MVP EPO HDHP	Retrospective Review
MVP PPO	Retrospective Review
MVP PPO HDHP	Retrospective Review
Student Health Plans	Retrospective Review
ASO	See SPD
Vermont Products	3333.2
POS In Plan	Retrospective Review
POS OOP	Retrospective Review
MVP Medicare Preferred Gold HMO POS	Retrospective Review
MVP Medicare Secure Plus HMO POS	Retrospective Review
MVP VT HMO	Retrospective Review
MVP VT HDHP HMO	Retrospective Review
MVP VT Plus HMO	Retrospective Review
MVP VT Plus HDHP HMO	Retrospective Review
MVP Secure	Retrospective Review
ASO	See SPD

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Revision History:

04/01/2022 - Add exclusion for AlloSure Heart to Commercial and Medicaid coverage. Update Medicare variation with current coverage for AlloMap, AlloSure and Prospera.

02/01/2024 - Medicare variation removed due to LCD L38380 being retired.

10/01/2024 - Title changes from Heart and Kidney to Solid Organ Transplant Rejection Testing because policy now addresses all solid organ transplant testing. Updated overview to address all solid organs. No changes to tests that are covered (Allomap for heart transplant is the only test covered). Clarified exclusions for peripheral blood measurement of donor-derived cell-free DNA tests (AlloSure, Prospera, Viracor TRAC tests) for all organ transplant graft dysfunction. Added retrospective review to Viracor TRAC test.



Speech Generating Devices

Type of Policy: DME

Prior Approval Date: 02/05/2024

Approval Date: 01/06/2025

Effective Date: 04/01/2025

Related Polices: Durable Medical Equipment

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

- E1902 Communication board, nonelectronic augmentative or alternative communication device
- E2351 Power wheelchair accessory, electronic interface to operate speech generating device using power wheelchair control interface
- E2510 Speech generating device, synthesized speech, permitting multiple methods of message formulation and multiple methods of device access
- E2511 Speech generating software program, for personal computer or personal digital assistant
- E2512 Accessory for speech generating device, mounting system
- E2513 Accessory for speech generating device, electromyographic sensor
- E2599 Accessory for speech generating device, not otherwise classified
- E3000 Speech volume modulation system, any type, including all components and accessories

For the list of Durable Medical Equipment (DME) that requires Prior Authorization, go to Reference Library - MVP Health Care

Codes Requiring Retrospective Review

Speech Generating Devices

Experimental/Investigational

HCPCS Code: K1009 - Speech volume modulation system, any type, including all components and accessories

Common Diagnosis Codes

N/A

Common Procedure Codes

E2500 - Speech generating device, digitized speech, using prerecorded messages, less than or equal to eight minutes recording time

E2502 - Speech generating device, digitized speech, using prerecorded messages, greater than eight minutes but less than or equal to 20 minutes recording time

E2504 - Speech generating device, digitized speech, using prerecorded messages, greater than 20 minutes but less than or equal to 40 minutes recording time

E2506 - Speech generating device, digitized speech, using prerecorded messages, greater than 40 minutes recording time

E2508 – Speech generating device, synthesized speech, requiring message formulation by spelling and access by physical contact with the device

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

A Speech Generating Device (SGD) is a device that generates speech output and can have electronic augmentation. These devices may also be known as assistive communication devices. SGD's can have digitized speech output or synthesized speech output. Synthesized speech output may require message formulation (spelling, device access or direct selection techniques). Synthesized speech devices translate what the user puts into the device into generated speech and requires that the patient can have contact with a keyboard or touch screen or indirect selection with specialized access devices such as a joystick, head-mouse, optical head-pointer, switch, light or infrared pointer, scanning device or Morse Code. Digitized speech has pre-recorded messages. With digitized speech, the user is limited to pre-recorded messages.

Indications/Criteria

A speech-generating device, utilizing either digitized or synthesized speech, is covered when all of the following criteria are met:

- 1. prior to the delivery of the speech-generating device, the patient has had a formal evaluation of their cognitive and communication abilities by a speech-language pathologist. The formal, written evaluation must include, at a minimum, the following elements:
 - a. current communication impairment, including the type, severity, language skills, cognitive ability, and anticipated course of the impairment;
 - b. an assessment of whether the individual's daily communication needs could be met using other natural modes of communication;
 - c. a description of the functional communication goals expected to be achieved and treatment options;
 - d. rationale for selection of a specific device and any accessories;
 - e. demonstration that the patient possesses a treatment plan that includes a training schedule for the selected device;
 - f. the patient has the cognitive and physical abilities to effectively use the selected device and any accessories to communicate;
 - g. for a subsequent upgrade to a previously issued speech-generating device, information regarding the functional benefit to the patient of the upgrade compared to the initially provided speech-generating device; and
- **2.** the patient's medical condition is one resulting in a severe expressive speech impairment; and
- **3.** the patient's speaking needs cannot be met using natural communication methods; and
- 4. other forms of treatment have been considered and ruled out; and
- 5. the patient's speech impairment will benefit from the device ordered; and
- **6.** a copy of the speech-language pathologist's written evaluation and recommendation have been forwarded to the patient's treating physician prior to ordering the device; and
- **7.** the speech-language pathologist performing the patient evaluation may not be an employee of, or have a financial relationship with, the supplier of the speech-generating device.

Accessories

Examples of separately covered accessories for speech generating devices include:

Ocular tracking device, head control mouse, alternative input device, protective key guard, protective case or cover, carrying case, includes shoulder strap or carrying

handle, and electronic components that allow the SGD to be operated by the drive control interface of a power wheelchair.

Accessories are covered for speech generating devices that enable letter, word or symbol selection such as optical head-pointers, joysticks, switches, communication boards, wheelchair integration devices, electromyographic sensors, and scanning devices when criteria for the device have been met and the medical necessity for each item is clearly documented in the formal evaluation by the speech-language pathologist, occupational therapist or physical therapist. This evaluation should indicate the most appropriate mode of accessing the speech generating device (i.e., eye tracking, gaze interaction or electromyographic sensor), seating and positioning needs, as well as to determine the mounting needs of the device. Medical necessity must be demonstrated for coverage of any accessory.

Software (E2511) that enables a laptop computer, desktop computer, tablet, or to function as a speech-generating device is covered as a speech-generating device. Software for the accessory or alternative access device is included and not separately billable.

Exclusions

- If one or more of the coverage criteria are not met, the speech-generating device will be denied as not medically necessary.
- Claims for more than one speech-generating device will be denied as not medically necessary.
- Laptop and desktop computers, tablets, smartphones, or other devices (general computing devices) are not considered DME as they are not primarily used for the purpose of generating speech.
- The DME benefit does **not** extend to the broader range of augmentative and alternative communication devices (AAC) that have capabilities exceeding the **sole** function(s) of speech generation. Furthermore, products provided as a dedicated device that have the capability to be expanded with additional hardware and/or software or where additional functionality may be made available by "unlocking" hardware or software limitations do not meet the requirement for classification as a dedicated device. Such non-dedicated devices are not eligible for coverage and will be coded A9270 (non-covered item or service).
- Installation of software and/or applications or technical support that enable a laptop, desktop, or tablet computer to function as a speech-generating device is not separately reimbursable.

- Upgrades to speech generating devices and/or software programs that are provided within the five-year useful lifetime of the device will be denied as statutorily noncovered.
- The following features of a speech generating device are non-covered because they do not fall within the scope of the durable medical equipment benefit:
 - o Specific features of a speech generating device that are not used by the individual who has a severe speech impairment to meet his or her functional speaking needs.
 - Video communications or conferencing.
 - o Any computing hardware or software not necessary to allow for generation of speech, email, text or phone messages. Examples include, but are not limited to:
 - Hardware or software used to create documents and spreadsheets; or,
 - Hardware or software used to play games or music.
- Internet service provider (ISP), phone service subscriptions or any modification to a patient's home to allow use of the speech generating device are non-covered because such services or modifications could be used for non-medical equipment such as standard phones or general computing devices.
- A carrying case (including shoulder strap or carrying handle, any type) (E2599) is a convenience item and is denied as non-covered.
- Accessories used with non-covered devices will be denied as not medically necessary
- A protective case or cover is not separately billable as the speech generating device is considered DME and must withstand repeated use and have an expected life of at least 5 years.

Communications Aids

The plan will not provide benefits for the purchase, rental, repair, replacement or maintenance of communication aids. Communication aides that do not generate synthesized or digital speech are not covered. Examples of non-covered communication aides include the following:

- assisted living devices;
- telephone amplifiers;
- alerting devices;
- television amplifiers;
- telecommunication devices for the deaf (TDDs);
- teletype machines (TTYs);

- Braille typewriters;
- flash cards; and
- devices that allow the patient to communicate messages to others with writing/typing rather than synthesized/digitized speech.

Medicare Variation

This policy follows the Medicare National Coverage Determination (NCD) for Speech Generating Devices (50.1). For full coverage details refer to: Centers for Medicare & Medicaid Services (CMS). Medicare Coverage Database. National Coverage Determination (NCD) for Speech Generating Devices (50.1)). Available: NCD - Speech Generating Devices (50.1) (cms.gov)

This policy follows the CGS Administrators Noridian Healthcare Solutions Local Coverage Determination (LCD) for Speech Generating Devices (L33739). For full coverage details refer to: Centers for Medicare & Medicaid Services (CMS). Medicare Coverage Database. Local Coverage Determination (LCD) for Speech Generating Devices (L33739)). Available: https://www.cms.gov/medicare-coverage-database/search.aspx

MVP Medicaid Managed Care Variation

See the New York State Medicaid Program Durable Medical Equipment, Orthotics, Prosthetics, and Supplies Procedure Codes and Coverage Guidelines provider manual coverage guidelines for Speech Generating Devices (Revised Version 2023 (04/01/2023)): https://www.emedny.org/ProviderManuals/DME/index.aspx

References (Updated 2025)

- American Speech-Language Hearing Association (ASHA) Practice Portal: Augmentative and Alternative Communication available at http://www.asha.org/PRPSpecificTopic.aspx?folderid=8589942773§ion=Key_Issues.
- 2. ASHA Position Statement on Access to Communication Services and Supports: Concerns Regarding the Application of Restrictive "Eligibility" Policies available at http://www.asha.org/policy/PS2003-00227/.
- Centers for Medicare & Medicaid Services Noridian Healthcare Solutions. Durable Medical Equipment Medicare Administrative Contractor. LCD for speech generating devices (L33739). Revision Effective Date01/01/2020. Available: MCD Search (cms.gov).
- 4. Centers for Medicare & Medicaid Services Noridian Healthcare Solutions. Durable Medical Equipment Medicare Administrative Contractor. Article for speech generating devices (A52469). Revision Effective Date 01/01/2020. Available: MCD Search (cms.gov).

- 5. Centers for Medicare & Medicaid Services. National Coverage Determinations (NCD) for Speech Generating Devices (50.1). Revision Effective Date 07/29/2015. Available: MCD Search (cms.gov).
- 6. McKesson Health Solutions LLC ("McKesson"), InterQual® Clinical Decision Support Criteria. Copyright © 2021 McKesson Corporation.
- 7. Noridian Healthcare Solutions. PDAC Medicare Pricing, Data Analysis and Coding. Available: https://www.dmepdac.com/.
- 8. New York State Department of Health eMedNY Provider Manuals Durable Medical Equipment, Orthotics, Prosthetics, and Supplies Procedure Codes and Coverage Guidelines provider manual for coverage guidelines Version 2023 (04/01/2023): eMedNY: Provider Manuals: DME.

Customer Product	Medical Management Requirements*
New York Products	
HMO	Prior Auth
PPO in Plan	Prior Auth
PPO OOP	Prior Auth
POS In plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Prior Auth
MVP Child Health Plus	Prior Auth
MVP Medicare Complete Wellness	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP Medicare WellSelect PPO	Prior Auth
MVP Medicare WellSelect Plus PPO	Prior Auth
MVP Patriot Plan PPO	Prior Auth
MVP DualAccess D-SNP HMO	Prior Auth
MVP DualAccess Complete D-SNP HMO	Prior Auth
MVP DualAccess Plus D-SNP HMO	Prior Auth
UVM Health Advantage Select PPO	Prior Auth
USA Care	Potential for Retrospective Review
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	
POS in Plan	Prior Auth
POS OOP	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP VT HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure ASO	Prior Auth See SPD

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

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MVP Health Care Medical Policy Revision History:

04/01/2021: Annual Review; Added exclusions regarding accessories, cases and covers, updated formatting in clinical indications section, updated references and websites.

04/01/2024: Annual review; added common procedure codes that are not managed, added Medicare coverage determinations, and reviewed references.

04/01/2025: Added: "electromyographic sensor" to the accessories noted as covered when furnished to individuals with a demonstrated medical need for such accessories.



MVP Health Care

Speech Therapy (Outpatient) and Cognitive Rehabilitation

Type of Policy: Medical

Prior Approval Date: 06/06/2022

Approval Date: 05/06/2024

Effective Date: 08/01/2024

Related Polices: Speech Generating Devices

Autism Spectrum Disorders New

York State

Applied Behavior Analysis for Autism Spectrum Disorder Habilitation Services (Individual and Small Group Products Only) Early Childhood Development

Disorders - Vermont

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

N/A

Codes Requiring Retrospective Review

СРТ	Description
92508	Treatment of speech, language, voice, communication, and/or auditory processing disorder; group, 2 or more individuals
97533	Sensory integrative techniques to enhance sensory processing and promote adaptive responses to environmental demands, direct (one-on-one) patient contact, each 15 minutes

Experimental/Investigational

97533	Sensory integrative techniques to enhance sensory processing and
	promote adaptive responses to environmental demands, direct (one-
	on-one) patient contact, each 15 minutes

Common Diagnosis Codes

ICD-10- CM Diagnosis Codes

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C32.0, C32.1, C32.2, C32.3, C32.8, C32.9, D14.1, D02.0, S11.01, S11.011, S11.011A, S11.011D, S11.011S, S11.012, S11.012A, S11.012D, S11.012S, S11.013, S11.013A, S11.013D, S11.013S, S11.014, S11.014A, S11.014D, S11.014S, S11.015, S11.015A, S11.015D, S11.015S, S11.019, S11.019A, S11.019D, S11.019S, S11.021, S11.021A, S11.021D, S11.021S, S11.022, S11.022A, S11.022D, S11.022S, S11.023, S11.023A, S11.023D, S11.023S, S11.024, S11.024A, S11.024D, S11.024S, S11.025, S11.025A, S11.025D, S11.025S, S11.029, S11.029A, S11.029D, S11.029S, S11.03, S11.031, S11.031A, S11.031D, S11.031S, S11.032, S11.032A, S11.032D, S11.032S, S11.033, S11.033A, S11.033D, S11.033S, S11.034, S11.034A, S11.034D, S11.034S, S11.20, S11.21, S11.22, S11.23, S11.24, S11.25
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Common Diagnosis Codes associated with this policy have been provided for informational purposes only. The list of codes may not be all-inclusive and may be updated to reflect any applicable revisions to the ICD-10 code set and/or medical necessity quidelines applied in this policy.

Common Procedure Codes

CPT codes	Description
92507	Treatment of speech, language, voice, communication, and/or auditory processing disorder; individual
92521	Evaluation of speech fluency (eg, stuttering, cluttering)
92522	Evaluation of speech sound production (eg, articulation, phonological process, apraxia, dysarthria); with evaluation of language comprehension and expression (eg, receptive and expressive language)
92523	Evaluation of speech sound production with evaluation of language comprehension and expression
92524	Behavioral and qualitative analysis of voice and resonance
92526	Treatment of swallowing dysfunction and/or oral function for feeding
92609	Therapeutic services for the use of speech-generating device, including programming and modification

92610	Evaluation of oral and pharyngeal swallowing function
97129	Therapeutic interventions that focus on cognitive function, initial 15 minutes
97130	Therapeutic interventions that focus on cognitive function, each additional 15 minutes

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

Speech therapy, also known as speech-language therapy, is a field of healthcare that focuses on assessing, diagnosing, and treating communication and speech disorders. Speech therapists, also called speech-language pathologists (SLPs), work with individuals of all ages, from children to adults, who experience difficulties in various aspects of communication.

Speech therapy focuses on receptive language, or the ability to understand spoken words, and expressive language, or the ability to use words to express oneself. It also deals with the mechanics of producing words, such as articulation disorders, fluency disorders, and voice disorders (problems with pitch, volume, or quality).

Additionally, speech therapists evaluate and treat swallowing and feeding problems. Dysphagia is a frequently occurring impairment for children or adults with disabilities because many disabling conditions are associated with oropharyngeal or esophageal dysfunction.

Speech therapists also provide therapeutic services for the use of a speech-generating device. When the patient has the device, the therapist may work on appropriate use of the device for communication, on how to use the device or programming or modifying the device for the patient.

Cognitive rehabilitation is a systematic, goal-oriented treatment program designed to improve cognitive functions and functional abilities and increase levels of self-management and independence following neurological damage to the central nervous system. Treatment generally emphasizes restoring lost functions; teaching compensatory strategies to circumvent impaired cognitive functions; and improving competence in performing instrumental activities of daily living (IADL).

The assessment of functional status is critical when assessing and caring for patients that have experienced neurologic damage to the central nervous system. Cognitive

impairment can result in significant changes in instrumental activities of daily living (IADL). These functional activities can be assessed utilizing the Lawton Instrumental Activities of Daily Living Scale by scoring the following activities: ability to use the telephone, shopping, food preparation, housekeeping, laundry, mode of transportation, responsibility for own medications and ability to handle finances.

Medical Record Documentation Requirements

Evaluation: prior functional level; specific standardized and non-standardized tests, assessments, and tools; summary of baseline findings; objective, measurable, and functional descriptions of the customer's specific deficits; summary of clinical reasoning with recommendations; plan of care with specific treatment techniques and/or activities to be used in treatment sessions; frequency and duration of treatment plan which should include functional, measurable, and time-framed long term and short term goals based on the customer's relevant evaluation data; rehabilitation prognosis, including level or degree of improvement expected; and discharge plan that is initiated at the start of treatment.

Reevaluation: A reevaluation includes all the components of the initial evaluation, in addition to discussion regarding the appropriateness of continuing skilled therapy; list of current problems and deciding a priority/focus of treatment; identifying the appropriate intervention(s) for new or ongoing goal achievement; modification of interventions(s); revision of plan of care, as needed; correlation to meaningful change in function; and deciphering effectiveness of intervention(s).

Treatment session: Documentation of a treatment session should include date of treatment; specific treatment(s) provided that match the procedure codes billed (Total treatment time; customer's response to treatment; progress towards goals; any problems or changes to the plan of care; name and credentials of the treating clinician.

Indications/Criteria

Speech evaluation and therapy will be covered for the assessment and treatment of speech, language, swallowing and voice impairment when the following criteria have been met.

- the services are performed on an outpatient basis by a licensed speech language pathologist;
- intervention to restore functional ability when loss is caused by an objective disease or injury;
- outpatient speech therapy is covered for acute conditions which are subject to significant clinical improvement through short-term therapy.

Examples of conditions that may be covered are:

- recent cerebrovascular accident (CVA); or
- head trauma; or
- orofacial trauma; or
- congenital anomaly; or
- neuromuscular disorders; or
- surgery of the larynx or vocal cords

Cognitive Rehabilitation

Cognitive rehabilitation is covered for the treatment of brain injury due to trauma, stroke, aneurysm, anoxia, encephalitis, and brain tumors when all of the following criteria are met:

- customer has a documented cognitive impairment with related compromised function status; and
- significant cognitive improvement should be documented on a weekly basis; and
- in order for continued treatment, significant improvement in functional status should be documented on a weekly basis; and
- the customer is willing and able to actively participate in the treatment plan.

Exclusions

- Speech therapy for the treatment of delays in speech development (unless resulting from an acute condition or as part of an early intervention program) is not covered.
- The services involve non-diagnostic, non-therapeutic, routine, or repetitive procedures to maintain general welfare and do not require the skilled assistance of a licensed therapist.
- The treatment is for a dysfunction that is self-correcting (for example, natural dysfluency or developmental articulation errors).
- The treatment is for stuttering or stammering that is not caused by a neurological condition or brain injury.
- Speech therapy (92508) in a group setting is not medically necessary because it is not one-on-one and individualized to the specific needs of the customer.
- Swallowing and feeding rehabilitation therapy (92526) may be done with speech Rehabilitation Services; when performed together both should be billed and only the speech therapy will count toward the speech therapy benefit limit, if applicable.
- Laryngoscopy, flexible or rigid telescopic, with stroboscopy (CPT 31579) is a diagnostic procedure to be performed by a physician. It may not be performed by a speech-language pathologist.

MVP Health Care Medical Policy Cognitive Rehabilitation

Cognitive rehabilitation is not covered to improve academic or work performance because it is primarily educational and training in nature and is considered not medically necessary.

Cognitive rehabilitation for the following indications is not supported in peer reviewed literature and is considered investigational:

- treatment of cerebral palsy;
- Down syndrome;
- Alzheimer's disease;
- attention deficit hyperactivity disorder, attention deficit disorder;
- Parkinson's disease;
- · Schizophrenia;
- learning disabilities;
- developmental delay; and mild traumatic brain injury, including concussion and postconcussion syndrome

Sensory Integration Therapy (CPT 97533)

Sensory integration therapy and auditory integration therapy are considered experimental and investigational for the management of persons with various communication, behavioral, emotional, and learning disorders and for all other indications. The effectiveness of these therapies is unproven.

Medicare Variation

Speech therapy in a group setting (92508) is covered when the following criteria are met:

- Services are rendered under an individualized plan of care
- the group has no more than four group customers
- Group therapy does not represent the entire plan of treatment.

Laryngoscopy (CPT 31579) may be performed by a qualified speech-language pathologist for assessing voice production and vocal function.

For more details on Medicare coverage for speech-language pathology, see Local Coverage Determination (LCD) Speech-Language Pathology (L33580) available: MCD Search (cms.gov)

Sensory Integration

Sensory integration treatments are often associated with pediatric populations. For non-pediatric patients, these services may be medically necessary for acquired sensory problems resulting from head trauma, illness, or acute neurologic events including cerebrovascular accidents. They are not appropriate for patients with progressive neurological conditions without potential for functional adaptation. Therapy is not considered a cure for sensory integrative impairments but is used to facilitate the development of the nervous system's ability to process sensory input differently.

For more details on coverage, see the Local Coverage Determination (LCD) Outpatient Physical and Occupational Therapy Services (L33631) available: MCD Search (cms.gov)

Medicaid Variation

Long Term Therapy

Long Term Therapy Services Speech therapy services, that due to a customer's unique physical, cognitive or psychological status, require the knowledge or expertise of a licensed practitioner in order to maintain their physical and/or functional status. Outcomes must be functional, individualized, relevant, and transferrable to the current or anticipated environment. Therapeutic goals must meet at least one of the following characteristics: prevent deterioration and sustain function; provide interventions that enable the Customer to live at their highest level of independence in the case of a chronic or progressive disability; and/or provide treatment interventions for a customer who is progressing, but not at a rate comparable to the expectations of restorative care.

Restorative Therapy

Speech therapy services that require the knowledge or expertise of a licensed practitioner. Services include diagnostic evaluation and therapeutic intervention designed to improve, develop, correct, or rehabilitate physical functions that have been lost, impaired, or reduced as a result of acute or chronic medical conditions, congenital abnormalities, or injuries.

Restorative or Long-Term Speech therapy services are considered medically necessary when:

- The therapy services require the skills of, and are delivered by, a qualified practitioner; and
- The customer has been evaluated or reevaluated for continuation of therapy services, and has an established treatment plan with reasonable and attainable goals that can be objectively measured by the use of standardized or non-standardized measures and tools; and
- The customer has an identifiable clinical condition/diagnosis, is symptomatic, and the therapeutic interventions are directed at preventing disability and/or regression, improving, adapting, or restoring functions impaired or lost as a result of a specific

illness, injury, neurodevelopmental disease or condition, surgery, loss of a body part, or congenital abnormality; and

- Therapeutic benefit has not been reached and the therapeutic interventions are for conditions that require the unique knowledge, skills, and judgment of a qualified practitioner and cannot or have not been met by a comprehensive maintenance services program or home program; and
- There is reasonable expectation that the therapeutic interventions, based on a customer's rehabilitation potential, will result in objective/measurable functional outcomes within a reasonable and predictable period of time and the outcomes are documented in the customer's file; and
- The treatments are not routine education, training, conditioning, or fitness and the customer's function could not reasonably be expected to improve as they gradually resume normal activities; and
- The treatments are not a duplicate therapy; and
- The treatments are not solely recreational (such as hobbies and/or arts and crafts), and
- The customer has not refused therapy.

Swallowing and feeding rehabilitation therapy may be done with speech Rehabilitation Services; when performed together both should be billed and only the speech therapy will count toward the speech therapy benefit limit, if applicable.

Sensory Integration

According to New York State Department of Health, there is currently no adequate scientific evidence (based on controlled studies using generally accepted scientific methodology) that demonstrates the effectiveness of sensory integration.

For more details, see the New York State Department of Health website on Other Experiential Approaches available:

https://www.health.ny.gov/community/infants_children/early_intervention/disorders/autism/ch4_pt4.htm

References (Reviewed 2024)

 Centers for Medicare & Medicaid Services (CMS). Pub. 100-02, Chapter 15, Section 220. Coverage of Outpatient Rehabilitation Therapy Services (Physical Therapy, Occupational Therapy, and Speech-Language Pathology Services) Under Medical Insurance and Section 230 Practice of Physical Therapy, Occupational Therapy, and Speech-Language Pathology. July 12, 2019. Available at: http://www.cms.hhs.gov/manuals/Downloads/bp102c15.pdf.

- 2. New York State Insurance Department (2003), Health Insurer's Obligation in the Administration of Benefits for Covered Persons Receiving Services Under the New York State Early Intervention Program: Circulation Letter No. 16.
- 3. New York State, (1997). Regulations of the commissioner of education subchapter p. Education Law: sections 207, 4403 and 4410.
- 4. The Vermont Statutes Online. Title 8: Banking and Insurance, Chapter 107: HEALTH INSURANCE 8 V.S.A. § 4088i. Coverage for diagnosis and treatment of autism spectrum disorders.
- 5. National Government Services Inc. Local Coverage Determination (LCD): SPEECH-Language Pathology (L33580). Revision Effective Date 12/19/2019.
- 6. American Speech-Language Hearing Association (ASHA). Speech Language Pathology Medical Review Guidelines. Available: <u>ASHA</u>
- 7. Brasure M, Lamberty GJ, Sayer NA, et al. Multidisciplinary Post acute Rehabilitation for Moderate to Severe Traumatic Brain Injury in Adults. (Prepared by the Minnesota Evidence-based Practice Center under Contract No. 290-2007-10064-I.)
- 8. AHRQ Publication No. 12-EHC101-EF. Rockville, MD: Agency for Healthcare Research and Quality; June 2012. Available: https://www.ncbi.nlm.nih.gov/pubmed/22834016.
- Carney N, du Coudray H, Davis-O'Reilly C, et al. Rehabilitation for Traumatic Brain Injury in Children and Adolescents (Supplement). Evidence Reports/Technology Assessments, No. 2S Prepared by Oregon Health Sciences University under Contract No. 290-97-0018). Rockville, MD: Agency for Healthcare Research and Quality; September 1999. AHRQ Publication No. 00-E001. Available: http://www.ncbi.nlm.nih.gov/books/NBK32918/
- 10. Graf C., The Lawton Instrumental Activities of Daily Living (IADL) Scale. Try This. Issue Number 23, Revised 2013.
- 11. New York State Medicaid Program. Provider Manuals. Rehabilitation Services Policy Guidelines. Available: https://www.emedny.org/ProviderManuals/index.aspx.

Customer Product	Medical Management Requirements*
New York Products	
НМО	Retrospective Review
PPO in Plan	Retrospective Review
PPO OOP	Retrospective Review
POS in Plan	Retrospective Review
POS OOP	Retrospective Review
Essential Plan	Retrospective Review
MVP Medicaid Managed Care	Retrospective Review
MVP Child Health Plus	Retrospective Review
MVP Harmonious Health Care Plan	Retrospective Review
MVP Medicare Preferred Gold HMO POS	Retrospective Review
MVP Medicare Complete Wellness	Retrospective Review
MVP Medicare Secure HMO POS	Retrospective Review
MVP Medicare Secure Plus HMO POS	Retrospective Review
MVP Medicare WellSelect PPO	Retrospective Review
MVP Medicare WellSelect Plus PPO	Retrospective Review
MVP Medicare Patriot Plan PPO	Retrospective Review
MVP DualAccess D-SNP HMO	Retrospective Review
MVP DualAccess Complete D-SNP HMO	Retrospective Review
MVP DualAccess Plus D-SNP HMO	Retrospective Review
UVM Health Advantage Select PPO	Retrospective Review
USA Care	Retrospective Review
Healthy NY	Retrospective Review
MVP Premier	Retrospective Review
MVP Premier Plus	Retrospective Review
MVP Premier Plus HDHP	Retrospective Review
MVP Secure	Retrospective Review
MVP EPO	Retrospective Review
MVP EPO HDHP	Retrospective Review
MVP PPO	Retrospective Review
MVP PPO HDHP	Retrospective Review
Student Health Plans	Retrospective Review
ASO	See SPD
Vermont Products	See St D
POS in Plan	Retrospective Review
POS OOP	Retrospective Review
MVP Medicare Preferred Gold HMO POS	Retrospective Review
MVP Medicare Secure Plus HMO POS	Retrospective Review
MVP VT HMO	Retrospective Review
MVP VT HDHP HMO	Retrospective Review
MVP VT Plus HMO	Retrospective Review
MVP VT Plus HDHP HMO	Retrospective Review
MVP Secure	Retrospective Review
ASO	See SPD
	JEE JFD

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

*Medical Management Requirements

Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

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MVP Health Care Medical Policy Revision History:

12/01/2021 – Prior authorization was removed from Medicaid Managed Care (MMC) plans. Policy was updated to reflect that there are no longer visit limits for speech therapy for MMC plans. Coverage was added to Medicare plans for speech therapy in a group setting.

08/01/2022 – Added sensory integration therapy and laryngoscopy to policy exclusions with Medicare variation.

08/01/2024 – Annual Review. Updated overview to include full practice areas, added examples of covered conditions, and updated reference section.



Spinal Cord Stimulator

Type of Policy: Surgical

Prior Approval Date: N/A

Approval Date: 12/04/2024

Effective Date: 04/01/2025

Related Polices: N/A

Codes Requiring Prior Authorization

63650 – Percutaneous implantation of neurostimulator electrode array, epidural

63655 – Laminectomy for implantation of neurostimulator electrodes, plate/paddle, epidural

63685 – Insertion or replacement of spinal neurostimulator pulse generator or receiver, requiring pocket creation and connection between electrode array and pulse generator or receiver

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

Codes Requiring Retrospective Review

N/A

Experimental/Investigational

N/A

Common Diagnosis Codes

N/A

Common Diagnosis Codes associated with this policy have been provided for informational purposes only. The list of codes may not be all-inclusive and may be updated to reflect any applicable revisions to the ICD-10 code set and/or medical necessity quidelines applied in this policy.

Common Procedure Codes

CPT Codes: 63663, 63688, 95970, C1823

Spinal Cord Stimulator Page 1 of 5

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

The implantation of central nervous system stimulators may be covered as therapies for the relief of chronic intractable pain.

Implanted electrical spinal cord stimulators may be medically necessary for treating the following conditions:

- Complex regional pain syndrome (CRPS); or
- Painful lower limb diabetic neuropathy; or
- Failed back surgery syndrome.
- Chronic intractable back pain without prior spine surgery; or
- Refractory Canadian Class III or IV angina

Indications/Criteria

For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures, Spinal Cord Stimulator (SCS) Insertion.

The complete Change Healthcare InterQual imaging criteria are available on-line at www.mvphealthcare.com then click on Change Healthcare InterQual or by calling 1-800-568-0458.

Electronic analysis service (CPT code 95970) is considered medically necessary when provided at a frequency more often than once every 30 days. More frequent analysis may be necessary in the first month after implantation.

Exclusions

Following the first month after implantation, electronic analysis services (CPT code 95970) is not considered medically necessary when provided at a frequency more often than once every 30 days.

Medicare

Refer to the following link for full coverage of the Centers for Medicare & Medicaid Services (CMS). Medicare Coverage Database. National Coverage Determination (NCD) for Electrical Nerve Stimulators (160.7). August 7, 1995. Available: MCD Search (cms.gov)

References (2024)

- Centers for Medicare & Medicaid Services (CMS) Medicare Coverage Database. National Coverage Determination (NCD) for Electrical Nerve Stimulators (160.7). August 7, 1995 Available: MCD Search (cms.gov)
- 2. InterQual® Clinical Decision Support Criteria. Change Healthcare LLC, Copyright © 2020 Change Healthcare.

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Member Product	Medical Management Requirements*
New York Products	-
НМО	Prior Authorization
PPO in Plan	Prior Authorization
PPO OOP	Prior Authorization
POS in Plan	Prior Authorization
POS OOP	Prior Authorization
Essential Plan	Prior Authorization
MVP Medicaid Managed Care	Prior Authorization
MVP Child Health Plus	Prior Authorization
MVP Harmonious Health Care Plan	Prior Authorization
MVP Medicare Complete Wellness	Prior Authorization
MVP Medicare Preferred Gold HMO POS	Prior Authorization
MVP Medicare Secure HMO POS	Prior Authorization
MVP Medicare Secure Plus HMO POS	Prior Authorization
MVP Medicare WellSelect PPO	Prior Authorization
MVP Medicare WellSelect Plus PPO	Prior Authorization
MVP Medicare Patriot Plan (PPO)	Prior Authorization
USA Care PPO	Potential for Retrospective Review
MVP DualAccess D-SNP HMO	Prior Authorization
MVP DualAccess Complete D-SNP HMO	Prior Authorization
MVP DualAccess Plus D-SNP HMO	Prior Authorization
UVM Health Advantage Select PPO	Prior Authorization
Healthy NY	Prior Authorization
MVP Premier	Prior Authorization
MVP Premier Plus	Prior Authorization
MVP Premier Plus HDHP	Prior Authorization
MVP Secure	Prior Authorization
MVP EPO	Prior Authorization
MVP EPO HDHP	Prior Authorization
MVP PPO	Prior Authorization
MVP PPO HDHP	Prior Authorization
Student Health Plans	Prior Authorization
ASO Student Health Haris	See SPD
Vermont Products	See Si D
POS in Plan	Prior Authorization
POS OOP	Prior Authorization
MVP Medicare Preferred Gold HMO POS POS	Prior Authorization
MVP Medicare Secure Plus HMO POS	Prior Authorization
MVP VT HMO	Prior Authorization
MVP VT HDHP HMO	Prior Authorization
MVP VT Plus HMO	Prior Authorization
MVP VT Plus HDHP HMO	Prior Authorization
MVP Secure	Prior Authorization
ASO	See SPD
AJU	JEE JFD

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review.

Retro ReviewRetrospective Review RequiredNot CoveredService is not a covered benefit.See SPDSee Specific Plan Design

Spinal Cord Stimulator Page 4 of 5

Revision History:

04/01/2025 – New Policy created from the InterQual Criteria Medical Policy.

Spinal Cord Stimulator Page 5 of 5



Surgical Procedures for Glaucoma

Type of Policy: Surgical

Prior Approval Date: 05/06/2024

Approval Date: 10/02/2024

Effective Date: 02/01/2025

Related Polices: N/A

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

N/A

Experimental/Investigational Codes Requiring Retrospective Review

CPT Codes:

0449T - Insertion of aqueous drainage device, without extraocular reservoir, internal approach, into the subconjunctival space; initial device

0450T - Insertion of aqueous drainage device, without extraocular reservoir, internal approach, into the subconjunctival space; each additional device

0660T – Implantation of anterior segment intraocular nonbiodegradable drug-eluting system, internal approach

0661T - Removal and reimplantation of anterior segment intraocular nonbiodegradable drug-eluting implant

65820 - Goniotomy

66174 - Transluminal dilation of aqueous outflow canal; without retention of device or stent (e.g., canaloplasty)

66175 - Transluminal dilation of aqueous outflow canal; with retention of device or stent (e.g., canaloplasty)

68841 - Insertion of drug-eluting implant, including punctal dilation when performed, into lacrimal canaliculus, each

66999 - Unlisted procedure, anterior segment of eye

Common Diagnosis Codes

ICD-10- CM Diagnosis Codes: H40.11X0, H40.11X1, H40.11X2, H40.11X3, H40.11X4

Common Diagnosis Codes associated with this policy have been provided for informational purposes only. The list of codes may not be all-inclusive and may be updated to reflect any applicable revisions to the ICD-10 code set and/or medical necessity quidelines applied in this policy.

Common Procedure Codes

CPT Codes: 0253T 0474T, 66170, 66172, 66179, 66180, 66183, 66184, 66185, 66989, 66991, C1783, L8612

Please refer to the product grid for detailed authorization requirements for specific plans. Code lists may not be all inclusive. Codes requiring prior-authorization for some products may be retrospectively reviewed for plans that do not require prior-authorization. Common diagnosis and procedure codes are included for informational purposes. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

Glaucoma is a disease of the optic nerve, characterized by loss of retinal ganglion cells, remodeling of the lamina cribrosa, structural changes to the nerve, elevated intraocular pressure (IOP), and progressive, irreversible loss of vision leading to blindness. Two main types of glaucoma are open-angle glaucoma (OAG) and angle-closure glaucoma. OAG is the primary cause of irreversible vision loss. First-line treatment of OAG employs medications that lower IOP, such as prostaglandin analogs, carbonic anhydrase inhibitors, and beta-blockers. Increases in IOP correlate with the severity of OAG, and fluctuations in IOP are associated with progressive loss of visual fields. Surgical approaches are indicated if medical treatment does not lower IOP adequately, the side effects of glaucoma medications limit medical therapy, or progressive disease is observed. Available surgical treatments are designed to either increase the exit of aqueous humor from the eye or decrease its production. The most common incisional surgical treatment for primary OAG is a type of filtration surgery known as trabeculectomy. Trabeculectomy is often effective in lowering IOP, but complications may include infection, bleb leakage, and progressive worsening of cataracts. Despite potential complications, trabeculectomy remains the current standard against which newer surgical techniques are measured.

Newer surgical procedures for glaucoma are under continual development and include a group of micro-invasive glaucoma surgery (MIGS) procedures which allow for general ophthalmologists or cataract surgeons to be trained to perform surgery to correct glaucoma, including at the time of concomitant cataract surgery.

Canaloplasty is a non-penetrating surgical procedure which aims at lowering the intraocular pressure of the eye by permanently stretching the trabecular meshwork and restoring the natural drainage of fluid out of the eye. Viscocanalostomy involves

creating a scleral reservoir and an injection of a viscoelastic biocompatible polymer to open the ostia of the canal. This opening allows passage of fluid from the anterior chamber into the canal which lowers the intraocular pressure. Viscocanalostomy avoids full thickness penetration of the anterior chamber of the eye. Canaloplasty and viscocanalostomy are not as effective as trabeculectomy in decreasing intraocular pressure in adult patients with primary open angle glaucoma.

There are several types of glaucoma drainage implants or devices, also known as a shunt tube, which can be implanted to maintain an artificial drainage pathway to control intraocular pressure for patients with glaucoma. Intraocular pressure is lowered when aqueous humor flows from inside the eye through the tube into the space between the plate that rests on the scleral surface and surrounding fibrous capsule.

- The Trabecular Micro-Bypass Stent inserter is passed across the anterior chamber, and the stent is implanted through the nasal trabecular meshwork and into Schlemm's canal. When properly implanted, the stent is intended to create a bypass through the trabecular meshwork to Schlemm's canal to improve aqueous outflow through the natural physiologic pathway.
- The EX-PRESS Glaucoma Filtration Device (EGFD) is a miniature, stainless steel
 aqueous shunt that is implanted using a modified surgical trabeculectomy. Once
 inserted, the filtration device immediately begins to shunt aqueous humor from
 the anterior chamber to the subconjunctival space forming a conjunctival filtering
 bleb.
- The XEN Glaucoma Treatment Systems (XEN45 Gel Stent and XEN injector) device creates a permanent channel through the sclera allowing flow of aqueous humor from the anterior chamber into the subconjunctival space. The XEN45 Gel Stent is inserted via an ab interno approach, through a small corneal incision.

The Omni Surgical System is a minimally invasive, implant-free device cleared by the U.S. Food and Drug Administration (FDA) for the treatment of adult patients with primary open-angle glaucoma. It combines ab interno canaloplasty with trabeculotomy and goniotomy. This dual procedure is proposed to reduce interocular pressure by improving the outflow of aqueous humor from the eye.

Indications/Criteria

Trabecular Micro-Bypass Stent

MVP considers one (1) Micro-Bypass Stent per eye (i.e., iStent Trabecular Micro-Bypass Stent or the Hydrus® Microstent and iStent inject) (66989, 66991) medically reasonable and necessary for treatment of adults with mild or moderate open-angle glaucoma and a cataract when the individual is currently being treated with an ocular hypotensive medication and the procedure is being performed in conjunction with cataract surgery. Micro-bypass stents are not covered for any other indication, as the role of this

procedure within the glaucoma treatment algorithm continues to be clarified and differs from the role of more invasive, external filtration glaucoma surgeries such as trabeculectomy or external aqueous drainage implants. Therefore, all other indications are considered experimental and investigational.

Ex-Press Glaucoma Filtration Device

There is a moderate-quality body of evidence suggesting that the EX-PRESS glaucoma filtration device is comparable to current standard of care in terms of reducing intraocular pressure, treatment success, reducing medication use, complications, and the return of visual acuity in patients with open-angle glaucoma. Therefore, the use of the EX-PRESS Glaucoma Filtration Device (EGFD) (66183) is considered medically necessary for patients diagnosed with refractory open angle glaucoma, for whom trabeculectomy and other surgical therapies have failed or are contraindicated in controlling intraocular pressure.

Additional insertion of an anterior segment aqueous drainage device is not medically necessary because only one stent per eye is allowed.

Exclusions

Canaloplasty (CPT Code: 66174, 66175)

There is insufficient evidence in the peer reviewed literature to support long-term safety and efficacy of canaloplasty for the treatment of open angle glaucoma and is, therefore, considered investigational for all indications.

Goniotomy (CPT Code: 65820)

There is insufficient evidence in the peer reviewed literature to support long-term safety and efficacy of goniotomy (or gonioscopy-assisted transluminal trabeculotomy (GATT)) for the treatment of open angle glaucoma for cataracts and is, therefore, considered investigational for all indications.

Viscocanalostomy (CPT Code: 66999)

There is insufficient evidence in the peer reviewed literature that viscocanalostomy results in proven beneficial outcomes that are superior to conventional trabeculectomy in reducing intraocular pressure for the treatment of open angle glaucoma and is, therefore, considered investigational for all indications.

XEN Glaucoma Treatment System (CPT Code: 0449T, 0450T)

The safety and efficacy of the XEN Gel Stent has not been established and human studies comparing the XEN to trabeculectomy, tubes and shunts are lacking. Therefore, the XEN Glaucoma Treatment System is considered experimental and investigational.

iStent Supra (CPT code: 0253T)

The iStent Supra is a third-generation iStent device under development. There is insufficient evidence in the peer-reviewed literature that the iStent Supra results in proven beneficial outcomes that are superior to other stents that are used in reducing intraocular pressure for the treatment of open angle glaucoma and is, therefore, considered investigational for all indications.

Drug-eluting devices (CPT Code: 0660T, 0661T, 68841)

Drug-eluting devices are in development to combat low patient adherence with medications since many eye drops require multiple doses daily. These types of devices are implanted or inserted into the eye temporarily and purportedly release a steady dose of medication until they are removed, dissolve or are washed out via the tear duct. These are considered experimental and investigational as they are not identified as widely used and there is insufficient evidence in the peer-reviewed literature that they result in proven beneficial outcomes.

Medicare Variation

Per the National Government Services, Inc. Local Coverage Determination (LCD) Policy on Micro-invasive Glaucoma Surgery (MIGS), the following procedures are specifically covered as outlined:

One XEN45 device (0449T, 0450T) per eye is considered medically reasonable and necessary for the management of refractory glaucoma, defined (based on the pivotal trial criteria) as prior failure of filtering/cilioablative procedure and/or uncontrolled IOP (progressive damage and mean diurnal medicated IOP \geq 20 mm Hg) on maximally tolerated medical therapy (i.e., \geq 4 classes of topical IOP-lowering medications, or fewer in the case of tolerability or efficacy issues). XEN45 insertion must be performed by an ophthalmologist with experience with trabeculectomy and bleb management.

Medicare addresses use of a group of new surgical procedures for glaucoma referred to as micro-invasive glaucoma surgery (MIGS). NGS considers one iStent, iStent inject, or Hydrus device per eye medically reasonable and necessary for the treatment of adults with mild or moderate open-angle glaucoma and a cataract when the individual is currently being treated with an ocular hypotensive medication and the procedure is being performed in conjunction with cataract surgery. One XEN45 device per eye is covered for the management of refractory glaucoma, defined as prior failure of filtering/cilioablative procedure and/or uncontrolled IOP (progressive damage and mean diurnal medicated IOP \geq 20 mm Hg) on maximally tolerated medical therapy (i.e., \geq 4 classes of topical IOP-lowering medications, or fewer in the case of tolerability or efficacy issues). XEN45 insertion must be performed by an ophthalmologist with experience with trabeculectomy and bleb management.

For full Medicare coverage and limitations of Micro-invasive Glaucoma Surgery (MIGS) refer to: National Government Services, Inc. Local Coverage Determination (LCD)

(L37244) Micro-Invasive Glaucoma Surgery (MIGS). Original Effective Date: 12/01/17. Available: Medicare Coverage Database Search

Trabeculectomy is covered for primary open-angle glaucoma (POAG) in patients whose medical management is no longer providing adequate results.

Implantation, reimplantation or removal of anterior segment intraocular nonbiodegradable drug-eluting implants (Codes 0660T, 0661T) are covered for Medicare plans when used in conjunction with iDose TR (J7355) but not otherwise.

References (Reviewed 2024)

- 1. Prum, B.E>, et al American Academy of Ophthalmology (AAO). Preferred practice pattern® Guidelines. Primary open-angle glaucoma. Ophthalmology. January 2016; 123 (1): 41-111. Available: http://www.aaojournal.org/article/S0161-6420(15)01276-2/fulltext.
- 2. Lüke C, Dietlein TS, Jacobi PC, et al. A prospective randomized trial of viscocanalostomy versus trabeculectomy in open angle glaucoma: a 1-year follow-up study. J Glaucoma. 2002; 11(4):294-299.
- 3. U.S. Food and Drug Administration 510(k) Summary. Optonol Ltd. Ex-PRESS Miniature Glaucoma Implant. March 26, 2002.
- 4. Seibold LK, Rorrer RA, Kahook MY. MRI of the Ex-PRESS stainless steel glaucoma drainage device. Br J Ophthalmol. 2011;95:251-4.
- 5. American Academy of Ophthalmology (AAO). Primary Open-Angle Glaucoma Summary Benchmark- November 2017. Available: https://www.aao.org/summary-benchmark-detail/glaucoma-summary-benchmarks-2017.
- 6. Hayes Health Technology Assessment. iStent Inject Trabecular Micro-Bypass Stent (Glaukos Corp.) as a Standalone Procedure for Open-Angle Glaucoma. September 17, 2019 Annual Review November 10, 2022
- 7. Craven ER, et al. Cataract surgery with trabecular micro-bypass stent implantation in patients with mild-to-moderate open-angle glaucoma and cataract" two-year follow-up. J Cataract Refract Surg 2012 Aug;38(8):1339-45.
- 8. Fea AM. Phacoemulsification versus phacoemulsification with micro-bypass stent implantation in primary open-angle glaucoma: a randomized double-masked clinical trial. J Cataract Refract Surg 2010 Mar;36(3):407-12.
- 9. Fea AM, et al. Prospective unmasked randomized evaluation of the iStent inject® versus two ocular hypotensive agents in patients with primary open-angle glaucoma. Clin Ophthalmol 2014 May 7;875-82.
- 10. iStent® Trabecular Micro-Bypass. Glaukos® Available: http://www.glaukos.com/istent.

- 11. Samuelson TW, et al. Randomized evaluation of the trabecular micro-bypass stent with phacoemulsification in patients with glaucoma and cataract. Ophthalmology 2011 Mar 118(3):459-67.
- 12. Spiegel D, et al. Coexistent primary open-angle glaucoma and cataract: preliminary analysis of treatment by cataract surgery and the iStent trabecular micro-bypass stent. Adv Ther 2008 May;25(5):453-64.
- 13. Dahan E, et al. Comparison of trabeculectomy and Ex-PRESS implantation in fellow eyes of the same patient: a prospective, randomized study. Eye 2012 May;26(5):703-10.
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- 15. National Government Services, Inc. Local Coverage Determination (LCD) (L37244) Micro-Invasive Glaucoma Surgery (MIGS). Original Effective Date: 12/01/17. Available: www.cms.gov/\.
- 16. U.S. Food and Drug Administration (FDA). Premarket notification (PMA XEN Glaucoma Treatment System.K161457. Nov 21,2016. Available: https://www.accessdata.fda.gov/cdrh_docs/pdf16/K161457.pdf.
- 17. U.S. Food and Drug Administration. Premarket Approval (PMA P080030) Glaukos i Istent Trabecular Bypass Istent Model GTS100R/L. Date Available: 06/25/2012. Available: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P080030.
- U.S. Food and Drug Administration. Premarket Approval (PMA P150037). Date: 07/19/2016. CyPass Micro-Stent. Available: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm?id=P150037.
- 19. AqueSys Inc. XEN Gel Stent.2016. Accessed Jan 22,2018. Available: http://www.aquesys.com/xen.aspx.
- 20. Chaudhary A, Salinas L, Guidotti J, Mermoud A, Mansouri K. XEN Gel Implant: a new surgical approach in glaucoma. Expert Rev Med Devices.2018 Jan;15(1):47-59.
- 21. Colby A, Shane H. A Review of the Data on the Recently Approved XEN Surgical Gel Stent in the Management of Glaucoma. JOJ Ophthal. 2017; 3(4):555617.
- 22. Richter GM, Coleman AL. Minimally invasive glaucoma surgery: current status and future prospects. Clin Ophthalmol.2016 Jan 28;10:189-206.
- 23. Hayes Health Technology Assessment iStent inject Trabecular Micro-Bypass Stent (Glaukos Corp.) in Combination with Cataract Surgery for Management of Open-Angle Glaucoma. Hayes, a TractManager Company ©2020 TractManager July 2, 2019. Annual Review: July 6, 2022. Available: https://evidence.hayesinc.com/.

- 24. Hayes Health Technology Assessment XEN Glaucoma Treatment System (Allergan) for Treatment of Open-Angle Glaucoma. Hayes, a TractManager Company ©2020 TractManager December 19, 2019. Annual Review: April 4, 2023. Available: https://evidence.hayesinc.com/.
- 25. Hayes Health Technology Assessment. Canaloplasty for Open-Angle Glaucoma. Hayes, a TractManager Company ©2020 TractManager January 13, 2020. Annual Review: April 6, 2023. Available: https://evidence.hayesinc.com/.
- 26. Hayes, Inc. Emerging Technology Report. iStent Trabecular Micro-Bypass Stent (Glaukos Corp.) In Combination With Cataract Surgery For Treatment Of Open-Angle Glaucoma. March 17, 2016. Annual Review: March 30, 2018. Hayes, Inc. Available: https://evidence.hayesinc.com/

Customer Product	Medical Management Requirements*
New York Products	
HMO	Retrospective Review
PPO In Plan	Retrospective Review
PPO OOP	Retrospective Review
POS In Plan	Retrospective Review
POS OOP	Retrospective Review
Essential Plan	Retrospective Review
MVP Medicaid Managed Care	Retrospective Review
MVP Child Health Plus	Retrospective Review
MVP Harmonious Health Care Plan	Retrospective Review
MVP Medicare Complete Wellness	Retrospective Review
MVP Medicare Preferred Gold HMO POS	Retrospective Review
MVP Medicare Secure HMO POS	Retrospective Review
MVP Medicare Secure Plus HMO POS	Retrospective Review
MVP Medicare WellSelect PPO	Retrospective Review
MVP Medicare WellSelect Plus PPO	Retrospective Review
MVP Medicare Patriot Plan PPO	Retrospective Review
MVP DualAccess D-SNP HMO	Retrospective Review
MVP DualAccess Complete D-SNP HMO	Retrospective Review
MVP DualAccess Plus D-SNP HMO	Retrospective Review
UVM Health Advantage Select PPO	Retrospective Review
USA Care	Potential for Retrospective Review
Healthy NY	Retrospective Review
MVP Premier	Retrospective Review
MVP Premier Plus	Retrospective Review
MVP Premier Plus HDHP	Retrospective Review
MVP Secure	Retrospective Review
MVP EPO	Retrospective Review
MVP EPO HDHP	Retrospective Review
MVP PPO	Retrospective Review
MVP PPO HDHP	Retrospective Review
Student Health Plans	Retrospective Review
ASO	See SPD
Vermont Products	
POS In Plan	Retrospective Review
POS OOP	Retrospective Review
MVP Medicare Preferred Gold HMO POS	Retrospective Review
MVP Medicare Secure Plus HMO POS	Retrospective Review
MVP VT HMO	Retrospective Review
MVP VT HDHP HMO	Retrospective Review
MVP VT Plus HMO	Retrospective Review
MVP VT Plus HDHP HMO	Retrospective Review
MVP Secure	Retrospective Review
ASO	See SPD

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Revision History:

06/01/2021 – Format updated; no changes to the indications or criteria.

08/01/2022 – Removed Trabecular Micro-Bypass Stent (CPT Codes: 66991, 66989) from retrospective investigational review.

08/01/2024 – Annual Review. Create exclusions section, added drug-eluting devices. Updated references.

02/01/2025 – Added exclusion for goniotomy (CPT 65820) for all product lines. Removed coverage from canaloplasty and viscocanalostomy for Medicare plans. Added coverage criteria to 0660T and 0661T for Medicare plans.



Surgical Procedures for Glaucoma

Type of Policy: Surgical

Prior Approval Date: 06/06/2022

Approval Date: 05/06/2024

Effective Date: 08/01/2024

Related Polices: N/A

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

N/A

Experimental/Investigational Codes Requiring Retrospective Review

CPT Codes:

0449T - Insertion of aqueous drainage device, without extraocular reservoir, internal approach, into the subconjunctival space; initial device

0450T - Insertion of aqueous drainage device, without extraocular reservoir, internal approach, into the subconjunctival space; each additional device

0660T – Implantation of anterior segment intraocular nonbiodegradable drug-eluting system, internal approach

0661T - Removal and reimplantation of anterior segment intraocular nonbiodegradable drug-eluting implant

66174 - Transluminal dilation of aqueous outflow canal; without retention of device or stent

66175 - Transluminal dilation of aqueous outflow canal; with retention of device or stent

68841 - Insertion of drug-eluting implant, including punctal dilation when performed, into lacrimal canaliculus, each

66999 - Unlisted procedure, anterior segment of eye

Common Diagnosis Codes

ICD-10- CM Diagnosis Codes: H40.11X0, H40.11X1, H40.11X2, H40.11X3, H40.11X4

Common Diagnosis Codes associated with this policy have been provided for informational purposes only. The list of codes may not be all-inclusive and may be updated to reflect any applicable revisions to the ICD-10 code set and/or medical necessity guidelines applied in this policy.

Common Procedure Codes

CPT Codes: 0253T 0474T, 66170, 66172, 66179, 66180, 66183, 66184, 66185, 66989, 66991, C1783, L8612

Please refer to the product grid for detailed authorization requirements for specific plans. Code lists may not be all inclusive. Codes requiring prior-authorization for some products may be retrospectively reviewed for plans that do not require prior-authorization. Common diagnosis and procedure codes are included for informational purposes. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

Glaucoma is a disease of the optic nerve, characterized by loss of retinal ganglion cells, remodeling of the lamina cribrosa, structural changes to the nerve, elevated intraocular pressure (IOP), and progressive, irreversible loss of vision leading to blindness. Two main types of glaucoma are open-angle glaucoma (OAG) and angle-closure glaucoma. OAG is the primary cause of irreversible vision loss. First-line treatment of OAG employs medications that lower IOP, such as prostaglandin analogs, carbonic anhydrase inhibitors, and beta-blockers. Increases in IOP correlate with the severity of OAG, and fluctuations in IOP are associated with progressive loss of visual fields. Surgical approaches are indicated if medical treatment does not lower IOP adequately, the side effects of glaucoma medications limit medical therapy, or progressive disease is observed. Available surgical treatments are designed to either increase the exit of aqueous humor from the eye or decrease its production. The most common incisional surgical treatment for primary OAG is a type of filtration surgery known as trabeculectomy. Trabeculectomy is often effective in lowering IOP, but complications may include infection, bleb leakage, and progressive worsening of cataracts. Despite potential complications, trabeculectomy remains the current standard against which newer surgical techniques are measured.

Newer surgical procedures for glaucoma are under continual development and include a group of micro-invasive glaucoma surgery (MIGS) procedures which allow for general ophthalmologists or cataract surgeons to be trained to perform surgery to correct glaucoma, including at the time of concomitant cataract surgery.

Canaloplasty is a non-penetrating surgical procedure which aims at lowering the intraocular pressure of the eye by permanently stretching the trabecular meshwork and restoring the natural drainage of fluid out of the eye. Viscocanalostomy involves creating a scleral reservoir and an injection of a viscoelastic biocompatible polymer to

open the ostia of the canal. This opening allows passage of fluid from the anterior chamber into the canal which lowers the intraocular pressure. Viscocanalostomy avoids full thickness penetration of the anterior chamber of the eye. Canaloplasty and viscocanalostomy are not as effective as trabeculectomy in decreasing intraocular pressure in adult patients with primary open angle glaucoma.

There are several types of glaucoma drainage implants or devices, also known as a shunt tube, which can be implanted to maintain an artificial drainage pathway to control intraocular pressure for patients with glaucoma. Intraocular pressure is lowered when aqueous humor flows from inside the eye through the tube into the space between the plate that rests on the scleral surface and surrounding fibrous capsule.

- The Trabecular Micro-Bypass Stent inserter is passed across the anterior chamber, and the stent is implanted through the nasal trabecular meshwork and into Schlemm's canal. When properly implanted, the stent is intended to create a bypass through the trabecular meshwork to Schlemm's canal to improve aqueous outflow through the natural physiologic pathway.
- The EX-PRESS Glaucoma Filtration Device (EGFD) is a miniature, stainless steel aqueous shunt that is implanted using a modified surgical trabeculectomy. Once inserted, the filtration device immediately begins to shunt aqueous humor from the anterior chamber to the subconjunctival space forming a conjunctival filtering bleb.
- The XEN Glaucoma Treatment Systems (XEN45 Gel Stent and XEN injector) device creates a permanent channel through the sclera allowing flow of aqueous humor from the anterior chamber into the subconjunctival space. The XEN45 Gel Stent is inserted via an ab interno approach, through a small corneal incision.

Indications/Criteria

Trabecular Micro-Bypass Stent

MVP considers one (1) Micro-Bypass Stent per eye (i.e., iStent Trabecular Micro-Bypass Stent or the Hydrus® Microstent and iStent inject) (66989, 66991) medically reasonable and necessary for treatment of adults with mild or moderate open-angle glaucoma and a cataract when the individual is currently being treated with an ocular hypotensive medication and the procedure is being performed in conjunction with cataract surgery. Micro-bypass stents are not covered for any other indication, as the role of this procedure within the glaucoma treatment algorithm continues to be clarified and differs from the role of more invasive, external filtration glaucoma surgeries such as trabeculectomy or external aqueous drainage implants. Therefore, all other indications are considered experimental and investigational.

Ex-Press Glaucoma Filtration Device

There is a moderate-quality body of evidence suggesting that the EX-PRESS glaucoma filtration device is comparable to current standard of care in terms of reducing intraocular pressure, treatment success, reducing medication use, complications, and the return of visual acuity in patients with open-angle glaucoma. Therefore, the use of the EX-PRESS Glaucoma Filtration Device (EGFD) (66183) is considered medically necessary for patients diagnosed with refractory open angle glaucoma, for whom trabeculectomy and other surgical therapies have failed or are contraindicated in controlling intraocular pressure.

Additional insertion of an anterior segment aqueous drainage device is not medically necessary because only one stent per eye is allowed.

Exclusions

Canaloplasty (CPT Code: 66174, 66175)

There is insufficient evidence in the peer reviewed literature to support long-term safety and efficacy of canaloplasty for the treatment of open angle glaucoma and is, therefore, considered investigational for all indications.

Viscocanalostomy (CPT Code: 66999)

There is insufficient evidence in the peer reviewed literature that viscocanalostomy results in proven beneficial outcomes that are superior to conventional trabeculectomy in reducing intraocular pressure for the treatment of open angle glaucoma and is, therefore, considered investigational for all indications.

XEN Glaucoma Treatment System (CPT Code: 0449T, 0450T)

The safety and efficacy of the XEN Gel Stent has not been established and human studies comparing the XEN to trabeculectomy, tubes and shunts are lacking. Therefore, the XEN Glaucoma Treatment System is considered experimental and investigational.

iStent Supra (CPT code: 0253T)

The iStent Supra is a third-generation iStent device under development. There is insufficient evidence in the peer-reviewed literature that the iStent Supra results in proven beneficial outcomes that are superior to other stents that are used in reducing intraocular pressure for the treatment of open angle glaucoma and is, therefore, considered investigational for all indications.

Drug-eluting devices (CPT Code: 0660T, 0661T, 68841)

Drug-eluting devices are in development to combat low patient adherence with medications since many eye drops require multiple doses daily. These types of devices are implanted or inserted into the eye temporarily and purportedly release a steady dose of medication until they are removed, dissolve or are washed out via the tear duct. These are considered experimental and investigational as they are not identified as

widely used and there is insufficient evidence in the peer-reviewed literature that they result in proven beneficial outcomes.

Medicare Variation

Per the National Government Services, Inc. Local Coverage Determination (LCD) Policy on Micro-invasive Glaucoma Surgery (MIGS), the following procedures are specifically covered as outlined:

One XEN45 device (0449T, 0450T) per eye is considered medically reasonable and necessary for the management of refractory glaucoma, defined (based on the pivotal trial criteria) as prior failure of filtering/cilioablative procedure and/or uncontrolled IOP (progressive damage and mean diurnal medicated IOP \geq 20 mm Hg) on maximally tolerated medical therapy (i.e., \geq 4 classes of topical IOP-lowering medications, or fewer in the case of tolerability or efficacy issues). XEN45 insertion must be performed by an ophthalmologist with experience with trabeculectomy and bleb management.

Medicare addresses use of a group of new surgical procedures for glaucoma referred to as micro-invasive glaucoma surgery (MIGS). NGS considers one iStent, iStent inject, or Hydrus device per eye medically reasonable and necessary for the treatment of adults with mild or moderate open-angle glaucoma and a cataract when the individual is currently being treated with an ocular hypotensive medication and the procedure is being performed in conjunction with cataract surgery. One XEN45 device per eye is covered for the management of refractory glaucoma, defined as prior failure of filtering/cilioablative procedure and/or uncontrolled IOP (progressive damage and mean diurnal medicated IOP \geq 20 mm Hg) on maximally tolerated medical therapy (i.e., \geq 4 classes of topical IOP-lowering medications, or fewer in the case of tolerability or efficacy issues). XEN45 insertion must be performed by an ophthalmologist with experience with trabeculectomy and bleb management.

For full Medicare coverage and limitations of Micro-invasive Glaucoma Surgery (MIGS) refer to: National Government Services, Inc. Local Coverage Determination (LCD) (L37244) Micro-Invasive Glaucoma Surgery (MIGS). Original Effective Date: 12/01/17. Available: https://www.cms.gov/

Canaloplasty, viscocanalostomy and trabeculectomy are covered for primary open-angle glaucoma (POAG) in patients whose medical management is no longer providing adequate results.

References (Reviewed 2024)

1. Prum, B.E>, et al American Academy of Ophthalmology (AAO). Preferred practice pattern® Guidelines. Primary open-angle glaucoma. Ophthalmology. January 2016; 123 (1): 41-111. Available: http://www.aaojournal.org/article/S0161-6420(15)01276-2/fulltext.

- 2. Lüke C, Dietlein TS, Jacobi PC, et al. A prospective randomized trial of viscocanalostomy versus trabeculectomy in open angle glaucoma: a 1-year follow-up study. J Glaucoma. 2002; 11(4):294-299.
- 3. U.S. Food and Drug Administration 510(k) Summary. Optonol Ltd. Ex-PRESS Miniature Glaucoma Implant. March 26, 2002.
- 4. Seibold LK, Rorrer RA, Kahook MY. MRI of the Ex-PRESS stainless steel glaucoma drainage device. Br J Ophthalmol. 2011;95:251-4.
- 5. American Academy of Ophthalmology (AAO). Primary Open-Angle Glaucoma Summary Benchmark- November 2017. Available: https://www.aao.org/summary-benchmarks-2017.
- 6. Hayes Health Technology Assessment. iStent Inject Trabecular Micro-Bypass Stent (Glaukos Corp.) as a Standalone Procedure for Open-Angle Glaucoma. September 17, 2019 Annual Review November 10, 2022
- 7. Craven ER, et al. Cataract surgery with trabecular micro-bypass stent implantation in patients with mild-to-moderate open-angle glaucoma and cataract" two-year follow-up. J Cataract Refract Surg 2012 Aug;38(8):1339-45.
- 8. Fea AM. Phacoemulsification versus phacoemulsification with micro-bypass stent implantation in primary open-angle glaucoma: a randomized double-masked clinical trial. J Cataract Refract Surg 2010 Mar;36(3):407-12.
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- 10. iStent® Trabecular Micro-Bypass. Glaukos® Available: http://www.glaukos.com/istent.
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- 19. AqueSys Inc. XEN Gel Stent.2016. Accessed Jan 22,2018. Available: http://www.aquesys.com/xen.aspx.
- 20. Chaudhary A, Salinas L, Guidotti J, Mermoud A, Mansouri K. XEN Gel Implant: a new surgical approach in glaucoma. Expert Rev Med Devices. 2018 Jan; 15(1):47-59.
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НМО	Retrospective Review		
PPO In Plan	Retrospective Review		
PPO OOP	Retrospective Review		
POS In Plan	Retrospective Review		
POS OOP	Retrospective Review		
Essential Plan	Retrospective Review		
MVP Medicaid Managed Care	Retrospective Review		
MVP Child Health Plus	Retrospective Review		
MVP Harmonious Health Care Plan	Retrospective Review		
MVP Medicare Gold Giveback	Retrospective Review		
MVP Medicare Preferred Gold HMO POS	Retrospective Review		
MVP Medicare Secure HMO POS	Retrospective Review		
MVP Medicare Secure Plus HMO POS	Retrospective Review		
MVP Medicare WellSelect PPO	Retrospective Review		
MVP Medicare WellSelect Plus PPO	Retrospective Review		
MVP Medicare Patriot Plan PPO	Retrospective Review		
MVP DualAccess D-SNP HMO	Retrospective Review		
MVP DualAccess Complete D-SNP HMO	Retrospective Review		
MVP DualAccess Plus D-SNP HMO	Retrospective Review		
UVM Health Advantage Select PPO	Retrospective Review		
UVM Health Advantage Secure PPO	Retrospective Review		
UVM Health Advantage Preferred PPO	Retrospective Review		
USA Care	Potential for Retrospective Review		
Healthy NY	Retrospective Review		
MVP Premier	Retrospective Review		
MVP Premier Plus	Retrospective Review		
MVP Premier Plus HDHP	Retrospective Review		
MVP Secure	Retrospective Review		
MVP EPO	Retrospective Review		
MVP EPO HDHP	Retrospective Review		
MVP PPO	Retrospective Review		
MVP PPO HDHP	Retrospective Review		
Student Health Plans	Retrospective Review		
ASO	See SPD		
Vermont Products	3333.2		
POS In Plan	Retrospective Review		
POS OOP	Retrospective Review		
MVP Medicare Preferred Gold HMO POS	Retrospective Review		
MVP Medicare Secure Plus HMO POS	·		
UVM Health Advantage Select PPO	Retrospective Review		
UVM Health Advantage Secure PPO	Retrospective Review Retrospective Review		
UVM Health Advantage Preferred PPO	Retrospective Review Retrospective Review		
MVP VT HMO	Retrospective Review Retrospective Review		
MVP VT HIMO	Retrospective Review Retrospective Review		
MVP VT Plus HMO	Retrospective Review Retrospective Review		
MVP VT Plus HDHP HMO	Retrospective Review Retrospective Review		
MVP Secure			
ASO	Retrospective Review		
ASU	See SPD		

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

*Medical Management Requirements

Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

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Revision History:

06/01/2021 – Format updated; no changes to the indications or criteria.

08/01/2022 – Removed Trabecular Micro-Bypass Stent (CPT Codes: 66991, 66989) from retrospective investigational review.

08/01/2024 – Annual Review. Create exclusions section, added drug-eluting devices. Updated references.



Temporomandibular Joint Dysfunction New York

Type of Policy: Surgical

Prior Approval Date: 03/17/2023

Approval Date: 12/02/2024

Effective Date: 04/01/2025

Related Polices: Electromyography and Nerve Conduction

Studies

Botulinum Toxin Treatment Mechanical Stretching Devices

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

CPT Codes:

21010 - Arthrotomy, temporomandibular joint

21050- Condylectomy, temporomandibular joint (separate procedure)

21060- Meniscectomy, partial or complete, temporomandibular joint (separate procedure)

21240- Arthroplasty, temporomandibular joint, with or without autograft (includes obtaining graft)21243- Arthroplasty, temporomandibular joint, with prosthetic joint replacement

21480- Medial canthopexy (separate procedure)

21485-Closed treatment of temporomandibular dislocation; complicated (eg, recurrent requiring intermaxillary fixation or splinting), initial or subsequent

21490-Open treatment of temporomandibular dislocation

29800- Arthroscopy, temporomandibular joint, diagnostic, with or without synovial biopsy (separate procedure)

29804- Arthroscopy, temporomandibular joint, surgical

Codes Requiring Retrospective Review

N/A

Experimental/Investigational

N/A

Common Diagnosis Codes

ICD-10- CM Diagnosis Codes: M26.60, M26.61, M26.62, M26.63, M26.69

Common Procedure Code:

D7880 - Occlusal orthotic device, includes splints provided for treatment of temporomandibular joint dysfunction

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

Temporomandibular joint dysfunction is currently divided into three categories: myofascial pain-dysfunction syndrome, internal derangement, and degenerative joint disease. Myofascial pain-dysfunction is considered the most common cause of temporomandibular joint pain. Myofascial pain-dysfunction is thought to primarily involve the muscles of mastication. Internal derangement is defined as an abnormal relationship of the articular disc to the mandibular condyle, fossa and articular eminence. Degenerative joint disease is the organic degeneration of the articular surfaces within the temporomandibular joint. It is secondary to micro or macro trauma, infection and meniscal misalignment.

In order to evaluate a temporomandibular joint disorder, a relevant clinical examination is necessary. This will include a medical history review, physical examination, and imaging. Diagnostic testing may include CT, MRI, arthroscopy, panagraphs, plain films, or a dental cast study.

Indications/Criteria

Non-surgical Treatment

Non-surgical treatment of temporomandibular disorders will be considered medically necessary when a severe functional impairment is present and documented in the

medical record. Severe functional impairment is defined as the presence of one or more of the following symptoms:

- nutritional impairment requiring the customer to subsist on a soft dental diet;
- earaches;
- headaches;
- masticatory myalgia;
- clicking or popping of the joint;
- locking of the joint;
- crepitus;
- restriction of masticating function;
- restriction of jaw motion; or
- temporomandibular joint dysfunction in childhood related to congenital disease or anomaly.

Non-Surgical treatment options include:

- patient education (dietary recommendations, jaw rest, control of parafunctional habits e.g., bruxism, clenching and rocking of teeth, using teeth for tools);
- pharmacological pain control;
- physical medicine (PT, chiropractic, massage, heat, cold, ultrasound, NSAIDS, corticosteroids);
- intra-oral appliances (occlusal orthotic devices and splints for TMJ) are a covered Durable Medical Equipment (DME) benefit (Code D7880);
- intracapsular diagnostic and therapeutic injections.

All other non-surgical treatment options are considered experimental.

Surgical Treatment

Surgical treatment of temporomandibular joint disorder will be considered medically necessary when all of the following criteria have been met:

- there is documentation of physical examination and diagnostic imaging having confirmed the presence of disease; and
- the condition has been determined to be medical in nature (e.g., internal joint derangement, degenerative joint disease, tumor, cyst, or fracture); and
- the condition is refractory to non-surgical treatment for at least six (6) months.

Surgical treatment options include:

- arthrocentesis;
- arthroscopy;
- arthroplasty or arthrotomy; and
- prosthetic joint replacement.

All other surgical treatment options are considered experimental.

Diagnostic Procedures

The following diagnostic procedures may be considered medically necessary in the diagnosis of TMJ dysfunction when criteria in this policy have been met:

- x-ray, tomograms, and arthrograms;
- computed tomography (CT) scan or magnetic resonance imaging (MRI) for presurgical evaluations;
- cephalograms (x-rays of the jaws and skull);
- pantograms (x-rays of the maxilla and mandible).

Exclusions

- Requests not meeting Indications/Criteria stated in this policy.
- Botulinum toxin e.g., onabotulinumtoxinA (BOTOX®), abobotulinumtoxinA (DYSPORT™), rimabotulinumtoxinB (MYOBLOC®), and incobotulinumtoxinA (XEOMIN®), have not been proven to be safe and effective for use in TMJ disorders, have not been approved by the FDA for use in TMJ disorders, and medical necessity is not supported in the MVP pharmaceutical compendium for the treatment of TMJ disorders.^[8]
- Symptoms that are consistent with TMJ can be related to either dental or medical etiology. Those that are not associated with defined pathology of the temporomandibular joint are considered dental in nature and are not covered.
- All charges, including hospitalization and anesthesia, incurred in connection with non-covered dental related services are not covered.

The following procedures are not covered (This list is not all-inclusive.):

- electromyography or surface electromyography. (Refer to the MVP Medical Policy Electromyography and Nerve Conduction Studies);
- jaw tracking with oral magnets;
- transcranial or lateral skull x-ray;
- sonography;
- thermography;

- silent period duration studies;
- orthodontic treatment, crowns and bridges;
- insertion of silastic implants;
- intra-oral tracing or gothic arch tracing to document deviations in jaw positioning;
- grinding down of teeth;
- biofeedback;
- dental devices for joint range of motion or for development of muscles used in jaw function;
- dental prostheses/procedures (e.g., crowns, implants, dentures, extraction of wisdom teeth);
- low level light therapy;
- trigger point injections for myofascial pain
- tooth extractions; and
- microcurrent electrical therapy for the treatment of TMJ.

Medicare Variation

There are a wide variety of conditions that can be characterized as TMJ, and an equally wide variety of methods for treating these conditions. Many of the procedures fall within the Medicare program's statutory exclusion that prohibits payment for items and services that have not been demonstrated to be reasonable and necessary for the diagnosis and treatment of illness or injury (§1862(a)(1) of the Act). Other services and appliances used to treat TMJ fall within the Medicare program's statutory exclusion at 1862(a)(12), which prohibits payment "for services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth...." For these reasons, a diagnosis of TMJ on a claim is insufficient. The actual condition or symptom must be determined.

Dental Services or Oral Surgery, rendered by a physician or dental professional, for treatment of primarily a medical condition are covered. The dental procedures are not covered. Examples of these non-covered services are items and services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting the teeth.

Examples of covered services include but are not limited to: Setting of the jaw or facial bones, wiring of teeth when performed in connection with the reduction of a jaw fracture.

Dental Splints (D7880) occlusal orthotic device or splints for TMJ are a covered Durable Medical Equipment (DME) benefit.

Based upon review, there is no Medicare National Coverage Determination (NCD) or Local Coverage Determination (LCD) or Article specifically addressing temporomandibular joint dysfunction (TMJ).

See the Medicare Benefit Policy Manual, Chapter 15, §150 – Dental Services and §150.1 – Treatment of Temporomandibular Joint (TMJ) Syndrome for coverage information: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf

References (Updated 2025)

- 1. Al-Moraissi EA, Wolford LM, Ellis E 3rd, Neff A. The hierarchy of different treatments for arthrogenous temporomandibular disorders: A network meta-analysis of randomized clinical trials. J CraniomaxillofacSurg. 2020 Jan;48(1):9-23.
- 2. Al-Moraissi EA. Arthroscopy versus arthrocentesis in the management of internal derangement of the temporomandibular joint: a systematic review and meta-analysis. Int J Oral Maxillofac Surg. 2015 Jan;44(1):104-12.
- 3. American Academy of Pediatric Dentistry (AAPD). Acquired temporomandibular disorders in infants, children, and adolescents. The Reference Manual of Pediatric Dentistry. Chicago, Ill.: American Academy of Pediatric Dentistry; 2020:410-7.
- 4. American Association for Dental, Oral, and Craniofacial Research (AADOCR). Policy Statement: Temporomandibular Disorders (TMD). Reaffirmed 2015. Accessed October 12, 2021. Available at URL address: https://www.iadr.org/
- 5. American Association of Oral and Maxillofacial Surgeons (AAOMS). Clinical Condition Statements. Temporomandibular Disorders. 2017b. Accessed February 9, 2022. Available at URL address: https://www.aaoms.org/practice-resources/aaoms-advocacy-and-position-statements/clinical-resources
- 6. American Association of Oral and Maxillofacial Surgeons. Guidelines to the Evaluation of Impairment of the Oral and Maxillofacial Region. 2018.
- 7. Fleury B, Lowe AA. Current barriers and study needs for oral appliance therapy: The personal perspective of a physician and dentist. Journal of Dental Sleep Medicine. 2016; June; 3(3). http://dx.doi.org/10.15331/jdsm.4138.
- 8. Fricton J, Look JO, Wright E. et al. Systematic Review and Meta-analysis of Randomized Controlled Trials Evaluating Intraoral orthopedic Appliances for Temporomandibular Disorders. University of Minnesota School of Dentistry, Minneapolis Minnesota 55455, USA. J Orofac Pain, 2010 Summer; 24(3):237-54.
- 9. HAYES Health Technology Brief. Microcurrent Electrical Therapy For The Treatment Of Musculoskeletal Pain. HAYES, Inc.; © 2021 Hayes, a symplr company.. October 26, 2018; Annual Review January 21, 2021. Archived November 26, 2021.

- 10. Koh, H., Robinson, P.G. Occlusal adjustment for treating and preventing temporomandibular joint disorders (Cochrane Methodology Review). In: The Cochrane Library, Issue 4, 2003. Chichester, UK: John Wiley & Sons, Ltd.
- 11. Martinez-Gomis J, Willaert E, Nogues L, et al. Five years of sleep apnea with a mandibular advancement device. Angle Orthodontist. 2010; 80(1):30-36.
- 12. Napankangas R, Raunio A, Sipila K, Raustia A. Effect of mandibular advancement device therapy on the signs and symptoms of temporomandibular disorders. J Oral Maxillofac Res. 2012; Oct-Dec; 3(4): e5. doi: 10.5037/jomr.2012.3405
- 13. National Institutes of Health (NIH), National Institute of Dental and Craniofacial Research. TMD Disorders. Health Topics: TMD (Temporomandibular Disorders). January 2022. Bethesda, MD. Available at: www.nidcr.nih.gov/OralHealth/Topics/TMJ/TMJDisorders.htm
- 14. Petit F-X, Pepin J-L, Bettega G, et al. Mandibular advancement devices: Rate of contraindications in 100 consecutive obstructive sleep apnea patients. American Journal of Respiratory and Critical Care Medicine. 2002; 166(3): 274-278.
- 15. U.S. Food and Drug Administration (FDA). Drugs@FDA: FDA Approved Drug Products. Label and Approval History. Botox. Approved on 01/18/2013. Available: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process-84pplNo=103000

Customer Product	Medical Management Requirements*	
New York Products	-	
HMO	Prior Auth	
PPO in Plan	Prior Auth	
PPO OOP	Prior Auth	
POS in Plan	Prior Auth	
POS OOP	Prior Auth	
Essential Plan	Prior Auth	
MVP Medicaid Managed Care	Prior Auth	
MVP Child Health Plus	Prior Auth	
MVP Harmonious Health Care Plan	Prior Auth	
MVP Medicare Complete Wellness	Prior Auth	
MVP Medicare Preferred Gold HMO POS	Prior Auth	
MVP Medicare Secure HMO POS	Prior Auth	
MVP Medicare Secure Plus HMO POS		
MVP Medicare WellSelect PPO	Prior Auth	
	Prior Auth	
MVP Medicare WellSelect Plus PPO	Prior Auth	
MVP Medicare Patriot Plan PPO	Prior Auth	
MVP DualAccess D-SNP HMO	Prior Auth	
MVP DualAccess Complete D-SNP HMO	Prior Auth	
MVP DualAccess Plus D-SNP HMO	Prior Auth	
UVM Health Advantage Select PPO	Prior Auth	
USA Care PPO	Potential for Retrospective Review	
Healthy NY	Prior Auth	
MVP Premier	Prior Auth	
MVP Premier Plus	Prior Auth	
MVP Premier Plus HDHP	Prior Auth	
MVP Secure	Prior Auth	
MVP EPO	Prior Auth	
MVP EPO HDHP	Prior Auth	
MVP PPO	Prior Auth	
MVP PPO HDHP	Prior Auth	
Student Health Plans	Prior Auth	
ASO	See SPD	
Vermont Products		
POS in Plan	NA	
POS OOP	NA	
MVP Medicare Preferred Gold HMO POS	NA	
MVP Medicare Secure Plus HMO POS	NA NA	
MVP VT HMO	NA NA	
MVP VT HDHP HMO	NA NA	
MVP VT Plus HMO	NA NA	
MVP VT Plus HDHP HMO	NA NA	
MVP Secure	NA	

[♦] Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Revision History

08/01/2022 – No changes to the indications or criteria. Added descriptions to procedures codes. Updated references and websites.

04/01/2023 – Removed prior authorization from D7880 – oral appliance/splint for TMJ.

04/01/2025 - Medical Policy Task Force (MPTF) annual review, added examples of covered conditions and surgical options, added Medicare references, updated references.



Temporomandibular Joint Dysfunction Vermont

Type of Policy: Surgical

Prior Approval Date: 03/17/2023

Approval Date: 12/02/2024

Effective Date: 04/01/2025

Related Polices: Botulinum Toxin Treatment

Mechanical Stretching

Devices

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

CPT Codes:

21010 - Arthrotomy, temporomandibular joint

21050 - Condylectomy, temporomandibular joint (separate procedure)

21060 - Meniscectomy, partial or complete, temporomandibular joint (separate procedure)

21240 - Arthroplasty, temporomandibular joint, with or without autograft (includes obtaining graft)

21243 - Arthroplasty, temporomandibular joint, with prosthetic joint replacement

21480 - Medial canthopexy (separate procedure)

21485 - Closed treatment of temporomandibular dislocation; complicated (eg, recurrent requiring intermaxillary fixation or splinting), initial or subsequent

21490 - Open treatment of temporomandibular dislocation

29800 - Arthroscopy, temporomandibular joint, diagnostic, with or without synovial biopsy (separate procedure)

29804 - Arthroscopy, temporomandibular joint, surgical

Codes Requiring Retrospective Review

N/A

Experimental/Investigational

Experimental codes are not covered.

N/A

Common Diagnosis Codes

ICD-10- CM Diagnosis Codes: M26.60, M26.61, M26.62, M26.63, M26.69

Common Procedure Code

D7880 - Occlusal orthotic device, includes splints provided for treatment of temporomandibular joint dysfunction

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

Temporomandibular joint dysfunction is currently divided into three categories: myofascial pain-dysfunction syndrome, internal derangement, and degenerative joint disease. Myofascial pain dysfunction is considered the most common cause of temporomandibular joint pain. Myofascial pain dysfunction is thought to primarily involve the muscles of mastication. Internal derangement is defined as an abnormal relationship of the articular disc to the mandibular condyle, fossa and articular eminence. Degenerative joint disease (osteoarthritis) is the organic degeneration of the articular surfaces within the temporomandibular joint. It is secondary to micro or macro trauma, infection and meniscal misalignment.

In order to evaluate a temporomandibular joint dysfunction, a relevant clinical examination is necessary. This will include a medical history review, physical examination, and imaging. Diagnostic testing may include CT, MRI, arthroscopy, panagraphs, plain films, or a dental cast study.

Indications/Criteria

MVP will provide coverage for the diagnosis and medically necessary treatment, including surgical and non-surgical procedures for TMJ that is the result of accident, trauma, congenital defect, developmental defect, or pathology. [1, 2, 3]

Non-surgical Treatment

Coverage for non-surgical treatment for temporomandibular joint disorders includes:

- patient education (dietary recommendations, jaw rest, control of parafunctional habits e.g., bruxism, clenching and rocking of teeth, using teeth for tools);
- pharmacological pain control;
- physical therapy;
- chiropractic;
- intra-oral appliances (occlusal orthotic devices and splints for TMJ (Code D7880)) are a covered Durable Medical Equipment (DME) benefit.
- intracapsular diagnostic and therapeutic injections.

Surgical Treatment

Surgical treatment of TMJ will be covered when physical examination/diagnostic imaging has confirmed the presence of joint pathology and/or abnormal joint function and have met one of the following:

- refractory to non-surgical treatment for at least six (6) months;
- dysfunction that is disabling;
- internal derangement (intracapsular) of the TMJ is the source of pain and dysfunction; or
- evidence of a pathological condition such as arthritis, trauma, congenital deformity.

Surgical treatment options include:

- arthrocentesis;
- manipulation for reduction of fracture or dislocation;
- open surgical procedures, including arthroplasty, condylectomy, meniscus or disc placation, and disc removal;
- arthroscopic surgery; or
- prosthetic joint replacement.

Exclusions

Requests not meeting Indications/Criteria stated in this policy.

Botulinum toxin e.g., onabotulinumtoxinA (BOTOX®), abobotulinumtoxinA (DYSPORT™), rimabotulinumtoxinB (MYOBLOC®), and incobotulinumtoxinA (XEOMIN®), have not been proven to be safe and effective for use in TMJ disorders, have not been approved by the FDA for use in TMJ disorders, and medical necessity is not supported in the MVP pharmaceutical compendium for the treatment of TMJ disorders.^[7]

The following procedures are not covered (This list is not all-inclusive):

- electromyography or surface EMG. (Refer to MVP Medical Policy Electromyography (EMG) and Nerve Conduction Studies);
- jaw tracking with oral magnets;
- transcranial or lateral skull x-ray;
- sonography;
- thermography;
- silent period duration studies;
- orthodontic treatment, crowns and bridges;
- insertion of silastic implants;
- intra-oral tracing or gothic arch tracing to document deviations in jaw positioning;
- grinding down of teeth;
- biofeedback;
- dental devices for joint range of motion or for development of muscles used in jaw function;
- dental prostheses/procedures (e.g., crowns, implants, dentures, extraction of wisdom teeth);
- low level light therapy (LLLT);
- trigger point injections for myofascial pain
- tooth extractions; and
- microcurrent electrical therapy for the treatment of TMJ.

Medicare Variation

There are a wide variety of conditions that can be characterized as TMJ, and an equally wide variety of methods for treating these conditions. Many of the procedures fall within the Medicare program's statutory exclusion that prohibits payment for items and services that have not been demonstrated to be reasonable and necessary for the diagnosis and treatment of illness or injury (§1862(a)(1) of the Act). Other services and appliances used to treat TMJ fall within the Medicare program's statutory exclusion at

Temporomandibular Joint Dysfunction Vermont

1862(a)(12), which prohibits payment "for services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth...." For these reasons, a diagnosis of TMJ on a claim is insufficient. The actual condition or symptom must be determined.

Dental Services or Oral Surgery, rendered by a physician or dental professional, for treatment of primarily a medical condition are covered. The dental procedures are not covered. Examples of these non-covered services are items and services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting the teeth.

Examples of covered services include but are not limited to: Setting of the jaw or facial bones, wiring of teeth when performed in connection with the reduction of a jaw fracture.

Dental Splints (D7880) occlusal orthotic device or splints for TMJ are a covered Durable Medical Equipment (DME) benefit.

Based upon review, there is no Medicare National Coverage Determination (NCD) or Local Coverage Determination (LCD) or Article specifically addressing temporomandibular joint dysfunction (TMJ).

See the Medicare Benefit Policy Manual, Chapter 15, §150 – Dental Services and §150.1 – Treatment of Temporomandibular Joint (TMJ) Syndrome for coverage information: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf

References (Updated 2025)

- 1. Al-Moraissi EA, Wolford LM, Ellis E 3rd, Neff A. The hierarchy of different treatments for arthrogenous temporomandibular disorders: A network meta-analysis of randomized clinical trials. J CraniomaxillofacSurg. 2020 Jan;48(1):9-23.
- 2. Al-Moraissi EA. Arthroscopy versus arthrocentesis in the management of internal derangement of the temporomandibular joint: a systematic review and meta-analysis. Int J Oral Maxillofac Surg. 2015 Jan;44(1):104-12.
- 3. American Academy of Pediatric Dentistry (AAPD). Acquired temporomandibular disorders in infants, children, and adolescents. The Reference Manual of Pediatric Dentistry. Chicago, Ill.: American Academy of Pediatric Dentistry; 2020:410-7.
- 4. American Association for Dental, Oral, and Craniofacial Research (AADOCR). Policy Statement: Temporomandibular Disorders (TMD). Reaffirmed 2015. Accessed October 12, 2021. Available at URL address: https://www.iadr.org/
- 5. American Association of Oral and Maxillofacial Surgeons (AAOMS). Clinical Condition Statements. Temporomandibular Disorders. 2017b. Accessed February

- 9, 2022. Available at URL address: https://www.aaoms.org/practice-resources/aaoms-advocacy-and-position-statements/clinical-resources
- 6. American Association of Oral and Maxillofacial Surgeons. Guidelines to the Evaluation of Impairment of the Oral and Maxillofacial Region. 2018.
- 7. Fleury B, Lowe AA. Current barriers and study needs for oral appliance therapy: The personal perspective of a physician and dentist. Journal of Dental Sleep Medicine. 2016; June; 3(3). http://dx.doi.org/10.15331/jdsm.4138.
- 8. Fricton J, Look JO, Wright E. et al. Systematic Review and Meta-analysis of Randomized Controlled Trials Evaluating Intraoral orthopedic Appliances for Temporomandibular Disorders. University of Minnesota School of Dentistry, Minneapolis Minnesota 55455, USA. J Orofac Pain, 2010 Summer; 24(3):237-54.
- HAYES Health Technology Brief. Microcurrent Electrical Therapy For The Treatment Of Musculoskeletal Pain. HAYES, Inc.; © 2021 Hayes, a symplr company.. October 26, 2018; Annual Review January 21, 2021. Archived November 26, 2021.
- 10. Koh, H., Robinson, P.G. Occlusal adjustment for treating and preventing temporomandibular joint disorders (Cochrane Methodology Review). In: The Cochrane Library, Issue 4, 2003. Chichester, UK: John Wiley & Sons, Ltd.
- 11. Legislative Council of the General Assembly for the State of Vermont (2007) §4089q. Craniofacial Disorders.
- 12. Martinez-Gomis J, Willaert E, Nogues L, et al. Five years of sleep apnea with a mandibular advancement device. Angle Orthodontist. 2010; 80(1):30-36.
- 13. Napankangas R, RaunioA, Sipila K, Raustia A. Effect of mandibular advancement device therapy on the signs and symptoms of temporomandibular disorders. J Oral Maxillofac Res. 2012; Oct-Dec; 3(4): e5. doi: 10.5037/jomr.2012.3405
- 14. National Institutes of Health (NIH), National Institute of Dental and Craniofacial Research. TMD Disorders. Health Topics: TMD (Temporomandibular Disorders). January 2022. Bethesda, MD. Available at: www.nidcr.nih.gov/OralHealth/Topics/TMJ/TMJDisorders.htm
- 15. Petit F-X, Pepin J-L, Bettega G, et al. Mandibular advancement devices: Rate of contraindications in 100 consecutive obstructive sleep apnea patients. American Journal of Respiratory and Critical Care Medicine. 2002; 166(3): 274-278.
- 16. U.S. Food and Drug Administration (FDA). Drugs@FDA: FDA Approved Drug Products. Label and Approval History. Botox. Approved on 01/18/2013. Available: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=103000

Customer Product	Medical Management Requirements*	
New York Products	-	
HMO	NA	
PPO in Plan	NA NA	
PPO OOP	NA	
POS in Plan	NA NA	
POS OOP	NA NA	
Essential Plan	NA NA	
MVP Medicaid Managed Care	NA NA	
MVP Child Health Plus	NA NA	
MVP Harmonious Health Care Plan	NA NA	
MVP Medicare Complete Wellness	NA NA	
MVP Medicare Preferred Gold HMO POS	NA NA	
MVP Medicare Secure HMO POS	NA NA	
MVP Medicare Secure Plus HMO POS		
MVP Medicare WellSelect PPO	NA NA	
MVP Medicare WellSelect Plus PPO	NA NA	
MVP Medicare Patriot Plan PPO	NA NA	
	NA NA	
MVP DualAccess D-SNP HMO	NA NA	
MVP DualAccess Complete D-SNP HMO	NA NA	
MVP DualAccess Plus D-SNP HMO	NA NA	
UVM Health Advantage Select PPO	NA	
USA Care	NA NA	
Healthy NY	NA	
MVP Premier	NA	
MVP Premier Plus	NA	
MVP Premier Plus HDHP	NA	
MVP Secure	NA	
MVP EPO	NA	
MVP EPO HDHP	NA	
MVP PPO	NA	
MVP PPO HDHP	NA	
Student Health Plans	NA	
ASO	See SPD	
Vermont Products		
POS in Plan	Prior Auth	
POS OOP	Prior Auth	
MVP Medicare Preferred Gold HMO POS	Prior Auth	
MVP Medicare Secure Plus HMO POS	Prior Auth	
MVP VT HMO	Prior Auth	
MVP VT HDHP HMO	Prior Auth	
MVP VT Plus HMO	Prior Auth	
MVP VT Plus HDHP HMO	Prior Auth	
MVP Secure	Prior Auth	
IVIVE SECTIVE		

[♦] Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Revision History

08/01/2022 - No changes to the indications or criteria. Added descriptions to procedures codes. Updated references and websites.

04/01/2023 - Removed prior authorization from D7880 - oral appliance/splint for TMJ.

04/01/2025 - annual review, added examples of covered conditions and surgical options, added examples of non-surgical treatment, added Medicare references, updated references.



Therapeutic Footwear for Diabetics

Type of Policy: DME

Prior Approval Date: 10/03/2022

Approval Date: 09/14/2023

Effective Date: 12/01/2023

Related Polices: Orthotic Devices

Durable Medical Equipment

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

N/A

Codes Subject to Retrospective Review

HCPCS Codes:

A5508 - For diabetics only, deluxe feature of off-the-shelf depth-inlay shoe or custom molded shoe, per shoe

A5510 - For diabetics only, direct formed, compression molded to patient's foot without external heat source, multiple-density insert(s) prefabricated, per shoe

Experimental/Investigational

N/A

Common Diagnosis Codes

N/A

Common Procedure Codes

CPT Codes: A5500, A5501, A5503, A5504, A5505, A5506, A5507, A5512, A5513, A5514

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-Therapeutic Footwear for Diabetics

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authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy.

Overview

Therapeutic diabetic shoes, also known as diabetic footwear, are specialized shoes designed to provide support and protection from the risk of skin breakdown for customers with diabetes. These shoes are specifically engineered to address the unique foot related complications that can arise from diabetes, such as poor circulation, neuropathy (nerve damage), foot deformities, and increased risk of foot ulcers.

Depth shoes and custom molded shoes are some key features and benefits of therapeutic diabetic shoes.

No contract rider is necessary for coverage of therapeutic footwear for diabetics.

Therapeutic footwear for diabetics is only allowed when billed using the following procedure codes:

A5500, A5501, A5503, A5504, A5505, A5506, A5507, A5512, A5513, A5514 For foot orthotics coverage, refer to MVP Orthotic Devices medical policy.

Indications/Criteria for all MVP Plans (Commercial, Medicare Advantage (MA) and Medicaid Managed Care (MMC):

Therapeutic shoe inserts or modifications to therapeutic shoes are considered medically necessary if the following criteria are met:

- A. The customer has diabetes mellitus; and
- B. The customer has one or more of the following conditions:
 - 1. previous amputation of the other foot or part of either foot;
 - 2. history of previous foot ulceration of either foot;
 - 3. history or pre-ulcerative calluses of either foot;
 - 4. peripheral neuropathy with evidence of callus formation of either foot;
 - 5. foot deformity of either foot; or
 - 6. poor circulation in either foot.
- C. The medical practitioner (podiatrist, M.D., D.O., physician assistant, nurse practitioner, or clinical nurse specialist) who is managing the customer's systemic diabetes condition has certified that indications (A) and (B) above are met and that they are treating the customer under a comprehensive plan of care for their diabetes and that the customer needs therapeutic shoe inserts or modifications to therapeutic shoes.

Coverage is limited to one of the following within one calendar year:

- A. one pair of depth shoes (A5500) and three (3) pairs of inserts (A5512, A5513 or A5514); or
- B. one pair of custom molded shoes, which includes inserts (A5501) and two (2) additional pairs of inserts (A5512, A5513 or A5514).

A custom molded shoe (A5501) is indicated when the patient has a foot deformity that cannot be accommodated by a depth shoe.

Shoes are also covered if they are an integral part of a covered leg brace. However, different codes are used for footwear provided under this benefit.

Exclusions

- Not meeting criteria under Indications/Criteria in this policy.
- Inserts used with non-covered shoes are not covered.
- Items represented by code A5510 reflect compression molding to the beneficiary's foot over time through the heat and pressure generated by wearing a shoe with the insert present. Since these inserts are not considered total contact at the time of dispensing, they do not meet the requirements of the benefit category and will be denied as not covered.
- Deluxe features of diabetic shoes (A5508) will be denied as not covered. Deluxe features (A5508) do not contribute to the therapeutic function of the shoe. It may include, but is not limited to style, color, or type of leather.

MVP Medicaid Managed Care Variation

Coverage is limited to one pair of diabetic shoes and inserts per year.

Providers bill 1 unit per shoe (max 2 units every calendar year) for a total of 1 pair per year of diabetic shoes and inserts (A5500, A5501, A5503, A5504, A5505, A5506, A5507, A5512, A5513, A5514), regardless of age.

References (Updated 2023)

- 1. Noridian Healthcare Solutions. Local Coverage Determination (LCD) for Therapeutic Shoes for Persons with Diabetes (L33369) Revision Effective Date:01/01/2020. Available: https://med.noridianmedicare.com/web/jddme/policies/lcd/active.
- 2. Noridian Healthcare Solutions. Local Coverage Article for Therapeutic Shoes for Persons with Diabetes (A52501) Revision Effective Date: 01/01/2020. Available: https://med.noridianmedicare.com/web/jddme/policies/lcd/active.
- New York State Department of Health. New York State Medicaid Update. Important Notice. December 2013: Notice to Medicaid beneficiaries regarding Medicaid coverage of orthopedic footwear and compression stockings Effective 12/09/13. Available: https://www.health.ny.gov/health-care/medicaid/program/update/2013/noticejan2-013.htm.

4. New York State Medicaid Program. Durable Medical Equipment Orthotics, Prosthetics, and Supplies. Procedure Codes and Coverage Guidelines. Version 2023 (04/01/2023) Available: www.emedny.org/ProviderManuals/index.html.

Customer Product	Medical Management Requirements*		
New York Products			
HMO	Retrospective Review		
PPO in Plan	Retrospective Review		
PPO OOP	Retrospective Review		
POS in Plan	Retrospective Review		
POS OOP	Retrospective Review		
Essential Plan	Retrospective Review		
MVP Medicaid Managed Care	Retrospective Review		
MVP Child Health Plus	Retrospective Review		
MVP Harmonious Health Care Plan	Retrospective Review		
MVP Medicare Complete Wellness	Retrospective Review		
MVP Medicare Preferred Gold HMO POS	Retrospective Review		
MVP Medicare Secure HMO POS	Retrospective Review		
MVP Medicare Secure Plus HMO POS	Retrospective Review		
MVP Medicare WellSelect PPO	Retrospective Review		
MVP Medicare WellSelect Plus PPO	Retrospective Review		
MVP Medicare Patriot Plan PPO	Retrospective Review		
MVP DualAccess D-SNP HMO	Retrospective Review		
MVP DualAccess Complete D-SNP HMO	Retrospective Review		
MVP DualAccess Plus D-SNP HMO	Retrospective Review		
UVM Health Advantage Select PPO	Retrospective Review		
USA Care PPO	Potential for Retrospective Review		
Healthy NY	Retrospective Review		
MVP Premier	Retrospective Review		
MVP Premier Plus	Retrospective Review		
MVP Premier Plus HDHP	Retrospective Review		
MVP Secure	Retrospective Review		
MVP EPO	Retrospective Review		
MVP EPO HDHP	Retrospective Review		
Student Health Plans	Retrospective Review		
ASO	See SPD		
Vermont Products			
POS in Plan	Retrospective Review		
POS OOP	Retrospective Review		
MVP Medicare Preferred Gold HMO POS	Retrospective Review		
MVP Medicare Secure Plus HMO POS	Retrospective Review		
MVP VT HMO	Retrospective Review		
MVP VT HDHP HMO	Retrospective Review		
MVP VT Plus HMO	Retrospective Review		
MVP VT Plus HDHP HMO	Retrospective Review		
MVP Secure	Retrospective Review		
ASO	See SPD		
,	500 51 5		

[♦] Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

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MVP Health Care Medical Policy Revision History:

12/01/2022 – Annual review with changes reflect an in-person visit within 6 months is required to be consistent with Medicare ACD and NYS Medicaid manual. Added coverage criteria to Medicaid Managed Care variation.

12/01/2023 – Removed prescribing and supplier requirements. Expanded certifying medical practitioner eligibility. Removed 6 month visit requirement. Overview rewritten.



Tissue-Engineered Skin (and other) Substitutes

Type of Policy: Medical

Prior Approval Date: 04/01/2024

Approval Date: 12/04/2024

Effective Date: 04/01/2025

Related Polices: None

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

N/A

Codes Requiring Retrospective Review

A2022, A2023, A2024, A2025, A2027, A2028, A2029, Q4112, Q4113, Q4114, Q4115, Q4117, Q4118, Q4125, Q4126, Q4127, Q4130, Q4134, Q4135, Q4136, Q4137, Q4138, Q4139, Q4140, Q4141, Q4142, Q4143, Q4145, Q4146, Q4147, Q4148, Q4149, Q4150, Q4152, Q4153, Q4155, Q4156, Q4157, Q4158, Q4159, Q4160, Q4161, Q4162, Q4163, Q4164, Q4165, Q4166, Q4167, Q4168, Q4169, Q4170, Q4171, Q4173, Q4174, Q4175, Q4176, Q4177, Q4178, Q4179, Q4180, Q4181, Q4183, Q4184, Q4188, Q4189, Q4190, Q4191, Q4192, Q4193, Q4194, Q4195, Q4196, Q4197, Q4198, Q4200, Q4201, Q4202, Q4203, Q4204, Q4205, Q4206, Q4208, Q4209, Q4210, Q4211, Q4212, Q4213, Q4214, Q4215, Q4216, Q4217, Q4218, Q4219, Q4220, Q4221, Q4222, Q4226, Q4227, Q4228, Q4229, Q4230, Q4231, Q4232, Q4233, Q4234, Q4235, Q4236, Q4237, Q4238, Q4239, Q4240, Q4241, Q4242, Q4244, Q4245, Q4246, Q4247, Q4248, Q4249, Q4250, Q4251, Q4252, Q4253, Q4254, Q4255, Q4256, Q4257, Q4258, Q4259, Q4260, Q4261, Q4272, Q4273, Q4274, Q4275, Q4276, Q4277, Q4278, Q4279, Q4280, Q4281, Q4282, Q4283, Q4284, Q4285, Q4286, Q4287, Q4288, Q4299, Q4290, Q4291, Q4292, Q4293, Q4294, Q4295, Q4296, Q4297, Q4298, Q4299, Q4200, Q4201, Q4201, Q4202, Q4204, Q4274, Q4275, Q4276, Q4277, Q4278, Q4279, Q4280, Q4281, Q4282, Q4283, Q4284, Q4285, Q4286, Q4287, Q4288, Q4299, Q4290, Q4291, Q4292, Q4293, Q4294, Q4295, Q4296, Q4297, Q4298, Q4299, Q4300, Q4301, Q4302, Q4303, Q4304, Q4305, Q4395, Q4296, Q4297, Q4298, Q4299, Q4300, Q4301, Q4302, Q4303, Q4304, Q4305, Q4305, Q4304, Q4305, Q4

Q4306, Q4307, Q4308, Q4309, Q4310, Q4311, Q4312, Q4313, Q4314, Q4315, Q4316, Q4317, Q4318, Q4319, Q4320, Q4321, Q4322, Q4323, Q4324, Q4325, Q4326, Q4327, Q4328, Q4329, Q4330, Q4331, Q4332, Q4333, Q4334, Q4335, Q4336, Q4337, Q4338, Q4339, Q4340, Q4341, Q4342, Q4343, Q4344, Q4345, 0232T, G0460, 64910

Experimental/Investigational

A2011, A2012, A2013, A2019, A2020, A2021, A2022, A2023, A2024, A2025, A2027, A2028, A2029, A2030, A2031, A2032, A2033, A2034, A2035, A4100, C1849, Q4112, Q4113, Q4114, Q4115, Q4117, Q4118, Q4125, Q4126, Q4127, Q4130, Q4134, Q4135, Q4136, Q4137, Q4138, Q4139, Q4140, Q4141, Q4142, Q4143, Q4145, Q4146, Q4147, Q4148, Q4149, Q4150, Q4152, Q4153, Q4155, Q4156, Q4157, Q4158, Q4159, Q4160, Q4161, Q4162, Q4163, Q4164, Q4165, Q4166, Q4167, Q4168, Q4169, Q4170, Q4171, Q4173, Q4174, Q4175, Q4176, Q4177, Q4178, Q4179, Q4180, Q4181, Q4183, Q4184, Q4188, Q4189, Q4190, Q4191, Q4192, Q4193, Q4194, Q4195, Q4196, Q4197, Q4198, Q4200, Q4201, Q4202, Q4203, Q4204, Q4205, Q4206, Q4208, Q4209, Q4210, Q4211, Q4212, Q4213, Q4214, Q4215, Q4216, Q4217, Q4218, Q4219, Q4220, Q4221, Q4222, Q4224, Q4225, Q4226, Q4227, Q4228, Q4229, Q4230, Q4231, Q4232, Q4233, Q4234, Q4235, Q4236, Q4237, Q4238, Q4239, Q4240, Q4241, Q4242, Q4244, Q4245, Q4246, Q4247, Q4248, Q4249, Q4250, Q4251, Q4252, Q4253, Q4254, Q4255, Q4256, Q4257, Q4258, Q4259, Q4260, Q4261, Q4262, Q4263, Q4264, Q4265, Q4266, Q4267, Q4268, Q4269, Q4270, Q4271, Q4272, Q4273, Q4274, Q4275, Q4276, Q4277, Q4278, Q4279, Q4280, Q4281, Q4282, Q4283, Q4284, Q4285, Q4286, Q4287, Q4288, Q4289, Q4290, Q4291, Q4292, Q4293, Q4294, Q4295, Q4296, Q4297, Q4298, Q4299, Q4300, Q4301, Q4302, Q4303, Q4304, Q4305, Q4306, Q4307, Q4308, Q4309, Q4310, Q4334, Q4335, Q4336, Q4337, Q4338, Q4339, Q4340, Q4341, Q4342, Q4343, Q4344, Q4345, Q4354, Q4355, Q4356, Q4357, Q4358, Q4359, q4360, Q4361, Q4362, Q4363, Q4364, Q4365, Q4366, Q4367, 0232T, G0460, 64910

Common Procedure Codes

15271, 15272, 15273, 15274, 15275, 15276, 15277, 15278, 64911, 64912, 64913, Q4100, Q4101, Q4102, Q4103, Q4104, Q4105, Q4106, Q4107, Q4108, Q4110, Q4111, Q4116, Q4121, Q4122, Q4123, Q4124, Q4128, Q4132, Q4133, Q4151, Q4154, Q4182, Q4187

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

A wide variety of wound care products are available for clinicians to use when treating chronic wounds and during breast reconstruction. Many of these products propose to mimic or substitute some aspect of the skin's structure and function to promote healing and wound closure. Tissue-engineered skin substitutes are cellular or acellular matrices and can be derived from human tissue (autologous or allogeneic), nonhuman tissue (xenographic), synthetic materials or a composite of these materials. Cellular products contain living cells such as fibroblasts and keratinocytes with a matrix. The cells may be allogeneic (i.e., obtained from another individual) or autologous (i.e., from the same individual). Some products are derived from other species (i.e., bovine) are referred to as a xenograft. The skin substitutes can be used as either temporary or permanent wound coverings (Ho, et al., 2005; Sibbald, et al., 2005).

Indications/Criteria

The safety and efficacy of the skin substitutes listed below are supported by the evidence in the published peer reviewed scientific literature and/or proven to be medically effective and medically appropriate for the treatments indicated:

- A. Apligraf® (Q4101) or Oasis ™ Wound Matrix (Q4102) are considered medically necessary for wound healing of chronic, non-infected, partial and full-thickness venous stasis ulcers.
- B. AmnioBand® (Q4151), Apligraf® (Q4101), Biovance (Q4154), Dermagraft® (Q4106), Oasis™ Wound Matrix (Q4102), Omnigraft™ (Q4105), Grafix® (Q4132, Q4133), GraftJacket® (Q4107), TheraSkin® (Q4121), Epifix (Q4186) or Epicord (Q4187) may be used for the treatment of full-thickness neuropathic diabetic foot ulcers.
- C. AlloDerm® (Q4116), AlloMax™(Q4100), Cortiva™(Q4100), DermACELL AWM™ (Q4122), DermaMatrix™ (Q4100), GraftJacket NOW™ (Q4107) FlexHD® (Q4128) are medically necessary for breast reconstruction surgery following surgical mastectomy.
- D. Biobrane® (Q4100), Epicel® (Q4100), Integra® (Q4105) Dermal Regeneration Template, Oasis™(Q4103) or Transcyte® (Q4182) are medically necessary for temporary covering of superficial partial-thickness burn wounds, full thickness and deep partial-thickness burn wounds.

Exclusions

Nerve Repair, Synthetic Conduit (CPT Code: 64910, 64999)

There is insufficient evidence in the peer-reviewed literature that nerve repair with synthetic conduit or vein allograft (e.g., nerve tube) such as the NeuraGen Nerve Guide, the NeuraWrap Nerve Protector, Neuromatrix collagen nerve cuff, and NeuroMend collagen nerve wrap) are safe or effective and are, therefore, considered experimental and investigational.

All other tissue engineered skin substitutes:

Acesso

Based upon the lack of peer-reviewed literature, all other tissue engineered skin substitutes are considered investigational because the clinical value for this indication has not been established in peer-reviewed medical literature. These products include, but are not limited to, the following:

Abiomend	AmnioTX	Cymetra ®
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Abiomend XPlus Amnio Wound Cytal

ACAPatch Architect DermaBind FM

Acesso AC Artacent DermaSpan™

ArdeoGraf

Affinity Artacent Velos DuoAmnion

Allacor P Artacent Vericlen DurmaPure

AllopatchHD Artacent wound DurmaVest

alloPLY ArthroFlex™ E-Graft

AlloSkin Axolotl DualGraft EpiFix, injectable

AlloSkin AC Axolotl Graft EpiXpress

AlloWrap DS Bio-ConneKt wound Excellagen
AmchoPlast matrix E-Z Derm™

AmchoPlast FD BioDExcel Foundation DRS Solo

American Amnion BioDFence FlowerAmnioFlo

AmnioArmor BioDFence DryFlex FlowerAmnioPatch

Amnio Burgeon BioDMatrix FlowerDerm

Amnio Burgeon Dual- BioSkin Genesis Amniotic

Layer Caregra FT Membrane

Amnio Burgeon Cellesta Graftjacket xpress®

XMembrane Chloriply Guardian
Amnio Burgeon XPlus Clarix Helicoll

Amniocore SL Coll-e-Derm HMatrix

AmnioExcel Corplex P Hyalomatrix

AmnioExcel Plus Cygnus Integra flowable wound

AmnioMatrix Cygnus Disk matrix™

Dermacyte AC

InteguPly[™] PelloGraft Talymed®

Interfyl Plurivest Tensix

Keramatrix Procenta Theracor P

Kerecis Omega3 ProMatrX TheraMend

Matrion PuraPly TOTAL

MatriStem Reeva FT Transcyte

Matrix HD RegeneLink Amniotic TranZgraft

Mediskin Membrane Allograft Tri-Membrane Wrap

MemoDerm[™] RenoGraft Truskin

Micro3D Repriza™ Vendaje

Miroderm Restorigin Via Matrix

Mirodry Revita VIM

MOST Revitalon VitoGraft

Myriad Matrix SanoGraft WoundEx

Myriad Morcells Sanopelis WoundPlus

NeoPatch SimpliGraft XCM biologic tissue

Neox SimpliMax matrix

Neox Cord Singlay XWRAP

Novachor SkinTE XWRAP DUAL

Nushield Strattice TM XWRAP PLUS

PalinGen Stravix Zenith Amniotic

PalinGen Dual-Layer StravixPL

Membrane Surgigraft

Medicaid Variation

Nerve Repair (64910, 64912, 64913, 64999, various products)

There is insufficient evidence in the peer-reviewed literature that nerve repair with synthetic conduit or vein allograft (e.g., nerve tube) (CPT Code 64910) such as the NeuraGen Nerve Guide, the NeuraWrap Nerve Protector, Neuromatrix collagen nerve cuff, and NeuroMend collagen nerve wrap) are safe or effective and are, therefore, considered experimental and investigational.

Membrane

Nerve repair using nerve grafts (CPT Code 64912, 64913) are not covered under the NYS Medicaid program.

References (Updated 2024)

- Agency for Healthcare Research and Quality. Skin substitutes for treating chronic wounds. Technology assessment. 2012 Dec 18. Available: <u>Skin Substitutes for Treating Chronic Wounds - Technology Assessment; Final Report December 18, 2012. (ahrq.gov)</u> accessed 1/16/18.
- 2. Aldekhayel SA, et al. Acellular dermal matrix in cleft palate repair: an evidence-based review. Plast Reconstr Surg 2012 Jul;130(1):177-82.
- 3. American Society of Plastic Surgeons. Evidence-based clinical practice guideline: breast reconstruction with expanders and implants. 2013. Available: <u>guideline-2013-breast-recon-expanders-implants.pdf</u> (plasticsurgery.org)
- 4. Ball JF, et al. A direct comparison of porcine (Strattice[™]) and bovine (Surgimend[™]) acellular dermal matrices in implant-based immediate breast reconstruction. J Plast Reconstr Aesthet Surg. 2017 Aug;70(8):1076-1082.
- 5. Beers PJ, et al. Porcine tri-layer wound matrix for the treatment of stage IV pressure ulcers. JAAD Case Rep. 2016 Mar 4;2(2):122-4. doi: 10.1016/j.jdcr.2016.01.001.
- 6. Bianchi C, et al. A multicentre randomised controlled trial evaluating the efficacy of dehydrated human amnion/chorion membrane (EpiFix®) allograft for the treatment of venous leg ulcers. Int Wound J. 2018 Feb;15(1):114-122.
- 7. Dasgupta A, et al. A Novel Reticular Dermal Graft Leverages Architectural and Biological Properties to Support Wound Repair. Plast Reconstr Surg Glob Open. 2016 Oct 4;4(10):e1065.
- 8. DiDomenico, L. A. DPM et.al, Aseptically Processed Placental Membrane Improves Healing of Diabetic Foot Ulcerations: Prospective, Randomized Clinical Trial, Plast Reconstr Surg, 2016 Oct; 4(10): e1095. Published online 2016 Oct 12.
- 9. DiDomenico LA, et al. A Retrospective Crossover Study of the Use of Aseptically Processed Placental Membrane in the Treatment of Chronic Diabetic Foot Ulcers. Wounds. 2017 Jul 26. pii: WNDS20170726-2.
- 10. Driver VR, et al. A clinical trial of Integra Template for diabetic foot ulcer treatment. Wound Repair Regen 2015 Nov 12;23(6):891-900.
- 11. Dunn JC, Tadlock J, Klahs KJ, Narimissaei D, McKay P, Nesti LJ. Nerve Reconstruction Using Processed Nerve Allograft in the U.S. Military. Mil Med. 2021 May 3;186(5-6):e543-e548.

- 12. Everts PA, Jakimowicz JJ, van Beek M, Schönberger JP, Devilee RJ, Overdevest EP, Knape JT, van Zundert A. Reviewing the structural features of autologous platelet-leukocyte gel and suggestions for use in surgery. Eur Surg Res. 2007; 39(4):199-207.
- 13. Fleshman JW, et al; PRISM Study Group. A prospective, multicenter, randomized, controlled study of non-cross-linked porcine acellular dermal matrix fascial sublay for parastomal reinforcement in patients undergoing surgery for permanent abdominal wall ostomies. Dis Colon Rectum 2014 May;57(5):623-31.
- 14. Guest JF, et al. Cost-effectiveness of using adjunctive porcine small intestine submucosa tri-layer matrix compared with standard care in managing diabetic foot ulcers in the US. J Wound Care. 2017 Jan 2;26(Sup1):S12-S24.
- 15. Harding K, et al. A prospective, multicentre, randomised controlled study of human fibroblast-derived dermal substitute (Dermagraft) in patients with venous leg ulcers. Int Wound J 2013 Apr;10(2):132-7.
- 16. HAYES Comparative Effectiveness Review: Comparative Effectiveness Of Skin Substitutes For Chronic Foot Ulcers In Adults With Diabetes Mellitus: A Review of Reviews. Lansdale, PA: HAYES, Inc.; ©2019 Winifred S. Hayes, Inc. November 9, 2017; Annual Review: November 19, 2018.
- 17. HAYES Comparative Effectiveness Review: Human Acellular Dermal Matrix for Breast Reconstruction. HAYES, Inc. January 28, 2019. (Annual review February 28, 2022).
- 18. HAYES Health Technology Assessment. FlexHD Acellular Dermis (Musculoskeletal Transplant Foundation) For Breast Reconstruction. HAYES, Inc. August 3, 2012 Annual Review August 27, 2013.
- 19. Health Technology Assessment: Processed Nerve Allografts with the Avance Nerve Graft (Axogen Corporation) for Peripheral Nerve Discontinuities. HAYES, Inc. March 2, 2020. (Annual review May 11, 2023).
- 20. Herman ZJ, Ilyas AM. Sensory outcomes in digital nerve repair techniques: An updated meta-analysis and systemic review. Hand. 2019
- 21. Janis JE, et al. Acellular dermal matrices in abdominal wall reconstruction: a systematic review of the current evidence. Plast Reconstr Surg 2012 Nov;130(5 Suppl 2):183S-93S.
- 22. Keifer, OP, et al. A Complication Analysis of 2 Acellular Dermal Matrices in Prosthetic-based Breast Reconstruction. Plast Reconstr Surg Glob Open. 2016 Jul 13;4(7):e800.
- 23. Kirsner, R. S. MD, PhD, et.al., Comparative effectiveness of a bioengineered living cellular construct vs. a dehydrated human amniotic membrane allograft for the treatment of diabetic foot ulcers in a real world setting, Wound Rep Reg (2015) 23 737–744.

- 24. Lavery LA, et al; Grafix Diabetic Foot Ulcer Study Group. The efficacy and safety of Grafix® for the treatment of chronic diabetic foot ulcers: results of a multi-centre, controlled, randomised, blinded, clinical trial. Int Wound J 2014 Oct;11(5):554-60.
- 25. Leckenby JI, Furrer C, Haug L, Juon Personeni B, Vögelin E. A Retrospective Case Series Reporting the Outcomes of Avance Nerve Allografts in the Treatment of Peripheral Nerve Injuries. Plast Reconstr Surg. 2020 Feb;145(2):368e-381e
- 26. Liu DZ, et al. Comparison of outcomes using AlloDerm versus FlexHD for implant-based breast reconstruction. Annals Plast Surg 2014 May;72(5):503-7.
- 27. Local Coverage Determination Application of Bioengineered SKIN Substitutes to Lower Extremity Chronic Non-Healing Wounds (L35041). Centers for Medicare and Medicaid Services. Available: MCD Search (cms.gov).
- 28. Local Coverage Determination Wound Application of Cellular And/Or Tissue Based Products (Ctps), Lower Extremities (L36690). Centers for Medicare and Medicaid Services. Available: MCD Search (cms.gov).
- 29. Mendenhall SD, et al. The BREASTrial: stage I. Outcomes from the time of tissue expander and acellular dermal matrix placement to definitive reconstruction. Plast Reconstr Surg 2015 Jan;135(1):29e-42e.
- 30. Mauch JT, Bae A, Shubinets V, et al. A systemic review of sensory outcomes of digital nerve gap reconstruction with autograft, allograft, and conduit. Ann Plast Surg. 2019
- 31. Safa B, Jain S, Desai MJ, Greenberg JA, Niacaris TR, Nydick JA, Leversedge FJ, Megee DM, Zoldos J, Rinker BD, McKee DM, MacKay BJ, Ingari JV, Nesti LJ, Cho M, Valerio IL, Kao DS, El-Sheikh Y, Weber RV, Shores JT, Styron JF, Thayer WP, Przylecki WH, Hoyen HA, Buncke GM. Peripheral nerve repair throughout the body with processed nerve allografts: Results from a large multicenter study. Microsurgery. 2020 Jul;40(5):527-537.
- 32. Sanders L, et al. A prospective, multicenter, randomized, controlled clinical trial comparing a bioengineered skin substitute to a human skin allograft. Ostomy Wound Manage 2014 Sep;60(9):26-38.
- 33. Santema TB, et al. Skin grafting and tissue replacement for treating foot ulcers in people with diabetes. Cochrane Database Syst Rev 2016, Issue 2. Art. No.: CD011255.
- 34. Seth AK, et al. A comparative analysis of cryopreserved versus prehydrated human acellular dermal matrices in tissue expander breast reconstruction. Ann Plast Surg 2013 Jun;70(6):632-5.
- 35. Snyder, R.J. DPM et.al., A Prospective, Randomized, Multicenter, Controlled Evaluation of the Use of Dehydrated Amniotic Membrane Allograft Compared to Standard of Care for the Closure of Chronic Diabetic Foot Ulcers, Wounds 2016;28(3):70-77.

- 36. Uccioli L, et al. Two-step autologous grafting using HYAFF scaffolds in treating difficult diabetic foot ulcers: results of a multicenter, randomized controlled clinical trial with long-term follow-up. Int J Low Extrem Wounds 2011 Jun;10(2):80-5.
- 37. Walters J, et al. Healing rates in a multicenter assessment of a sterile, room temperature, acellular dermal matrix versus conventional care wound management and an active comparator in the treatment of full-thickness diabetic foot ulcers. Eplasty 2016 Feb 4;16:e10.
- 38. Weichman KE, et al. Sterile "ready-to-use" AlloDerm decreases postoperative infectious complications in patients undergoing immediate implant-based breast reconstruction with acellular dermal matrix. Plast Reconstr Surg 2013 Oct;132(4):725-36.
- 39. Zelen CM, et al. A prospective randomised comparative parallel study of amniotic membrane wound graft in the management of diabetic foot ulcers. Int Wound J 2013 Oct;10(5):502-7.
- 40. Zelen CM, et al. A prospective, randomised, controlled, multi-centre comparative effectiveness study of healing using dehydrated human amnion/chorion membrane allograft, bioengineered skin substitute or standard of care for treatment of chronic lower extremity diabetic ulcers. Int Wound J 2014 Nov 26; published 2015 Dec;12(6):724-32.
- 41. Zelen CM, et al. Human Reticular Acellular Dermal Matrix in the Healing of Chronic Diabetic Foot Ulcerations that Failed Standard Conservative Treatment: A Retrospective Crossover Study. Wounds. 2017 Feb;29(2):39-45.
- 42. Zelen CM, et al. The use of human amnion/chorion membrane in the clinical setting for lower extremity repair: a review. Clin Podiatr Med Surg 2015 Jan;32(1):135-46.
- 43. Zelen CM, et al. Treatment of chronic diabetic lower extremity ulcers with advanced therapies: a prospective, randomised, controlled, multi-centre comparative study examining clinical efficacy and cost. Int Wound J 2015 Dec 23 [Epub ahead of print]; published 2016 Apr;13(2):272-82.
- 44. Zelen CM, et.al., A prospective, randomised, controlled, multicentre clinical trial examining healing rates, safety and cost to closure of an acellular reticular allogenic human dermis versus standard of care in the treatment of chronic diabetic foot ulcers, Int Wound J 2016; p1-19, doi: 10.1111/iwj.12600.
- 45. Zenn MR and Salzberg CA. A direct comparison of Alloderm-ready to use (RTU) and Dermacell in immediate breast implant reconstruction. Eplasty 2016 Aug 11;16:e23.

Customer Product	Medical Management Requirements*		
New York Products	-		
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MVP Medicare WellSelect Plus PPO	Retrospective Review		
MVP Medicare Patriot Plan PPO	Retrospective Review		
MVP DualAccess D-SNP HMO	Retrospective Review		
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UVM Health Advantage Select PPO	Retrospective Review		
USA Care	Potential for Retrospective Review		
Healthy NY	Retrospective Review		
MVP Premier	Retrospective Review		
MVP Premier Plus	Retrospective Review		
MVP Premier Plus HDHP	Retrospective Review		
MVP Secure	Retrospective Review		
MVP EPO	Retrospective Review		
MVP EPO HDHP	Retrospective Review		
MVP PPO	Retrospective Review		
MVP PPO HDHP	Retrospective Review		
Student Health Plans	Retrospective Review		
ASO	See SPD		
Vermont Products			
POS in Plan	Retrospective Review		
POS OOP	Retrospective Review		
MVP Medicare Preferred Gold HMO POS	Retrospective Review		
MVP Medicare Secure Plus HMO POS	Retrospective Review		
MVP VT HMO	Retrospective Review		
MVP VT HDHP HMO	Retrospective Review		
MVP VT Plus HMO	Retrospective Review		
MVP VT Plus HDHP HMO	Retrospective Review		
MVP Secure	Retrospective Review		
ASO	See SPD		

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Revision History:

02/01/2022 - Added exclusions for newly developed skin substitutes called VIM, Vendaje and Zenith Amniotic Membrane.

08/01/2022 – Annual Review; artificial nerve grafts (CPT 64910, 64911) added as experimental/investigational with a Medicaid variation. Q4259, Q4260, Q4261 added as experimental/investigational.

01/01/2024- Added as experimental: Q4279, Q4287, Q4288, Q4289, Q4290, Q4291, Q4292, Q4293, Q4294, Q4295, Q4296, Q4297, Q4298, Q4299, Q4300, Q4301, Q4302, Q4303, Q4304

06/01/2024 – Added coverage for Amnioband, Grafix and Biovance.

04/01/2025 - Added coverage for nerve graft CPT Code 64911, 64912, 64913 to Commercial and Medicare plans.



Transcranial Magnetic Stimulation for Treatment-Resistant Depression

Type of Policy: Behavioral Health

 Prior Approval Date:
 02/06/2023

 Approval Date:
 01/06/2025

 Effective Date:
 04/01/2025

Related Polices:

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

CPT Codes:	Description:
90867	Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; initial, including cortical mapping, motor threshold determination, delivery, and management
90868	Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; subsequent delivery and management, per session
90869	Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; subsequent motor threshold re-determination with delivery and management
0889T	Personalized target development for accelerated, repetitive high-dose functional connectivity MRI-guided theta-burst stimulation derived from a structural and resting-state functional MRI, including data preparation and transmission, generation of the target, motor threshold-starting location, neuronavigation files and target report, review and interpretation
0890T	Accelerated, repetitive high-dose functional connectivity MRI-guided theta-burst stimulation, including target assessment, initial motor

	threshold determination, neuronavigation, delivery and management, initial treatment day
0891T	Accelerated, repetitive high-dose functional connectivity MRI-guided theta-burst stimulation, including neuronavigation, delivery and management, subsequent treatment day
0892T	Accelerated, repetitive high-dose functional connectivity MRI-guided theta-burst stimulation, including neuronavigation, delivery and management, subsequent motor threshold redetermination with delivery and management, per treatment day

Codes Requiring Retrospective Review

N/A

Experimental/Investigational

0889T	Personalized target development for accelerated, repetitive high-dose functional connectivity MRI-guided theta-burst stimulation derived from a structural and resting-state functional MRI, including data preparation and transmission, generation of the target, motor threshold-starting location, neuronavigation files and target report, review and interpretation
0890T	Accelerated, repetitive high-dose functional connectivity MRI-guided theta-burst stimulation, including target assessment, initial motor threshold determination, neuronavigation, delivery and management, initial treatment day
0891T	Accelerated, repetitive high-dose functional connectivity MRI-guided theta-burst stimulation, including neuronavigation, delivery and management, subsequent treatment day
0892T	Accelerated, repetitive high-dose functional connectivity MRI-guided theta-burst stimulation, including neuronavigation, delivery and management, subsequent motor threshold redetermination with delivery and management, per treatment day

Common Diagnosis Codes

Common Diagnosis Codes associated with this policy have been provided for informational purposes only. The list of codes may not be all-inclusive and may be updated to reflect any applicable revisions to the ICD-10 code set and/or medical necessity guidelines applied in this policy.

F32.1 – Major depressive disorder, single episode, moderate

F33.1 – Major depressive disorder, recurrent, moderate

F32.2 – F32.3 - Major depressive disorder, single episode, severe without psychotic features

F33.2 – F33.3 - Major depressive disorder, recurrent, severe without psychotic features Common Procedure Codes

N/A

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

Transcranial Magnetic Stimulation (TMS) is a non-invasive neuromodulation procedure that uses pulsed magnetic fields to induce an electric current in a localized region of the cerebral cortex. An electromagnetic coil placed on the scalp induces focal, patterned currents in the brain that temporarily modulate cerebral cortical functioning. Stimulation parameters may be adjusted to alter the excitability of the targeted structures in specific cortical regions. TMS parameters include cranial location, stimulation frequency, pattern, duration, intensity and the state of the brain during treatment. Clinical treatment usually involves multiple stimulations during a single session and for that reason is commonly called repetitive TMS (rTMS).

rTMS using an excitatory protocol to the left dorsolateral prefrontal cortex (DLPFC) is FDA-approved for the treatment of moderate to severe Major Depressive Disorder in adult patients who have failed to receive satisfactory improvement from antidepressant medication treatment during the current episode. High frequency and intermittent theta burst (iTBS) stimulation are both excitatory protocols that have been shown to have benefit in the appropriate treatment population.

In March 2024, The US Food and Drug Administration issued Class II clearance for the Neurostar TMS device for use as an adjunctive treatment for Major Depressive Disorder in patients 15 years of age and older. Of note, the figure 8-style coil in in the Neurostar device is the most commonly used coil design among TMS devices in clinical use in the US. The protocol and target treatment area for adolescents is the same as has been previously approved for use in adults (high frequency stimulation to the left DLPFC).

Accelerated functional connectivity MRI-guided, repetitive high-dose theta-burst stimulation is currently being investigated as a newer type of TMS in which higher doses of TMS are applied several times per day rather than once per day.

Indications/Criteria

Must meet all of the below:

Initial and repeat treatments of TMS are considered medically necessary when the customer meets all of the following:

- 1. The customer must:
 - a. be age 15 years or older; and
 - b. have a diagnosis of Major Depressive Disorder (MDD), moderate or severe, single episode or recurrent as per the most recent Diagnostic and Statistical Manual of Mental Disorders (DSM) criteria. The diagnosis must be documented by the TMS-prescribing psychiatrist from a thorough clinical evaluation; and
 - c. currently experiencing a depressive episode that meets criteria for treatmentresistant depression as defined below.
- 2. The customer's TMS treatment must be prescribed and supervised by a physician psychiatrist who:
 - a. has personally examined the customer; and
 - b. reviewed available treatment records; and
 - c. has collaborated with customer's other current treating providers (i.e., psychiatric prescriber, therapist, or referring psychiatrist if applicable) with the aim of confirming diagnostic impressions, medication reconciliation, and/or ensuring continuity of care following the proposed TMS treatment period.
- 3. The TMS treatment should be prescribed and supervised by a licensed physician psychiatrist trained in the use of TMS and using a U.S. Food and Drug Administration (FDA) approved device for treatment-resistant depression and in accordance with the manufacturer's recommendations for safe and effective usage of the device. For the purposes of this policy, "prescribed" means a written order for treatment that includes device parameters, target brain region, and schedule of treatments. For the purposes of this policy, "supervised" means the physician psychiatrist must be in the area and be immediately available.

Clinical Criteria for Medical Necessity for Initial Treatment

- 1. Adequate documentation must include all of the following components:
 - a. A comprehensive psychiatric evaluation to include a longitudinal timeline of the customer's symptoms including periods of partial or full remission, gaps in treatment and reason(s) for gaps; and
 - b. Documentation supporting the diagnosis of Major Depressive Disorder (unipolar), single versus recurrent episode, without psychotic features, as defined by the most recent edition of the DSM; and

- c. Assessment of moderate to severe symptoms in the current depressive episode as measured by a standardized, evidence-based rating scale using one of the following:
 - i. Beck Depression Inventory (BDI) Available: https://www.ismanet.org/doctoryourspirit/pdfs/Beck-Depression-Inventory-BDI.pdf; or
 - ii. Hamilton Rating Scale for Depression (HAM-D) Available: https://dcf.psychiatry.ufl.edu/files/2011/05/HAMILTON-DEPRESSION.pdf; or
 - iii. Inventory for Depressive Symptomatology Self-Report (IDS-SR) Available: IDS-SR English.doc (umich.edu); or
 - iv. Montgomery Asberg Depression Rating Scale (MADRS) Available:
 Montgomery-Asberg Depression Rating Scale (MADRS) (psychologytools.com); or
 - v. Patient Health Questionnaire (PHQ-9) Available: Clinical Outcome Measures | The Academy (ahrq.gov); or
 - vi. Quick Inventory of Depressive Symptomatology (QIDS) Available: https://loricalabresemd.com/wp-content/uploads/2017/12/qids-sr16.pdf
- **d.** Documentation supporting that symptoms have been treatment-resistant in the *current episode* with one of the following for members 18 years old and older:
 - i. Lack of a clinically significant response to one (1) trial of psychopharmacologic agents in the **current depressive episode** from at least two different agent classes (A trial of medication is defined as at least eight (8) weeks of medication given at FDA-approved treatment doses); or
 - ii. Inability to tolerate psychopharmacologic agents as evidenced by two (2) trials of psychopharmacologic agents from at least two different agent classes, with distinct side effects (Intolerance to a medication is defined as experiencing side effects that would not normally resolve or be significantly reduced with continued medication adherence or that the customer has a documented medical contraindication); or
 - iii. History of response to electroconvulsive therapy (ECT) in a previous or current MDD episode, or inability to tolerate ECT, and rTMS is considered a less invasive treatment option.
- e. Documentation supporting that symptoms have been treatment-resistant in the *current episode* for members 15-17 years old with the following:
 - i. Lack of clinically adequate response to two (2) trials of antidepressant medications approved by FDA for treatment in this age group at doses that are approved by FDA.

- f. Concurrent documented trial of an evidence-based form of psychotherapy known to be effective in the treatment of MDD and compliance for three to six months without significant improvement.
- g. Documentation of psychiatric co-morbidities and the management of those co-morbid conditions.
 - i. The existence of additional psychiatric conditions beyond MDD is not a contraindication to TMS treatment however the depressive symptoms must be the primary concern for treatment and the other conditions reasonably well-managed.
- h. Documentation of customer-specific risks (e.g., medications that may increase seizure risk) for treatment
 - i. This documentation could in part be captured by a structured safety screen such as the TMS Adult Safety Screen (TASS) developed by Keel et al.
- 2. The customer must supply upon request documentation of the use of standard evidence-based rating scales (as defined in 1.c.) at least once per week to monitor response to the TMS treatment.

Clinical Criteria for Medical Necessity for Repeat Treatment (re-treatment)

Repeat transcranial magnetic stimulation (TMS) treatment is considered medically necessary for a recurrence or an acute relapse of Major Depressive Disorder when ALL of the following are met:

- 1. Criteria for the initial TMS therapy were met prior to the initial course of TMS; and
- 2. The Customer experienced a positive response to TMS during a previous depressive episode as evidenced by 50% or more improvement in depressive symptoms as documented on evidence-based rating scales (as defined in 1.c.) or achieved remission of depressive symptoms as evidenced by a symptom score below the defined threshold of the evidence-based rating scale; **and**
- 3. Documentation submitted includes ongoing collaboration with providers who have provided active treatment following the initial TMS therapy or during the current relapse of symptoms, including medication trials and/or psychotherapy, and evidence-based rating scales (as defined in 1.c.)
- 4. TMS providers are encouraged but not required to administer symptom rating scales at routine intervals post-treatment (eg 30, 60, 90 days) to document the durability of response to TMS treatments in each individual.

Duration of Treatment

A treatment course should not exceed 5 days a week for 6 weeks, followed by a 3-week taper of 3 TMS treatments in week 1, 2 TMS treatments the next week, and 1 TMS treatment in the last week. (Total of 36 sessions)

TMS response should be assessed at least weekly throughout the treatment course using evidence-based rating scales as defined above. Requests for additional treatment sessions beyond the standard practice of 36 sessions may be considered on an individual basis if supported by evidence of progress and need for additional sessions. A small evidence base supports that some customers may require additional treatment sessions to achieve full response.

Up to 10 additional sessions will be considered medically necessary when the following criteria are met:

- a. Member has attended at least 4 treatments/week with no treatment gaps of more than 3 sessions AND
- b. Member has had at least 25% improvement on their symptom scale scores OR
- c. Member has reached response and has a treatment goal of reaching remission.

Exclusions

Transcranial magnetic stimulation (TMS) maintenance therapy for depression is experimental and investigational because the effectiveness and safety of TMS maintenance therapy has not been established in peer-reviewed literature and randomized trials conducted using standardized protocols.

Accelerated treatment protocols such as Stanford Accelerated Intelligent Neuromodulation Therapy (SAINT), Stanford Neuromodulation Therapy (SNT), or the Magnus Medical system (Codes: 0889T, 0890T, 0891T, 0892T) are considered experimental and investigational because there is a lack of evidence from peer-reviewed literature demonstrating safety, efficacy, or substantially improved patient outcomes.

TMS is considered investigational and experimental for psychiatric or neurologic conditions other than treatment-resistant Major Depressive Disorder in the current episode because there is a lack of evidence from peer-reviewed literature demonstrating safety, efficacy, or substantially improved patient outcomes. These conditions include but are not limited to:

- Alzheimer disease, dementia and other neurocognitive disorders
- Anxiety, Generalized Anxiety Disorder, Social Anxiety Disorder
- Attention deficit hyperactivity disorder (ADHD);
- Chronic pain;
- Headache (including migraine);
- Seasonal affective disorder (SAD) or Depression with Seasonal Pattern;
- Insomnia;
- Obsessive compulsive disorder (OCD);

- Eating disorder;
- Posttraumatic stress disorder (PTSD);
- Customer psychotic disorders including schizoaffective disorder, schizophrenia, or schizophreniform disorder
- Affective disorders with current psychosis including bipolar disorder, or major depression with psychotic features;
- Bipolar Disorder
- Customers who have had no prior antidepressant medication failure;
- Customers who have an active suicide plan, recent suicidal behavior or have recently attempted suicide;
- Customers with an active and untreated substance use disorder within the prior six months;.
- Customer with neurological conditions that include a history of seizures, cerebrovascular disease, dementia, movement disorders, increased intracranial pressure, having a history of repetitive or severe head trauma, or with primary or secondary tumors in the CNS;
- Customer Metal in or around the head, including metal plates, aneurysm coils, cochlear implants, ocular implants, deep brain stimulation devices and stents;.
- Customer vagus nerve stimulators or implants controlled by physiologic signals, including pacemakers, and implantable cardioverter defibrillators;
- Customers with major depressive disorder who have failed to receive clinical benefit from ECT or VNS; or.
- Customer cardiovascular disease
- Customers who are pregnant or nursing.
- Tattoos on the face or neck, particularly those with red dyes or inks

Medicare Variation

Repetitive transcranial magnetic stimulation (rTMS) is only considered medically necessary by Medicare in adults who have a confirmed diagnosis of major depressive disorder (MDD), single or recurrent episode and meet the following criteria:

- Resistance to treatment as evidenced by a lack of a clinically significant response
 to one (1) trial of psychopharmacologic agents in the current depressive
 episode from at least two different agent classes; or
- Inability to tolerate psychopharmacologic agents as evidenced by two (2) trials of psychopharmacologic agents from at least two different agent classes, with distinct side effects; or
- History of response to rTMS in a previous depressive episode; or

- History of response to electroconvulsive therapy (ECT) in a previous or current MDD episode, or inability to tolerate ECT, and rTMS is considered a less invasive treatment option; and
- A trial of an evidence-based psychotherapy known to be effective in the treatment of MDD of an adequate frequency and duration without significant improvement in depressive symptoms as documented by standardized rating scales that reliably measure depressive symptoms; and
- The rTMS treatment is delivered by a device that is FDA-approved or –cleared for the treatment of MDD in a safe and effective manner. rTMS treatment should generally follow the protocol and parameters specified in the manufacturer's user manual, with modifications only as supported by the published scientific evidence base; and
- The order for treatment (or retreatment) is written by a physician (MD or DO) who has examined the patient and reviewed the record. The physician must have experience in administering rTMS therapy and the treatment must be given under direct supervision of this physician, i.e., he or she must be in the area and be immediately available.

The benefits of TMS use must be carefully considered against the risk of potential side effect in patients with any of the following:

- Seizure disorder or any history of seizure (except those induced by ECT or isolated febrile seizures in infancy or childhood without subsequent treatment or recurrence). Additional consideration should be given for individuals on medications which may lower the seizure threshold or with conditions rendering the patient more prone to seizures, such as alcoholism;
- Presence of vagus nerve stimulators leads in the carotid sheath;
- Presence of an implanted medical device located <30 cm from the TMS magnetic coil, including but not limited to pacemakers, implanted defibrillators, or vagus nerve simulators.

TMS is not considered reasonable and necessary for any of the following:

Presence of psychotic symptoms in the current depressive episode;

Acute or chronic psychotic disorder such as schizophrenia, schizophreniform disorder, or schizoaffective disorder, or any other neuropsychiatric disorder;

Neurologic conditions that include epilepsy, cerebrovascular disease, dementia, increased intracranial pressure, having a history of repetitive or severe head trauma, or with primary or secondary tumors in the central nervous system;

Persons with conductive, ferromagnetic or other magnetic-sensitive metals implanted in their head which are non-removable and within 30 cm of the TMS magnetic coil.

Examples include cochlear implants, implanted electrodes/stimulators, aneurysm clips or coils stents, and bullet fragments. (Dental amalgam fillings are not affected by the magnetic field and are acceptable for use with TMS.)

Maintenance therapy is not currently supported by evidence from clinical trials and therefore, is considered not reasonable and necessary.

All other conditions not included in the above list of "Indications."

Deep TMS (d-TMS) is not considered reasonable and necessary for Obsessive Compulsive Disorder (OCD).

For full details see the National Government Services, Inc Local Coverage Determination (LCD) Transcranial Magnetic Stimulation (L33398) Original effective: 10/01/2015 Revision Effective: 04/01/2023 Available: MCD Search (cms.gov)

References (Updated 2025)

- 1. Angelakis E, Liouta E, Andreadis N, et al. Transcranial direct current stimulation effects in disorders of consciousness. Arch Phys Med Rehabil. 2014;95(2):283-289.
- 2. Benninger DH, Lomarev M, Lopez G, et al. Transcranial direct current stimulation for the treatment of Parkinson's disease. J Neurol Neurosurg Psychiatry. 2010;81(10):1105-1111.
- 3. Allan CL, Herrmann LL, Ebmeier KP. Transcranial magnetic stimulation in the management of mood disorders. Neuropsychobiology 2011; 64(3):163-169.
- 4. American Psychiatric Association (APA). Practice guideline for the treatment of patients with major depressive disorder. 3rd ed. Arlington, VA: APA; 1993 (revised October 2010; reaffirmed October 31, 2015).
- 5. American Psychiatric Association (APA). Guideline watch (March 2013): practice guideline for the treatment of patients with obsessive-compulsive disorder. https://www.psychiatry.org. Published March 2013.
- 6. American Psychiatric Association (APA). Practice guideline for the treatment of patients with obsessive compulsive disorder. Jul 2007. Accessed Jan 18, 2022. Available at URL address: http://psychiatryonline.org/guidelines
- 7. Avery DH, Isenberg KE, Sampson SM, et al. Transcranial magnetic stimulation in the acute treatment of major depressive disorder: Clinical response in an open-label extension trial. J Clin Psychiatry. 2008;69(3):441-451.
- 8. Benadhira R, Saba G, Samaan A, et al. Transcranial magnetic stimulation for refractory depression. Am J Psychiatry. 2005;162(1):193.
- 9. Benninger DH, Berman BD, Houdayer E, et al. Intermittent theta-burst transcranial magnetic stimulation for treatment of Parkinson disease. Neurology. 2011;76(7):601-609

- 10. Benussi A, Di Lorenzo F, Dell'Era V, et al. Transcranial magnetic stimulation distinguishes Alzheimer disease from frontotemporal dementia. Neurology. 2017;89(7):665-672.
- 11. Berlim MT, Neufeld NH, Van den Eynde F. Repetitive transcranial magnetic stimulation (rTMS) for obsessive-compulsive disorder (OCD): An exploratory meta-analysis of randomized and sham-controlled trials. J Psychiatr Res. 2013;47(8):999-1006.
- 12. Berlim MT, Van den Eynde F, Jeff Daskalakis Z. Clinically meaningful efficacy and acceptability of low-frequency repetitive transcranial magnetic stimulation (rTMS) for treating primary major depression: A meta-analysis of randomized, double-blind and sham-controlled trials. Neuropsychopharmacology. 2013;38(4):543-551.
- 13. Carpenter LL, Conelea C, Tyrka AR, et al. 5 Hz repetitive transcranial magnetic stimulation for posttraumatic stress disorder comorbid with major depressive disorder. J Affect Disord. 2018;235:414-420.
- 14. Couturier JL. Efficacy of rapid-rate repetitive transcranial magnetic stimulation in the treatment of depression: A systematic review and meta-analysis. J Psychiatry Neurosci. 2005;30(2):83-90.
- 15. Daskalakis ZJ, Levinson AJ, Fitzgerald PB. Repetitive transcranial magnetic stimulation for major depressive disorder: A review. Can J Psychiatry. 2008;53(9):555-566.
- 16. Demirtas-Tatlidede A, Mechanic-Hamilton D, Press DZ, et al. An open-label, prospective study of repetitive transcranial magnetic stimulation (rTMS) in the long-term treatment of refractory depression: Reproducibility and duration of the antidepressant effect in medication-free patients. J Clin Psychiatry. 2008;69(6):930-934.
- 17. Demitrack MA, Thase ME. Clinical significance of transcranial magnetic stimulation (TMS) in the treatment of pharmacoresistant depression: Synthesis of recent data. Psychopharmacol Bull. 2009;42(2):5-38.
- 18. Dunner DL, Aaronson ST, Sackeim HA, et al. A multisite, naturalistic, observational study of transcranial magnetic stimulation for patients with pharmacoresistant major depressive disorder: Durability of benefit over a 1-year follow-up period. J Clin Psychiatry. 2014;75(12):1394-1401.
- 19. Eranti S, Mogg A, Pluck G, et al. A randomized, controlled trial with 6-month follow-up of repetitive transcranial magnetic stimulation and electroconvulsive therapy for severe depression. Am J Psychiatry. 2007;164(1):73-81.
- 20. Euser AM, Stapert AF, Oosterhoff M, et al. Transcranial magnetic stimulation in obsessive compulsive disorder: A systematic review. Tijdschr Psychiatr. 2017;59(10):617-625.
- 21. George MS, Lisanby SH, Avery D, et al. Daily left prefrontal transcranial magnetic stimulation therapy for major depressive disorder: A sham-controlled randomized trial. Arch Gen Psychiatry. 2010;67(5):507-516.

- MVP Health Care Medical Policy
- 22. George MS, Lisanby SH, Sackeim HA. Transcranial magnetic stimulation. Applications in neuropsychiatry. Arch Gen Psychiatry. 1999;56(4):300-311.
- 23. Gershon AA, Dannon PN, Grunhaus L. Transcranial magnetic stimulation in the treatment of depression. Am J Psychiatry. 2003;160(5):835-845.
- 24. Gorelick DA, Zangen A, George MS. Transcranial magnetic stimulation in the treatment of substance addiction. Ann N Y Acad Sci. 2014;1327:79-93.
- 25. Hayes Inc. Evaluating the efficacy of transcranial magnetic stimulation to treat major depression. Hayes Overview. Lansdale, PA: Hayes; May 25, 2010.
- 26. Hayes Inc. Nonpharmacological treatments for treatment-resistant depression. Health Technology Assessment. Final Report. Olympia, WA: Washington State Healthcare Authority; 2014.
- 27. Hayes, Inc. Medical Technology Directory. Transcranial magnetic stimulation for the treatment of obsessive-compulsive disorder. https://evidence.hayesinc.com. Published March 5, 2019. Updated February 15, 2022.
- 28. Holtzheimer PE, Russo J, Avery DH. A meta-analysis of repetitive transcranial magnetic stimulation in the treatment of depression. Psychopharmacol Bull. 2001;35(4):149-169.
- 29. Janicak PG, Nahas Z, Lisanby SH, et al. Durability of clinical benefit with transcranial magnetic stimulation (TMS) in the treatment of pharmacoresistant major depression: Assessment of relapse during a 6-month, multisite, open-label study. Brain Stimul. 2010;3(4):187-199.
- 30. Kedzior KK, Gerkensmeier I, Schuchinsky M. Can deep transcranial magnetic stimulation (DTMS) be used to treat substance use disorders (SUD)? A systematic review. BMC Psychiatry. 2018;18(1):137.
- 31. Kedzior KK, Gierke L, Gellersen HM, Berlim MT. Cognitive functioning and deep transcranial magnetic stimulation (DTMS) in major psychiatric disorders: A systematic review. J Psychiatr Res. 2016;75:107-115.
- 32. Keel JC, Smith MJ and Wassermann EM. A safety screening questionnaire for transcranial magnetic stimulation (TASS). Clin. Neurophysial. 2000 Apr;112(4):720
- 33. Kirkcaldie M, Pridmore S, Reid P. Bridging the skull: Electroconvulsive therapy (ECT) and repetitive transcranial magnetic stimulation (rTMS) in psychiatry. Convul Ther. 1997;13(2):83-91.
- 34. Klein E, Kreinin I, Chistyakov A, et al. Therapeutic efficacy of right prefrontal slow repetitive transcranial magnetic stimulation in major depression. Arch En Psychiatry. 1999;56(4):315-320.
- 35. Kozel FA, George MS. Meta-analysis of left prefrontal repetitive transcranial magnetic stimulation (rTMS) to treat depression. J Psych Pract. 2002;8(5):270-275.

- 36. Kupfer DJ, Frank E, Phillips ML. Major depressive disorder: New clinical, neurobiological, and treatment perspectives. Lancet. 2012;379(9820):1045-1055.
- 37. Lam RW, Chan P, Wilkins-Ho M, Yatham LN. Repetitive transcranial magnetic stimulation for treatment-resistant depression: A systematic review and metaanalysis. Can J Psychiatry. 2008;53(9):621-631.
- 38. National Institute for Health and Care Excellence (NICE). Repetitive transcranial magnetic stimulation for depression. NICE Interventional Procedure Guidance 542. London, UK: NICE; December 2015.
- 39. National Institute for Health and Clinical Excellence (NICE). Transcranial magnetic stimulation for treating and preventing migraine. NICE Interventional Procedure Guidance 477. London, UK: NICE; January 2014.
- 40. National Institute for Health and Clinical Excellence. Transcranial magnetic stimulation for severe depression. Interventional Procedure Guidance 242. London, UK: NICE; November 2007.
- 41. O'Reardon JP, Solvason HB, Janicak PG, et al. Efficacy and safety of transcranial magnetic stimulation in the acute treatment of major depression: A multisite randomized controlled trial. Biol Psychiatry. 2007;62(11):1208-1216.
- 42. Padberg F, Moller HJ. Repetitive transcranial magnetic stimulation: Does it have potential in the treatment of depression? CNS Drugs. 2003;17(6):383-403.
- 43. Philip NS, Ridout SJ, Albright SE, et al. 5-Hz transcranial magnetic stimulation for comorbid posttraumatic stress disorder and major depression. J Trauma Stress. 2016a;29(1):93-96.
- 44. Pigot M, Loo C, Sachdev P. Repetitive transcranial magnetic stimulation as treatment for anxiety disorders. Expert Rev Neurother. 2008;8(10):1449-1455.
- 45. Prasko J, Zalesky R, Bares M, et al. The effect of repetitive transcranial magnetic stimulation (rTMS) add on serotonin reuptake inhibitors in patients with panic disorder: A randomized, double blind sham controlled study. Neuro Endocrinol Lett. 2007;28(1):33-38.
- 46. Pridmore S, Erger S, Rybak M, et al. Early relapse (ER) transcranial magnetic stimulation (TMS) in treatment resistant major depression. Brain Stimul. 2018;11(5):1098-1102.
- 47. Rapinesi C, Saverio Bersani F, Kotzalidis Gd, et al. Maintenance deep transcranial magnetic stimulation sessions are associated with reduced depressive relapses in patients with unipolar or bipolar depression. Front Neurol. 2015; 6: 16
- 48. Serafini G, Pompili M, Belvederi Murri M, et al. The effects of repetitive transcranial magnetic stimulation on cognitive performance in treatment-resistant depression. A systematic review. Neuropsychobiology. 2015;71(3):125-139.

- MVP Health Care Medical Policy
- 49. Silverstein WK, Noda Y, Barr MS, et al. Neurological Predictors of response to dorsolateral prefrontal cortex repetitive transcranial magnetic stimulation in depression: A systematic review. Depress Anxiety. 2015;32(12):871-891.
- 50. Singh S, Kumar S, Gupta A, et al. Effectiveness and predictors of response to 1-Hz repetitive transcranial magnetic stimulation in patients with obsessive-compulsive disorder. J ECT. 2019;35(1):61-66.
- 51. Trevizol AP, Shiozawa P, Cook IA, et al. Transcranial magnetic stimulation for obsessive-compulsive disorder: An updated systematic review and meta-analysis. J ECT. 2016;32(4):262-266.
- 52. U.S. Food and Drug Administration. FDA permits marketing of transcranial magnetic stimulation for treatment of obsessive compulsive disorder. FDA News Release. Silver Spring, MD: FDA; August 17, 2018. Available at: https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm617244.htm.
- 53. Wang HN, Wang XX, Zhang RG, et al. Clustered repetitive transcranial magnetic stimulation for the prevention of depressive relapse/recurrence: A randomized controlled trial. Transl Psychiatry. 2017;7(12):1292.
- 54. Wang J, Zhou Y, Gan H, et al. Efficacy towards negative symptoms and safety of repetitive transcranial magnetic stimulation treatment for patients with schizophrenia: A systematic review. Shanghai Arch Psychiatry. 2017;29(2):61-76.
- 55. Yang LL, Zhao D, Kong LL, et al. High-frequency repetitive transcranial magnetic stimulation (rTMS) improves neurocognitive function in bipolar disorder. J Affect Disord. 2019;246:851-856.

Customer Product	Medical Management Requirements*		
New York Products	,		
НМО	Prior Authorization		
PPO in Plan	Prior Authorization		
PPO OOP	Prior Authorization		
POS in Plan	Prior Authorization		
POS OOP	Prior Authorization		
Essential Plan	Prior Authorization		
MVP Medicaid Managed Care	Prior Authorization		
MVP Child Health Plus	Prior Authorization		
MVP Harmonious Health Care Plan	Prior Authorization		
MVP Medicare Complete Wellness	Prior Authorization		
MVP Medicare Preferred Gold HMO POS	Prior Authorization		
MVP Medicare Secure HMO POS	Prior Authorization		
MVP Medicare Secure Plus HMO POS	Prior Authorization		
MVP Medicare WellSelect PPO	Prior Authorization		
MVP Medicare WellSelect Plus PPO	Prior Authorization		
MVP Medicare Patriot Plan PPO	Prior Authorization		
MVP DualAccess D-SNP HMO	Prior Authorization		
MVP DualAccess Complete D-SNP HMO	Prior Authorization		
MVP DualAccess Plus D-SNP HMO	Prior Authorization		
UVM Health Advantage Select PPO	Prior Authorization		
USA Care	Prior Authorization		
Healthy NY	Prior Authorization		
MVP Premier	Prior Authorization		
MVP Premier Plus	Prior Authorization		
MVP Premier Plus HDHP	Prior Authorization		
MVP Secure	Prior Authorization		
MVP EPO	Prior Authorization		
MVP EPO HDHP	Prior Authorization		
MVP PPO	Prior Authorization		
MVP PPO HDHP	Prior Authorization		
Student Health Plans	Prior Authorization		
ASO	See SPD		
Vermont Products	55557.2		
POS in Plan	Prior Authorization		
POS OOP	Prior Authorization		
MVP Medicare Preferred Gold HMO POS	Prior Authorization		
MVP Medicare Secure Plus HMO POS	Prior Authorization		
MVP VT HMO	Prior Authorization		
MVP VT HDHP HMO	Prior Authorization		
MVP VT Plus HMO	Prior Authorization		
MVP VT Plus HDHP HMO	Prior Authorization		
MVP Secure	Prior Authorization		
ASO	See SPD		
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♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review.

Retro Review Required
Not Covered Service is not a covered benefit.

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See Specific Plan Design

Revision History

04/01/2023 – Annual review with updated indications and criteria, added duration of treatment, updated exclusions

12/01/2024 – Added prior authorization to accelerated transcranial magnetic stimulation (TMS) CPT Codes: 0889T, 0890T, 0891T, 0892T.

04/01/2025 – Coverage added for adolescents, updated psychopharmacologic requirement criteria for initial treatments, added coverage criteria for additional treatment sessions, added exclusion for accelerated treatment protocols. Medicare variation updated.



Transplants

Type of Policy: Surgical

Prior Approval Date: 10/04/2021

Approval Date: 08/07/2023

Effective Date: 10/01/2023

Related Polices: Nulojix

Experimental Investigational

Procedures

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

CPT/HCPCS Code	Description
32851	Lung transplant, single; without cardiopulmonary bypass
32852	Lung transplant, single; with cardiopulmonary bypass
32853	Lung transplant, double (bilateral sequential or en bloc);
	without cardiopulmonary bypass
32854	Lung transplant, double (bilateral sequential or en bloc); with
	cardiopulmonary bypass
33935	Heart-lung transplant with recipient cardiectomy-
	pneumonectomy
33945	Heart transplant, with or without recipient cardiectomy
38205	Blood-derived hematopoietic progenitor cell harvesting for
	transplantation, per collection; allogeneic
38206	Blood-derived hematopoietic progenitor cell harvesting for
	transplantation, per collection; autologous
38207	Transplant preparation of hematopoietic progenitor cells;
	cryopreservation and storage
38208	Transplant preparation of hematopoietic progenitor cells;
	thawing of previously frozen harvest, without washing, per
	donor

	Transplant properties of boundary intigeness than called	
38209	Transplant preparation of hematopoietic progenitor cells;	
20240	thawing of previously frozen harvest, with washing, per donor	
38210	Transplant preparation of hematopoietic progenitor cells;	
20044	specific cell depletion within harvest, T-cell depletion	
38211	Transplant preparation of hematopoietic progenitor cells;	
	tumor cell depletion	
38212	Transplant preparation of hematopoietic progenitor cells; red	
	blood cell removal	
38213	Transplant preparation of hematopoietic progenitor cells;	
	platelet depletion	
38214	Transplant preparation of hematopoietic progenitor cells;	
	plasma (volume) depletion	
38215	Transplant preparation of hematopoietic progenitor cells; cell	
	concentration in plasma, mononuclear, or buffy coat layer	
38240	Hematopoietic progenitor cell (HPC); allogeneic	
	transplantation per donor	
38241	Hematopoietic progenitor cell (HPC); autologous	
	transplantation	
38242	Hematopoietic progenitor cell (HPC); HPC boost	
44133	Donor enterectomy (including cold preservation), open;	
	partial, from living donor	
44135	Intestinal allotransplantation; from cadaver donor	
44136	Intestinal allotransplantation; from living donor	
47135	Liver allotransplantation, orthotopic, partial or whole, fro	
	cadaver or living donor, any age	
48160	Pancreatectomy, total or subtotal, with autologous	
	transplantation of pancreas or pancreatic islet cells	
48554	Transplantation of pancreatic allograft	
50360	Renal allotransplantation, implantation of graft; without	
	recipient nephrectomy	
50365	Renal allotransplantation, implantation of graft; with recipient	
	nephrectomy	
50380	Renal autotransplantation, reimplantation of kidney	
G0341	Percutaneous islet cell transplant, includes portal vein	
	catheterization and infusion	
G0342	Laparoscopy for islet cell transplant, includes portal vein	
	catheterization and infusion	
G0343	Laparotomy for islet cell transplant, includes portal vein	
	catheterization and infusion	
S2060	Lobar lung transplantation	
	<u> </u>	

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S2061	Donor lobectomy (lung) for transplantation, living donor
S2065	Simultaneous pancreas kidney transplantation
S2102	Islet cell tissue transplant from pancreas; allogeneic
S2103	Adrenal tissue transplant to brain
S2142	Cord blood-derived stem-cell transplantation, allogeneic
S2150	Bone marrow or blood-derived stem cells (peripheral or umbilical), allogeneic or autologous, harvesting, transplantation, and related complications; including: pheresis and cell preparation/storage; marrow ablative therapy; drugs, supplies, hospitalization with outpatient follow-up; medical/surgical, diagnostic, emergency, and rehabilitative services; and the number of days of pre- and posttransplant care in the global definition
S2152	Solid organ(s), complete or segmental, single organ or combination of organs; deceased or living donor(s), procurement, transplantation, and related complications; including: drugs; supplies; hospitalization with outpatient follow-up; medical/surgical, diagnostic, emergency, and rehabilitative services, and the number of days of pre- and posttransplant care in the global definition

Codes Requiring Retrospective Review

N/A

Experimental/Investigational

N/A

Common Diagnosis Codes

ICD-10- CM Diagnosis Codes: B18.0, B18.1, B18.2, B18.8, B18.9, I42.0, I42.1, I42.2, I42.3, I42.4, I42.5, I42.6, I42.7, I42.8, I42.9, K70.0, K70.1, K70.10, K70.11, K70.2, K70.3, K70.30, K70.31, K70.4, K70.40, K70.41, K70.9, K71.0, K71.1, K71.10, K71.11, K71.2, K71.3, K71.4, K71.5, K71.50, K71.51, K71.6, K71.7, K71.8, K71.9, K72.0, K72.00, K72.01, K72.1, K72.10, K72.11, K72.9, K72.90, K72.91, K73.0, K73.1, K73.2, K73.8, K73.9, K74.0, K74.1, K74.2, K74.3, K74.4, K74.5, K74.6, K74.60, K74.69, K75.0, K75.1, K75.2, K75.3, K75.4, K75.8, K75.81, K75.89, K75.9, K76.0, K76.1, K76.2, K76.3, K76.4, K76.5, K76.6, K76.7, K76.8, K76.81, K76.89, K76.9

Common Diagnosis Codes associated with this policy have been provided for informational purposes only. The list of codes may not be all-inclusive and may be updated to reflect any applicable revisions to the ICD-10 code set and/or medical necessity guidelines applied in this policy.

Common Procedure Codes

N/A

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Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

Transplantation is a viable treatment option for many customers with end stage organ failure. The purpose of an organ transplant is not merely to prolong life, but to restore a quality of life that enables recipients to work and enjoy recreation with minimal disability.

A transplant candidate should have a realistic understanding of the implications of the organ transplant. Individuals must be able to comply with post-transplant therapies and outpatient management.

Indications/Criteria

MVP endorses United Health Group-OptumHealth criteria and Transplant Review Guidelines for Solid Organ and Stem Cell Transplantation.

The following transplants will be considered for medical necessity review on a case-bycase basis:

- hematopoietic stem cell transplantation;
- kidney transplantation;
- kidney/heart transplantation;
- kidney/lung transplantation
- pancreas transplantation;
- simultaneous kidney/pancreas, or kidney /liver transplantation;
- liver transplantation;
- intestinal, liver/intestinal, or multivisceral transplantation;
- heart transplantation;
- lung transplantation;
- heart/lung transplantation; and
- tandem autologous stem cell transplantation for multiple myeloma.

All Transplant requests are reviewed by the Medical Director.

Exclusions

- Services rendered and reviewed by the Medical Director as not meeting the criteria listed above.
- Multiple listings for organs i.e., registering at two or more transplant centers for a transplant organ, is considered to be not medically necessary.

Medicare Variation

Transplantations are covered under Medicare only when performed in a facility approved by Medicare as meeting institutional coverage criteria listed in CMS Ruling 87-1.

- Heart, lung, heart-lung, liver, kidney, pancreas, pancreas-kidney, and intestinal/multivisceral transplants are covered only when performed in a Medicare approved transplant facility.
- Medicare covers pancreas transplantation for diabetic patients who have experienced end-stage renal failure secondary to diabetes.
- Medicare covers pancreas transplants alone (PA) in other limited circumstances (Refer to CMS National Coverage Determination policy (NCD) for Pancreas Transplants.
- Medicare indications for liver transplantation include all customers with end-stage liver disease except those with malignancies.
- Medicare will cover a patient with primary hepatocellular carcinoma (HCC) who is not a liver resection candidate, whose tumor is < 5 cm. in diameter, in whom there is no macrovascular involvement and no identifiable extrahepatic spread of tumor to surrounding lymph nodes, lungs, abdominal organs, or bone.
- Liver transplantation is covered for children (under age 18) with extrahepatic biliary atresia or any other form of end stage liver disease, except that coverage is not provided for children with a malignancy extending beyond the margins of the liver or those with persistent viremia.
- Medicare will cover intestinal and multivisceral transplantation for the purpose of restoring intestinal function in patients with irreversible intestinal failure only when performed for patients who have failed total parenteral nutrition (TPN). TPN failure includes the following:
 - impending or overt liver failure due to TPN induced liver injury. The clinical manifestations include elevated serum bilirubin and/or liver enzymes, splenomegaly, thrombocytopenia, gastroesophageal varices, coagulopathy, stomal bleeding or hepatic fibrosis/cirrhosis;
 - thrombosis of the major central venous channels; jugular, subclavian, and femoral veins. Thrombosis of two or more of these vessels is considered a life-threatening

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complication and failure of TPN therapy. The sequelae of central venous thrombosis are lack of access for TPN infusion, fatal sepsis due to infected thrombi, pulmonary embolism, Superior Vena Cava syndrome, or chronic venous insufficiency;

- frequent line infection and sepsis. The development of two or more episodes of systemic sepsis secondary to line infection per year that requires hospitalization indicates failure of TPN therapy. A single episode of line related fungemia, septic shock and/or Acute Respiratory Distress Syndrome are considered indicators of TPN failure; and
- o frequent episodes of severe dehydration despite intravenous fluid supplement in addition to TPN. Under certain medical conditions such as secretory diarrhea and non-constructable gastrointestinal tract, the loss of the gastrointestinal and pancreatobiliary secretion exceeds the maximum intravenous infusion rates that can be tolerated by the cardiopulmonary system. Frequent episodes of dehydration are deleterious to all body organs particularly kidneys and the central nervous system with the development of multiple kidney stones, renal failure, and permanent brain damage.

Allergenic Stem Cell Transplantation

The following uses of allergenic bone marrow transplantation are covered under Medicare:

- for the treatment of leukemia, leukemia in remission, or aplastic anemia when it is reasonable and necessary; and
- for the treatment of severe combined immunodeficiency disease (SCID); and
- for the treatment of Wiskott Aldrich syndrome.

Autologous Stem Cell Transplantation

Autologous stem cell transplantation is considered reasonable and necessary under §1862(a)(1)(A) of the Act for the following conditions and is covered under Medicare for patients with:

- acute leukemia in remission who have a high probability of relapse and who have no human leucocyte antigens (HLA)-matched; and
- resistant Non-Hodgkin's or those presenting with poor prognostic features following an initial response; and
- recurrent or refractory neuroblastoma; and
- advanced Hodgkin's disease who have failed conventional therapy and have no HLAmatched donor; and
- Durie-Salmon Stage II or III patients that fit the following requirement:

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- o newly diagnosed or responsive multiple myeloma. This includes those patients with previously untreated disease, those with at least a partial response to prior chemotherapy (defined as a 50 percent decrease either in measurable paraprotein [serum and/or urine] or in bone marrow infiltration, sustained for at least one month), and those in responsive relapse; and
- o adequate cardiac, renal, pulmonary, and hepatic function.

When the Medicare criteria are not met, the following will be denied as not medically necessary:

- allogeneic stem cell transplantation as a treatment for multiple myeloma;
- multiple rounds of autologous stem cell transplantation (known as tandem transplantation) for multiple myeloma;
- acute leukemia not in remission; chronic granulocytic leukemia; solid tumors (other than neuroblastoma and non-primary amyloid light chain amyloidosis;
- high dose chemotherapy plus autologous bone marrow transplant/stem cell support for metastatic breast cancer;
- Medicare excludes transplantation of partial pancreatic tissue or islet cells performed outside the context of a clinical trial.

Medicare Non-covered Transplants

The following are considered non-covered for Medicare recipients:

- simultaneous kidney-heart transplants;
- simultaneous liver-heart transplants.

References (Reviewed 2023)

- 1. Centers for Medicare and Medicaid Services National Coverage Determination (NCD) for Pediatric Liver Transplantation (NCD) (260.2. Effective Date: 04/21/1991. Available: https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=71&ncdver=1&bc=AAAAgAAAAAA&

Transplants Page 7 of 10

- 5. Centers for Medicare and Medicaid Services National Coverage Determination (NCD) for Adult Liver Transplantation (260.1). Effective Date June 211, 2012. <u>Available:</u>
 https://www.cms.gov/
- 6. Centers for Medicare and Medicaid Services National Coverage Determination (NCD) for Intestinal and Multi-Visceral Transplantation (260.5). Effective Date May 11, 2006. Available: https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=280&ncdver=2&bc=AAAAgAAAAAA&
- 7. National Coverage Determination (NCD) for Stem Cell Transplantation (Formerly 110.8.1) (110.23) Effective Date January 27, 2016. Available: https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=366&ncdver=1&bc=AAAAgAAAAAA&
- 8. Farquhar C, Marjoribanks J, Basser R, Hetrick SE, Lethaby A. High dose chemotherapy and autologous bone marrow or stem cell transplantation versus conventional chemotherapy for women with metastatic breast cancer. Cochrane Database of Systemic Reviews. 2005 Last assessed as up-to-date: March 16, 2007. Available: www.cochrane.org/reviews/en/ab003142.html
- 9. Optum. 2022 Transplant Review Guidelines Solid Organ and Hematopoietic Stem Cell Transplantation. (Effective April 1, 2022). © 2022 United Health Group All Rights Reserved.
- 10. Centers for Medicare and Medicaid Services. Medicare Program; Hospital Conditions of Participation: Requirements for Approved and Re-Approval of Transplant Centers to Perform Organ Transplants. Federal Register. Vol 7. No 23. Feb 4, 2005. Available: http://www.gpo.gov/fdsys/pkg/FR-2005-02-04/pdf/05-1696.pdf

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Customer Product	Medical Management Requirements*		
New York Products			
HMO	Prior Auth		
PPO In Plan	Prior Auth		
PPO OOP	Not Covered		
POS In Plan	Prior Auth		
POS OOP	Not Covered		
Essential Plan	Prior Auth		
MVP Medicaid Managed Care	Prior Auth		
MVP Child Health Plus	Prior Auth		
MVP Harmonious Health Care Plan	Prior Auth		
MVP Medicare Complete Wellness	Prior Auth		
MVP Medicare Preferred Gold HMO POS	Prior Auth		
MVP Medicare Secure HMO POS	Prior Auth		
MVP Medicare WellSelect PPO	Prior Auth		
MVP Medicare WellSelect Plus PPO	Prior Auth		
MVP Medicare Patriot Plan	Prior Auth		
MVP DualAccess D-SNP HMO	Prior Auth		
MVP DualAccess Complete D-SNP HMO	Prior Auth		
MVP DualAccess Plus D-SNP HMO	Prior Auth		
UVM Health Advantage Select PPO	Prior Auth		
USACare PPO	Potential for Retrospective Review		
Healthy NY	Prior Auth		
MVP Secure	Prior Auth		
MVP EPO	Prior Auth		
MVP EPO HDHP	Prior Auth		
MVP PPO	Prior Auth		
MVP PPO HDHP	Prior Auth		
Student Health Plans	Prior Auth		
ASO	See SPD		
Vermont Products			
POS In Plan	Prior Auth		
POS OOP	Not Covered		
MVP Medicare Preferred Gold HMO POS	Prior Auth		
MVP Medicare Secure Plus HMO POS	Prior Auth		
MVP Medicare WellSelect PPO	Prior Auth		
MVP VT HMO	Prior Auth		
MVP VT HDHP HMO	Prior Auth		
MVP VT Plus HMO	Prior Auth		
MVP Secure	Prior Auth		
ASO	See SPD		

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Auth
Potential for Retrospective Review
Retro Review

Not Covered See SPD Prior Authorization Required

No Prior Authorization Required. May be subject to Retrospective Review

Retrospective Review Required Service is not a covered benefit. See Specific Plan Design

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Revision History:

12/1/2023 – Annual review. No changes to criteria, references updated.

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Treatment for Addictions (including Substance Use Disorders and Problem Gambling) Inpatient, Residential, and Outpatient Settings

Type of Policy: Behavioral Health

Prior Approval Date: 08/31/2020

Approval Date: 11/04/2024

Effective Date: 02/01/2025

Related Polices: Substance Use Disorders –

Behavioral Health

Codes Requiring Notification

Notification requirements may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed notification requirements for specific plans.

Service	NYS Rate	Revenue	Procedure
	Code	Code(s)	Code(s)
Inpatient Detoxification	N/A	0116	H0008
		0126	H0009
		0136	
		0146	
		0156	
Inpatient Rehabilitation	N/A	0118	
		0128	
		0138	
		0148	
		0158	

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Substance Use Residential	N/A	1002	H0010
			H0011
			H0017
			H0018
OASAS Certified Title 14 NYCRR Part 820	1144	0900	H2036 TG HF
Stabilization in a Residential Setting		0902	
		0911	
		0914	
		0944	
		0945	
		1002	
OASAS Certified Title 14 NYCRR Part 820	1145	0900	H2036 HF
Rehabilitation in a Residential Setting		0902	
		0911	
		0914	
		0944	
		0945	
		1002	

Note: OASAS Certified Title 14 NYCRR Part 820 Reintegration in a Residential Setting (NYS Rate Code 1146, Procedure Code H2036 HF) does not require notification or authorization.

Codes Requiring Retrospective Review

N/A

Experimental/Investigational

N/A

Common Diagnosis Codes

ICD-10 Codes: F10.10, F10.20, F10.21, F10.229, F10.231, F11.10, F11.20, F11.21, F12.10, F12.20, F12.21, F13.10, F13.20, F13.21, F14.20, F14.21, F15.20, F15.21, F16.10, F16.20, F16.21, F17.200, F19.20, F19.21, F19.939, F63.0

Common Procedure Codes

Revenue Codes: 0900, 0902, 0906, 0911, 0913, 0914, 0944, 0945

CPT Codes: 90791, 90792, 90834, 90846, 90847, 90853, 96372, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215

HCPCS Codes: G0396, G0397, H0001, H0002, H0004, H0005, H0014, H0020, H0033, H0038, H0049, H0050, H2001, H2011, H2036, H2036 HF, J0571, J0572, J0574, J2315, Q9991, Q9992, S9480, S9485, T1006, T1023

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Please refer to the product grid for detailed notification requirements for specific plans. Codes requiring notification for some products may require retrospective review for plans that do not require notification. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates and New York State's Office of Addiction Services and Supports APG Clinical and Medicaid Billing Guidance will be adopted and applied to this policy by MVP.

Overview

The Addictive Disorders represent a category of disruption and dysregulation in the brain reward system and brain inhibitory mechanisms resulting in continued problem behavior despite negative consequences. Addictions are characterized by groups of cognitive, behavioral, and physiological symptoms. Changes in brain circuitry can persist long after the stimulus has stopped and as a result addictions can be chronic as well as relapsing-remitting. The DSM5 recognizes Substance Use Disorders (SUD) and Gambling Disorder (GD) as addictions. Other behavioral addictions (e.g., exercise, shopping, or internet gaming) have not been studied to the point of consensus and are not included.

Substance Use Disorders are characterized by pathological behaviors representing impaired control (over one's own behavior related to the substance), social impairment, risky use, and pharmacological consequences. A variety of genetic, psychosocial, and environmental factors may influence the development, manifestation, and course of an SUD. These addictions may be progressive, chronic, relapsing-remitting, or a combination of patterns and may also be fatal. SUDs can be distinguished from substance-induced disorders or withdrawal-related conditions in the way their symptoms and behavioral patterns persist over time and in the absence of the pharmacological effect of the substance. Substances of abuse may include alcohol, caffeine, cannabis, hallucinogens, inhalants, opioids, sedatives, stimulants, or tobacco. Despite markedly different primary mechanisms of intoxication, the impact on the brain reward system is similar.

Gambling Disorder is characterized by repeated and problematic gambling behaviors that can compromise, disrupt, or damage personal, family, educational, and/or vocational relationships and responsibilities. Those with problematic gambling behaviors will continue despite the significant problems it may cause in their life. In extreme cases, problem gambling can result in financial ruin, legal issues, loss of family, loss of employment, and even suicide. Gambling Disorder can be episodic, with symptoms subsiding for several months in between periods of problem gambling, or persistent with continuous symptoms.

Indications/Criteria for Substance Use Treatment

For substance use treatment services, MVP Health Care uses the most current version of the New York State Office of Addiction Services and Support (OASAS) Level of Care for

Treatment for Addictions Page 3 of 9

Alcohol and Drug Treatment Referral (LOCADTR) and Change Healthcare's InterQual Criteria, determined by the line of business for which the customer is covered.

For all New York customers and lines of business (excluding Medicare and Medicare D-SNP), MVP uses the OASAS LOCADTR when treatment is provided within New York State. The LOCADTR placement and concurrent review tools are used for the following services:

INPATIENT

- 1. Hospital Based Inpatient Detoxification
- 2. Medically Supervised Inpatient Detoxification
- 3. Inpatient Rehabilitation
- 4. Residential Rehabilitation Services for Youth (RRSY) (Not covered for Medicaid, Medicare)

RESIDENTIAL

- 1. Stabilization Services in a Residential Setting
- 2. Rehabilitation Services in a Residential Setting
- 3. Reintegration in a Residential Setting (Medicaid Only Benefit)

OUTPATIENT

- 1. Outpatient Day Rehabilitation
- 2. Intensive Outpatient Service
- 3. Ancillary Withdrawal Service
- 4. Opioid Treatment Program (OTP)
- 5. Outpatient Clinic
- 6. Brief Intervention

The LOCADTR 3.0 Client Placement manual can be found on the NYS OASAS website:

https://oasas.ny.gov/system/files/documents/2019/10/LOCADTRManual3.0.pdf

The LOCADTR 3.0 Concurrent Review manual can be found on the NYS OASAS website: https://oasas.ny.gov/system/files/documents/2019/10/CRMANUAL19June2019_Final%2 https://oasas.ny.gov/system/files/documents/2019/https://oasas.ny.gov/system/files/documents/2019/https://oasas.ny.gov/system/files/documents/2019/https://oasas.ny.gov/system/files/documents/2019/https://oasas.ny.gov/system/files/documents/2019/https://oasas.ny.gov/system/files/documents/2019/https://oasas.ny.gov/system/files/documents/2019

For all Medicare (including Medicare D-SNP) and Vermont customers and lines of business, and for New York customers and lines of business when treatment is provided outside of New York State, MVP uses Change Healthcare's InterQual criteria for the following services:

INPATIENT

- 1. Inpatient Detoxification
- 2. Inpatient Rehabilitation

RESIDENTIAL (not covered by Medicare, Medicare D-SNP)

1. Residential Treatment Center

OUTPATIENT

- 1. Partial Hospital Program
- 2. Intensive Outpatient Program
- 3. Outpatient

Note: InterQual criteria is consistent with Centers for Medicare and Medicaid Services (CMS) National Coverage Determination (NCD) 130.1 Inpatient Hospital Stays for Treatment of Alcoholism, 103.2 Outpatient Hospital Services for Treatment of Alcoholism, 130.5 Treatment of Alcoholism and Drug Abuse in a Freestanding Clinic, 130.6 Treatment of Drug Abuse (Chemical Dependency) Outpatient Services, and 130.7 Withdrawal Treatment for Narcotic Addictions.

For providers directly contracted with MVP, the complete Change Healthcare InterQual criteria can be found in the provider self-service application under resources. For all other providers and customers, a copy of the criteria can be requested by contacting MVP customer care at 1-800-568-0458.

Indications/Criteria for Problem Gambling

MVP covers treatment for problematic gambling for customers enrolled in an MVP Medicaid Plan.

MVP uses the most current version of the Level of Care for Gambling Disorder Treatment Referral (LOCADTR Gambling Module). Treatment for Gambling Disorder is covered when provided through the following OASAS certified programs:

- OASAS Certified Title 14 NYCRR Part 818 Inpatient Rehabilitation Programs
- OASAS Certified Title 14 NYCRR Part 820 Residential Treatment Programs
- OASAS Certified Title 14 NYCRR Part 822 Outpatient Clinic with a Problem Gambling designation
- OASAS Certified Title 14 NYCRR Part 825 Integrated Outpatient Services with a Problem Gambling designation

The LOCADTR Gambling Module can be found on the NY OASAS website: https://oasas.ny.gov/system/files/documents/2019/10/LOCADTRManualGD_FINAL9Apr2 019.pdf

Exclusions

• Inpatient provider visits are not covered if the admission is not approved.

Treatment for Addictions Page 5 of 9

- Inpatient hospitalizations where admission and discharge occur on the same day
- Inpatient and/or Residential treatment or services that are determined to be not medically necessary by the above criteria.
- Gambling Disorder Treatment is not covered for Child Health Plus, Essential, On/Off Exchange, Fully Insured Commercial, or Medicare Plans. Coverage for ASO plans is determined by employer specific SPDs.

References (Updated 2024)

- New York State Office of Addiction Services and Supports (OASAS) Level of Care Determination (LOCADTR) - 2019. https://oasas.ny.gov/system/files/documents/2019/10/LOCADTRManual3.0.pdf
- New York State Office of Addiction Services and Supports LOCADTR 3.0 Concurrent Review Module – June 2019. https://oasas.ny.gov/system/files/documents/2019/10/CRMANUAL19June2019 Final1%20%281%29.pdf
- New York State Office of Addiction Services and Supports, Level of Care for Gambling Disorder Treatment Referral – April 2019. https://oasas.ny.gov/system/files/documents/2019/10/LOCADTRManualGD_FINAL9 Apr2019.pdf
- New York State Office of Addiction Services and Supports. Guidance for Implementation and Utilization Review for Addiction Services. Revised September 2022. https://oasas.ny.gov/system/files/documents/2022/09/utilization review concurrent-guidance.pdf
- 5. Change Healthcare InterQual 2024 Substance Use Disorders Criteria.
- 6. 2019.1 March Crosswalk to the Centers for Medicare and Medicaid Coverage Determinations. Change Healthcare, InterQual Behavioral Health Criteria.
- 7. May 24, 2022 OASAS Notification to Managed Care Organizations re: Part 820 Reintegration retroactive to November 1, 2021.
- 8. National Council on Problem Gambling, What is Problem Gambling? https://www.ncpgambling.org/help-treatment/faq/
- 9. American Psychiatric Association, What is Gambling Disorder?

 https://www.psychiatry.org/patients-families/gambling-disorder/what-is-gambling-disorder
- 10. American Psychiatric Association. (2022). *Diagnostic and statistical manual of mental disorders* (5th ed., text rev.).

Treatment for Addictions Page 6 of 9

11. New York State Office of Addiction Services and Supports (OASAS) Ambulatory Patient Group (APG) Clinical and Medicaid Billing Guidance – September 2023. APG
Manual 042021 (ny.gov).

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Medical Management Requirements*			
Customer Product	Inpatient	Residential	Outpatient
New York Products			
НМО	Notification Required	Notification Required	Potential for Retrospective Review
PPO in Plan	Notification Required	Notification Required	Potential for Retrospective Review
PPO OOP	Notification Required	Notification Required	Potential for Retrospective Review
POS in Plan	Notification Required	Notification Required	Potential for Retrospective Review
POS OOP	Notification Required	Notification Required	Potential for Retrospective Review
Essential Plan	Notification Required	Notification Required	Potential for Retrospective Review
MVP Medicaid Managed Care	Notification Required	Notification Required	Potential for Retrospective Review
MVP Child Health Plus	Notification Required	Notification Required	Potential for Retrospective Review
MVP Harmonious Health Care Plan	Notification Required	Notification Required	Potential for Retrospective Review
MVP Medicare Complete Wellness	Notification Required	Not Covered	Potential for Retrospective Review
MVP Medicare Preferred Gold HMO POS	Notification Required	Not Covered	Potential for Retrospective Review
MVP Medicare Secure HMO POS	Notification Required	Not Covered	Potential for Retrospective Review
MVP Medicare Secure Plus HMO POS	Notification Required	Not Covered	Potential for Retrospective Review
MVP Medicare WellSelect PPO	Notification Required	Not Covered	Potential for Retrospective Review
MVP Medicare WellSelect Plus PPO	Notification Required	Not Covered	Potential for Retrospective Review
MVP Medicare Patriot Plan PPO	Notification Required	Not Covered	Potential for Retrospective Review
MVP DualAccess D-SNP HMO	Notification Required	Not Covered	Potential for Retrospective Review
MVP DualAccess Complete D-SNP HMO	Notification Required	Not Covered	Potential for Retrospective Review
MVP DualAccess Plus D-SNP HMO	Notification Required	Not Covered	Potential for Retrospective Review
UVM Health Advantage Select PPO	Notification Required	Not Covered	Potential for Retrospective Review
USA Care	Notification Required	Not Covered	Potential for Retrospective Review
Healthy NY	Notification Required	Notification Required	Potential for Retrospective Review
MVP Premier	Notification Required	Notification Required	Potential for Retrospective Review
MVP Premier Plus	Notification Required	Notification Required	Potential for Retrospective Review
MVP Premier Plus HDHP	Notification Required	Notification Required	Potential for Retrospective Review
MVP Secure	Notification Required	Notification Required	Potential for Retrospective Review
MVP EPO	Notification Required	Notification Required	Potential for Retrospective Review
MVP EPO HDHP	Notification Required	Notification Required	Potential for Retrospective Review
MVP PPO	Notification Required	Notification Required	Potential for Retrospective Review
MVP PPO HDHP	Notification Required	Notification Required	Potential for Retrospective Review
Student Health Plans	Notification Required	Notification Required	Potential for Retrospective Review
ASO	See SPD	See SPD	See SPD
Vermont Products			
POS in Plan	Notification Required	Notification Required	Potential for Retrospective Review
POS OOP	Notification Required	Notification Required	Potential for Retrospective Review
MVP Medicare Preferred Gold HMO POS	Notification Required	Not Covered	Potential for Retrospective Review
MVP Medicare Secure Plus HMO POS	Notification Required	Not Covered	Potential for Retrospective Review
MVP VT HMO	Notification Required	Notification Required	Potential for Retrospective Review
MVP VT HDHP HMO	Notification Required	Notification Required	Potential for Retrospective Review
MVP VT Plus HMO	Notification Required	Notification Required	Potential for Retrospective Review
MVP VT Plus HDHP HMO	Notification Required	Notification Required	Potential for Retrospective Review
MVP Secure	Notification Required	Notification Required	Potential for Retrospective Review
ASO	See SPD	See SPD	See SPD

♦ Note: notification requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Notification Required Notification Required

Potential for Retrospective Review No Notification Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

**MVP adheres to the most recent version of NYS guidance as it pertains to Inpatient Substance Use admissions for in-network OASAS licensed providers and facilities.

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Revision History:

12/01/2020 – Updated medical management requirements grid, updated OASAS LOCADTR and InterQual references.

12/01/2022 – Annual review; added exclusions

01/01/2023 – Changed name of policy from Substance Use Disorder Treatment to Treatment for Additions, added grid for codes requiring authorization, rewrote overview of policy, added treatment for problematic gambling for customers enrolled in an MVP Medicaid Plan, updated references.

02/01/2025 – Annual review with no changes to the indications or criteria.

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Umbilical Cord Blood Banking

Type of Policy: Medical

Prior Approval Date: 04/04/2022

Approval Date: 03/04/2023

Effective Date: 06/01/2024

Related Polices: N/A

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

N/A

Codes Requiring Retrospective Review

CPT Codes:

85999 - Unlisted hematology and coagulation procedure

HCPCS Codes:

S2140 - Cord blood harvesting for transplantation, allogeneic

Experimental/Investigational

N/A

Common Diagnosis Codes

N/A

Common Procedure Codes

N/A

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are

subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

Blood harvested from the umbilical cord and placenta shortly after delivery of neonates contains stem and progenitor cells capable of restoring hematopoietic function. Cord blood has been used as an alternative source of allogeneic stem cells. Cord blood is readily available and is thought to be antigenically "naive," thus hopefully minimizing the incidence of graft-versus-host disease (GVHD) and permitting the broader use of unrelated cord blood transplants.

Indications/Criteria

Collection and storage of cord blood from a neonate may be considered medically necessary when all of the following criteria have been met:

- there is an identified recipient who is an MVP customer; and
- an allogeneic transplant is imminent for whom a suitable bone marrow donor cannot be found; and
- a suitable cord blood sample with a maximum of three human leukocyte antigen mismatches is available.

Exclusions

Umbilical cord blood banking is not covered for any indication not listed in the Indications/Criteria section of the medical policy.

Prophylactic collection and storage of umbilical cord blood for an unspecified future use for an autologous stem cell transplant in the original donor or for an unspecified future use as an allogeneic stem cell transplant in a related or unrelated donor does not meet medical necessity criteria for any indication and is considered not medically necessary.

Medicare

Based on review there is no Medicare Local Coverage Determination (LCD) or Medicare National Coverage Determination (NCD) for Umbilical Cord Blood Banking.

References (Reviewed 2024)

- 1. American Academy of Pediatrics. Cord Blood Banking for Possible Future
 Transplantation. Policy Statement. PEDIATRICS Volume 119, Number 1, January 2007.
 Available: http://pediatrics.aappublications.org/content/119/1/165.full
- 2. American College of Obstetricians and Gynecologists (ACOG). Committee Opinion Number 814. December 2020. Delayed Umbilical Cord Clamping After Birth.
- 3. American Society for Blood and Marrow Transplantation (ASBMT) Position Statement. Collection and Preservation of Cord Blood for Personal Use. © 2008 American

Society for Blood and Marrow Transplantation. Available: https://www.astct.org/advocate/policy-statements

- 4. American College of Obstetricians and Gynecologists (ACOG). ACOG Committee Opinion. Umbilical Cord Blood Banking. ACOG Committee Opinion No. 771. Published 2019. Available: https://www.acog.org/clinical/clinicalguidance/committee-opinion/articles/2019/03/umbilical-cord-blood-banking
- 5. Shearer WT, Lubin BH, Cairo MS, Notarangelo LD; SECTION ON HEMATOLOGY/ONCOLOGY; SECTION ON ALLERGY AND IMMUNOLOGY. Cord Blood Banking for Potential Future Transplantation. Pediatrics. 2017 Nov;140(5). pii: e20172695.
- 6. National Marrow Donor Program. Cord blood donation frequently asked questions. Copyright© 1996–2021. National Marrow Donor Program. Page not dated. Accessed April 2021. Available at URL address: https://bethematch.org/support-the-cause/donate-cord-blood/cord-blood-fags/
- 7. World Marrow Donor Association (WMDA). WMDA Policy Statement for the Utility of Autologous or Family Cord Blood Unit Storage. Updated May 2019.

Customer Product	Medical Management Requirements*
New York Products	
HMO	Retrospective Review
PPO in Plan	Retrospective Review
PPO OOP	Retrospective Review
POS in Plan	Retrospective Review
POS OOP	Retrospective Review
Essential Plan	Retrospective Review
MVP Medicaid Managed Care	Retrospective Review
MVP Child Health Plus	Retrospective Review
MVP Harmonious Health Care Plan	Retrospective Review
MVP Medicare Complete Wellness	Retrospective Review
MVP Medicare Preferred Gold HMO POS	Retrospective Review
MVP Medicare Secure HMO POS	Retrospective Review
MVP Medicare Secure Plus HMO POS	Retrospective Review
MVP Medicare WellSelect PPO	Retrospective Review
MVP Medicare WellSelect Plus PPO	Retrospective Review
MVP Medicare Patriot Plan PPO	Retrospective Review
MVP DualAccess D-SNP HMO	Retrospective Review
MVP DualAccess Complete D-SNP HMO	Retrospective Review
MVP DualAccess Plus D-SNP HMO	Retrospective Review
UVM Health Advantage Select PPO	Retrospective Review
USA Care	Potential for Retrospective Review
Healthy NY	Retrospective Review
MVP Premier	Retrospective Review
MVP Premier Plus	Retrospective Review
MVP Premier Plus HDHP	Retrospective Review
MVP Secure	Retrospective Review
MVP EPO	Retrospective Review
MVP EPO HDHP	Retrospective Review
MVP PPO	Retrospective Review
MVP PPO HDHP	Retrospective Review
Student Health Plans	Retrospective Review
ASO	See SPD
Vermont Products	See St D
POS in Plan	Retrospective Review
POS OOP	Retrospective Review
MVP Medicare Preferred Gold HMO POS	Retrospective Review
MVP Medicare Secure Plus HMO POS	Retrospective Review
MVP VT HMO	Retrospective Review
MVP VT HIMO	Retrospective Review
MVP VT Plus HMO	Retrospective Review
MVP VT Plus HDHP HMO	Retrospective Review
MVP Secure	Retrospective Review
ASO	See SPD
AJU	JEE JFD

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit
See SPD See Specific Plan Design

Revision History:

06/01/2022 – Annual Review with no changes to the indications or criteria, Medicare statement added, references updated.

06/01/2024 – Annual Review no changes to criteria.



Vagus Nerve Stimulation

Type of Policy: Medical

Prior Approval Date: n/a

Approval Date: 12/02/2024 **Effective Date:** 04/01/2025

Related Polices: none

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

E0735 - Noninvasive vagus nerve stimulator

Codes Requiring Retrospective Review

64999 - Unlisted procedure, nervous system

Experimental/Investigational

64999 – Unlisted procedure, nervous system

E0735 - Noninvasive vagus nerve stimulator

Covered Medically Necessary Diagnosis Codes:

ICD 10 Diagnosis Code:	Description:
G40.0001 – G40.219	Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset
G40.301 – G40.319	Generalized idiopathic epilepsy and epileptic syndromes
G40.A01- G40.A19	Absence epileptic syndrome
G40.B01- G40.B19	Juvenile myoclonic epilepsy, not intractable
G40.401- G40.419	Other generalized epilepsy and epileptic syndromes

Vagus Nerve Stimulator Page 1 of 6

G40.501- G40.509	Epileptic seizures related to external causes
G40.801- G40.919	Other epilepsy and recurrent seizures

All other ICD10 diagnosis codes are considered investigational.

Common Diagnosis Codes associated with this policy have been provided for informational purposes only. The list of codes may not be all-inclusive and may be updated to reflect any applicable revisions to the ICD-10 code set and/or medical necessity guidelines applied in this policy.

Common Procedure Codes

CPT Codes: 64568, 64569, 64570, 95970, 95976, 95977

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

This Coverage Policy addresses the indications for use of an implantable vagus nerve stimulator (VNS) and a non-implantable transcutaneous VNS (tVNS) stimulator for the treatment of medically intractable seizures and as a treatment of other indications. These devices are used as a treatment of medically and surgically refractory seizures associated with intractable epilepsy.

Indications/Criteria

- 1. Implantation of a vagus nerve stimulation device is considered medically necessary in an individual with medically and surgically refractory seizures when there is failure, contraindication or intolerance to all suitable medical and pharmacological management.
- 2. Replacement or revision of an implanted neurostimulator pulse generator system (with or without lead changes) for vagus nerve stimulation is considered medically necessary when:
 - a. The implantation occurred because the above criteria were met; and
 - Documentation includes initial date of implantation, that customer has been compliant with device and is expected to continue to benefit from device, and
 - c. The current implanted device is no longer functioning appropriately.

Exclusions

An implantable vagus nerve stimulation device has not been medically proven to be effective and, therefore, is considered investigational as a treatment for patients with depression or any other non-epileptic conditions (e.g., heart failure, fibromyalgia,

Vagus Nerve Stimulator Page 2 of 6

tinnitus, traumatic brain injury, Parkinson's disease, essential tremor, headache, post-stroke).

Non-implantable vagus nerve stimulation devices, including transcutaneous vagus nerve stimulation (tVNS) (E0735) devices, are considered investigational for all indications (e.g., headache or migraines) because the long-term outcomes in the published peer-reviewed scientific literature do not support their safety and effectiveness.

References (2024)

- 1. Aihua L, Lu S, Liping L, Xiuru W, Hua L, Yuping W. A controlled trial of transcutaneous vagus nerve stimulation for the treatment of pharmacoresistant epilepsy. Epilepsy Behav. 2014 Oct;39:105-10.
- 2. Apovian CM, et al. Two-year outcomes of vagal nerve blocking (vBloc) for the treatment of obesity in the ReCharge trial. Obes Surg 2017 Jan;27(1):169-176.
- 3. Ardesch JJ, Buschman HPJ, Wagner-Schimmel LJJC, van der Aa HE, Hageman G. Vagus nerve stimulation for medically refractory epilepsy: A long-term follow-up study. Seizure. 2007 Oct;16(7):579-85.
- 4. Beekwilder JP, Beems T. Overview of the clinical applications of vagus nerve stimulation. J Clin Neurophysiol. 2010 Apr;27(2):130-8.
- 5. Centers for Medicare and Medicaid Services (CMS). National Coverage Determinations. Vagus nerve stimulation. NCD #160.18. Effective February 15, 2019. Available at:
- 6. De Herdt V, Boon P, Ceulemans B, Hauman H, Lagae L, Legros B, et al. Vagus nerve stimulation for refractory epilepsy: A Belgian multicenter study. Eur J Paediatr Neurol. 2007 Sep;11(5):261-9.
- 7. Di Lazzaro V, Oliviero A, Pilato F, Saturno E, Dileone M, Meglio M, et al. Effects of VNS on cortical excitability in epileptic patients. Neurology. 2004;62(12):1-6.
- 8. gammaCore®. electroCore, LLC. Manufacturer website. Accessed October 16, 2023. Available at URL address: https://www.electrocore.com/
- 9. Ghaemi K, Elsharkawy AE, Schulz R, Hoppe M, Polster T, Pannek H, Ebner A. Vagus nerve stimulation: outcome and predictors of seizure freedom in long-term follow-up. Seizure. 2010 Jun;19(5):264-8.
- 10. He W, Jing X, Wang X, Rong P, Li L, Shi H, et al. Transcutaneous auricular vagus nerve stimulation as a complementary therapy for pediatric epilepsy: A pilot trial. Epilepsy Behav. 2013 Sep;28(3):343-6.
- 11. Heck C, Helmers S, DeGiorgio. VNS therapy, epilepsy, and device parameters: scientific parameters and recommendations for use. Neurology. 2002;59(6):1-12.

- 12. Klinkenberg S, van den Bosch CN, Majoie HJ, Aalbers MW, Leenen L, Hendriksen J, et al. Behavioural and cognitive effects during vagus nerve stimulation in children with intractable epilepsy A randomized controlled trial. Eur J Paediatr Neurol. 2012 Aug 6.
- 13. Levy ML, Levy KM, Hoff D, Amar AP, Park MS, Conklin JM, et al. Vagus nerve stimulation therapy in patients with autism spectrum disorder and intractable epilepsy: results from the vagus nerve stimulation therapy patient outcome registry. J Neurosurg Pediatr. 2010 Jun;5(6):595-602.
- 14. Lund C, Kostov H, Blomskjøld B, Nakken KO. Efficacy and tolerability of long-term treatment with vagus nerve stimulation in adolescents and adults with refractory epilepsy and learning disabilities. Seizure. 2011 Jan;20(1):34-7.
- 15. Morris GL 3rd, Gloss D, Buchhalter J, Mack KJ, Nickels K, Harden C. Evidence-based guideline update: Vagus nerve stimulation for the treatment of epilepsy: Report of the Guideline Development Subcommittee of the American Academy of Neurology. Neurology. 2013 Aug 28.
- 16. Ryvlin P, Gilliam FG, Nguyen DK, Colicchio G, Iudice A, Tinuper P, et al. The long-term effect of vagus nerve stimulation on quality of life in patients with pharmacoresistant focal epilepsy: the PuLsE (Open Prospective Randomized Long-term Effectiveness) trial. Epilepsia. 2014 Jun;55(6):893-900.
- 17. Uthman B, Reichl A, Dean J, Eisenschenk S, Gilmore R, Reid S, et al. Effectiveness of VNS in epilepsy patients: a 12-year observation. Neurology. 2004;63(6):1-8.
- 18. Vonck K, Dedeurwaerdere S, De Groote L, Thadani V, Claeys P, Gossiaux F, Van Roost D, Boon P. Generator replacement in epilepsy patients treated with vagus nerve stimulation. Seizure. 2005 Mar;14(2):89-99.
- 19. You SJ, Kang HC, Kim HD, Ko TS, Kim DS, Hwang YS, et al. Vagus nerve stimulation in intractable childhood epilepsy: a Korean multicenter experience. J Korean Med Sci. 2007 Jun;22(3):442-5.

Member Product	Medical Management Requirements*
New York Products	
НМО	Prior Authorization
PPO in Plan	Prior Authorization
PPO OOP	Prior Authorization
POS in Plan	Prior Authorization
POS OOP	Prior Authorization
Essential Plan	Prior Authorization
MVP Medicaid Managed Care	Prior Authorization
MVP Child Health Plus	Prior Authorization
MVP Harmonious Health Care Plan	Prior Authorization
MVP Medicare Complete Wellness	Prior Authorization
MVP Medicare Preferred Gold HMO POS	Prior Authorization
MVP Medicare Secure HMO POS	Prior Authorization
MVP Medicare Secure Plus HMO POS	Prior Authorization
MVP Medicare WellSelect PPO	Prior Authorization
MVP Medicare WellSelect Plus PPO	Prior Authorization
MVP Medicare Patriot Plan (PPO)	Prior Authorization
USA Care PPO	Potential for Retrospective Review
MVP DualAccess D-SNP HMO	Prior Authorization
MVP DualAccess Complete D-SNP HMO	Prior Authorization
MVP DualAccess Plus D-SNP HMO	Prior Authorization
UVM Health Advantage Select PPO	Prior Authorization
Healthy NY	Prior Authorization
MVP Premier	Prior Authorization
MVP Premier Plus	Prior Authorization
MVP Premier Plus HDHP	Prior Authorization
MVP Secure	Prior Authorization
MVP EPO	Prior Authorization
MVP EPO HDHP	Prior Authorization
MVP PPO	Prior Authorization
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POS in Plan	Prior Authorization
POS OOP	Prior Authorization
MVP Medicare Preferred Gold HMO POS POS	Prior Authorization
MVP Medicare Secure Plus HMO POS	Prior Authorization
MVP VT HMO	Prior Authorization
MVP VT HDHP HMO	Prior Authorization
MVP VT Plus HMO	Prior Authorization
MVP VT Plus HDHP HMO	Prior Authorization
MVP Secure	Prior Authorization
ASO	See SPD

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review.

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

MVP Health Care Medical Policy
Revision History:

04/01/2025 – New Policy Implementation. Prior authorization for DME only, all other procedures have potential for retrospective review.



Varicose Vein Treatment

Type of Policy: Surgical

Prior Approval Date: 03/25/2025 **Provisional Approval** 05/30/2025

Date:

Provisional Effective 07/01/2025

Date:

Related Polices: N/A

Codes Requiring Prior Authorization

36465	Injection of non-compounded foam sclerosant (e.g. Varithena) with ultrasound compression maneuvers to guide dispersion of the injectate, inclusive of all imaging guidance and monitoring; single incompetent extremity truncal vein
36466	Injection of non-compounded foam sclerosant (e.g. Varithena) with ultrasound compression maneuvers to guide dispersion of the injectate, inclusive of all imaging guidance and monitoring; multiple incompetent truncal veins

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

CPT Codes: N/A

Experimental/Investigational Codes Requiring Retrospective Review:

CPT Codes	Code Description
36473	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; first vein treated

Varicose Vein Treatments Page 1 of 10

36474	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; subsequent vein(s) treated in a single extremity, each through separate access sites
36482	Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a chemical adhesive (e.g., VariClose/VenaSeal) (e.g., cyanoacrylate) remote from the access site, inclusive of all imaging guidance and monitoring, percutaneous; first vein treated
36483	Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a chemical adhesive (e.g., VariClose/VenaSeal) (e.g., cyanoacrylate) remote from the access site, inclusive of all imaging guidance and monitoring, percutaneous; subsequent vein(s) treated in a single extremity, each through separate access sites
37799	Unlisted procedure, vascular surgery

Common Diagnosis Codes

ICD-10- CM Diagnosis Codes

I83.10,I83.11,I83.12, I83.201, I83.202, I83.203, I83.204,I83.205,I 83.208, I83.209,I83.211, I83.212, I83.213, I83.214, I83.215, I83.218, I83.219, I83.221, I83.222, I83.223, I83.224, I83.225, I83.228, I83.229, I83.811, I83.812, I83.813, I83.819, I83.891, I83.892, I83.893, I83.899

Common Diagnosis Codes associated with this policy have been provided for informational purposes only. The list of codes may not be all-inclusive and may be updated to reflect any applicable revisions to the ICD-10 code set and/or medical necessity guidelines applied in this policy.

Common Procedure Codes

HCPCS Code: 36475, 36476, 36478, 36479, S2202

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

Endovascular laser treatment of the saphenous vein and endoluminal radiofrequency ablation employ the delivery of thermal energy via an intraluminal catheter for the treatment of varicose veins of the lower extremity. Both procedures are considered to be minimally invasive alternatives to vein ligation and stripping. Endovenous

Varicose Vein Treatments Page 2 of 10

radiofrequency ablation is FDA-approved for the treatment of the greater saphenous vein, perforators and tributary veins. Endovenous laser ablation is FDA-approved for the treatment of varicose veins and varicosities associated with superficial reflux of the greater saphenous vein.

Sclerotherapy is a proposed treatment that uses a solution injected into veins to cause the walls of the veins to stick together and seal off. The chemical solution can either be a liquid, foam or glue.

Indications/Criteria

Documentation Requirements

- Documentation in the patient's medical record must contain a history and physical examination supporting the diagnosis of symptomatic varicose veins, including the symptoms and indicators in Indications/Criteria and must be available upon request.
- It must be documented in the medical record that the patient has failed a trial of conservative, non-surgical management for at least six (6) weeks, including:
 - NSAIDS, unless not tolerated;
 - exercise e.g., walking, bicycling, swimming, leg lifts, leg squats;
 - elevate legs; take several short breaks daily to elevate legs above the level of the heart;
 - compressive hose;
 - weight loss (if applicable);
 - o avoid sitting with legs crossed.
- Photographs may be requested.

Endovenous Radiofrequency Ablation and Endovenous Laser Ablation

Endovenous radiofrequency ablation and endovenous laser ablation of the saphenous vein(s) may be covered when the following criteria are met and when they are performed by the following specialists:

- general surgeons;
- vascular surgeons; or
- interventional radiologists.

Endovenous radiofrequency ablation and endovenous laser ablation are covered only for the treatment of the great saphenous vein (GSV), small saphenous vein (SSV) and the anterior accessory GSV (AAGSV) to improve symptoms attributable to saphenofemoral or saphenopopliteal reflux.

Endovenous radiofrequency ablation and endovenous laser ablation of the saphenous vein(s) may be medically necessary when the following criteria have been met:

- the patient has persistent symptoms that interfere with activities of daily living and has one, or more, of the following:
 - stasis ulcer of the lower leg
 - persistent aching, cramping, burning, itching, swelling which significantly interferes with the activities of daily living in refractory to conservative nonsurgical management;
 - o significant attacks of superficial phlebitis;
 - o bleeding associated with the diseased vessel of the lower extremities,
 - hemorrhage from ruptured varix
 - stasis dermatitis
 - o refractory dependent edema; or
 - ulceration from venous stasis where incompetent varices are a contributing factor; and
- the patient's anatomy and clinical condition must be amenable to the proposed treatment, including all of the following:
 - absence of aneurysm in the target segment;
 - absence of thrombosis or vein tortuosity which would impair catheter advancement;
 - vein diameter of <u>></u> 3mm;
 - o a maximum vein diameter of 20mm for laser ablation for endovascular laser treatment;
 - o absence of significant peripheral arterial disease;
 - o no history of DVT with incomplete re-canalization; and
 - evidence from a duplex scan indicating saphenofemoral junction incompetence and reflux at the level of the procedure is required for all requests.

Liquid or Foam Sclerotherapy

Liquid or Foam Sclerotherapy (e.g. Varithena) will be considered medically necessary for the treatment of symptomatic saphenous veins, varicose tributaries, accessory and perforator veins when the following criteria are met:

Vein size is 2.5 mm or greater in diameter, measured by recent ultrasound;
 and

- Documentation of one or more of the following:
 - Ulceration due to venous stasis;
 - hemorrhage or recurrent bleeding from ruptured superficial varicosity,
 - Recurrent superficial thrombophlebitis despite a 3-month trial of conservative management (i.e. elevating legs, exercise, weight loss, compression stockings); or
 - Severe and persistent pain, swelling, itching, burning, or other symptom that interfere with activities of daily living despite a 3month trial of conservative management (i.e. elevating legs, exercise, weight loss, compression stockings).

Exclusions

- Endovenous Mechanochemical Ablation (MOCA) of Varicose Veins (CPT code 36473 and 36474) (e.g. ClariVein Occlusion Catheter)
 - Endovenous mechanochemical ablation (MOCA) for the treatment of varicose veins is not covered. There is insufficient evidence in peer reviewed literature that endovenous mechanochemical ablation results in proven beneficial outcomes and, therefore, is considered investigational.
- Contraindications to endovenous radiofrequency ablation and endovenous laser ablation include:
 - o pregnancy or patients who are breast feeding;
 - o severe distal arterial occlusive disease;
 - o deep vein thrombosis;
 - vein diameter of >20mm for laser ablation; and
- The use of transilluminated powered phlebectomy for symptomatic varicose veins, also known as the TRIVEXTM procedure, is not supported in peer-reviewed literature to be as effective as VNUS/EVLT. Transilluminated powered phlebectomy for symptomatic varicose veins is considered investigational.
- The following interventional treatments are considered to be cosmetic and not medically necessary:
 - o interventional treatment of asymptomatic varicosities;
 - o treatment of telangiectases; and
 - o any vascular treatment or procedure performed for cosmetic purposes.

- The use of medical adhesive (also referred to as cyanoacrylate superglue, n-butyl-cyanoacrylate) (e.g., VariClose Vein Sealing System, VenaSeal Closure System (CPT: 36482, 36483) for the treatment of varicose veins is considered experimental and investigational because its effectiveness has not been established in the medical literature.
- Endovenous foam sclerotherapy (e.g., Varithena (CPT: 36465, 36466) is not covered for any other indication and for veins less than 2.5 mm in diameter.

Medicare Variation

The accepted treatments for eliminating saphenous (great saphenous vein (GSV), anterior accessory GSV (AAGSV), small saphenous vein (SSV)) reflux (saphenofemoral or saphenopopliteal) are:

- radiofrequency ablation (RFA);
- laser ablation (EVLA);
- polidocanol microfoam (PEM) or endovenous foam sclerotherapy (e.g. Varithena (CPT: 36465, 36466));
- cyanoacrylate embolization (CAE) ablation (e.g., VariClose Vein Sealing System, VenaSeal Closure System (CPT: 36482, 36483)), and
- mechanochemical ablation (MOCA) CPT code 36473 and 36474 (e.g. ClariVein Occlusion Catheter).

Coverage is only for devices with FDA approval or clearance consistent with saphenous ablation and used according to its approved instructions for use.

The treatments of the tributary veins will be considered medically necessary if saphenous reflux is not present or already successfully eliminated, the veins are > than 4 mm in diameter and if the patient remains symptomatic after a six-week trial of conservative therapy.

The patient is considered symptomatic if any of the following signs and symptoms of significantly diseased vessels of the lower extremities are documented in the medical record:

- stasis ulcer of the lower leg,
- significant pain and significant edema that interferes with activities of daily living,
- bleeding associated with the diseased vessels of the lower extremities,
- recurrent episodes of superficial phlebitis,
- stasis dermatitis, or
- refractory dependent edema.

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Coverage of endovenous ablation therapy is limited to patients with:

- a maximum vein diameter of 12 mm for CAE, PEM and MOCA; and
- absence of thrombosis or vein tortuosity, which would impair catheter advancement (except for PEM).

The following interventional treatments are not considered medically reasonable or necessary and are denied as such:

- Surgery, endovenous ablation, or sclerotherapy are typically not performed for varicose veins that develop or worsen during pregnancy.
- Reinjection following recanalization or failure of vein closure without recurrent signs or symptoms.
- Sclerotherapy of the saphenous vein at its junction with the deep system.
- Noncompressive sclerotherapy.
- Compressive sclerotherapy for large, extensive or truncal varicosities.
- Sclerotherapy, ligation and/or stripping of varicose veins, or endovenous ablation therapy are generally not covered for patients with severe distal arterial occlusive disease; obliteration of deep venous system; an allergy to the sclerosant; or a hypercoagulable state.

For full Medicare coverage details about treatment of varicose veins of the lower extremity please refer to the following LCD for Medicare Customers: National Government Services, Inc. Local Coverage Determination (LCD) Varicose Veins of the Lower Extremity, Treatment of (L33575) Revision Effective Date: 11/21/2019. Available: https://www.cms.gov/

References (Reviewed 2025)

- Centers for Medicare and Medicaid Services. National Government Services, Inc. Local Coverage Determination (LCD) for varicose veins of the lower extremity, treatment of (L33575) (Revision Effective Date 11/21/2019). Available: https://www.cms.gov/
- 2. Mayo Clinic. Varicose veins. Available: www.mayoclinic.com/health/varicose-veins/DS00256
- 3. Jones, RH, MD, MSPH, Carek, PJ, MD, MS,. Management of Varicose Veins. American Academy of Family Physicians. American Family Physician Dec 1, 2008. Available: https://www.aafp.org/afp/2008/1201/p1289.html
- 4. McKesson Health Solutions LLC. Varicose Veins. Copyright © 2012 McKesson Health Solutions LLC. All rights reserved.

Varicose Vein Treatments Page 7 of 10

- 5. Bishawi M, Bernstein R, Boter M, et al. Mechanochemical ablation in patients with chronic venous disease: A prospective multicenter report. *Phlebology*. 2013;29(6):397-400.
- 6. Boersma D, van Eekeren RR, Werson DA, van der Waal RI, Reijnen MM, de Vries JP. Mechanochemical endovenous ablation of small saphenous vein insufficiency using the ClariVein® device: one-year results of a prospective series. *Eur J Vasc Endovasc Surg*. 2013;45(3):299-303.
- 7. Bootun R, Lane T, Dharmarajah B, et al. Intra-procedural pain score in a randomised controlled trial comparing mechanochemical ablation to radiofrequency ablation: The Multicentre Venefit™ versus ClariVein® for varicose veins trial. *Phlebology*. Epub ahead of print. September 5, 2014. Available: http://phl.sagepub.com/content/early/2014/09/04/0268355514551085.long. Accessed November 2016.
- 8. Hayes, Inc. Health Technology Assessment. Mechanochemical Endovenous Ablation (MOCA) with the ClariVein Infusion Catheter Nonthermal Vein Ablation System (Merit Medical Systems Inc.) for Treatment of Varicose Veins. Hayes, Inc. February 25, 2022.
- 9. Lam YL, De Maeseneer M, Lawson J, et al. Expert review on the VenaSeal® system for endovenous cyano-acrylate adhesive ablation of incompetent saphenous trunks in patients with varicose veins. Expert Rev Med Devices. 2017;14(10):755-762.
- 10. Gibson K, Ferris B. Cyanoacrylate closure of incompetent great, small and accessory saphenous veins without the use of post-procedure compression: initial outcomes of a post-market evaluation of the VenaSeal System (the Waves study). Vascular. 2017;25(2):149-156
- 11. Hayes, Inc.Health Technology Assessment. Polidocanol Endovenous Microfoam (Varithena) 1% for Treatment of Varicose Veins. Hayes, Inc. November 10, 2022.
- 12. Hayes Inc. Health Technology Assessment. Cyanoacrylate Embolization With the VenaSeal Closure System (Medtronic Inc.) for the Treatment of Varicose Veins. Hayes, Inc. September 2, 2022.

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Customer Product	Medical Management Requirements*
New York Products	
HMO	Prior Auth
PPO In Plan	Prior Auth
PPO OOP	Prior Auth
POS In Plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Prior Auth
MVP Child Health Plus	Prior Auth
MVP Harmonious Health Care Plan	Prior Auth
MVP Medicare Complete Wellness	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP Medicare WellSelect PPO	Prior Auth
MVP Medicare WellSelect Plus PPO	Prior Auth
MVP Medicare Patriot Plan PPO	Prior Auth
MVP DualAccess D-SNP HMO	Prior Auth
MVP DualAccess Complete D-SNP HMO	Prior Auth
MVP DualAccess Plus D-SNP HMO	Prior Auth
UVM Health Advantage Select PPO	Prior Auth
USA Care	Prior Auth
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	
POS In Plan	Prior Auth
POS OOP	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP VT HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD
	·

[♦] Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

*Medical Management Requirements

Prior Auth
Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

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Revision History

04/01/2023 – Annual review with no changes to the indications or criteria, references updated.

08/01/2025 – Annual review, no changes to criteria.

07/01/2025 – Coverage has been added to liquid or foam sclerotherapy (e.g., Varithena) with criteria and the procedures added to prior authorization. Title of policy changed to Varicose Vein Treatments.

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Ventricular Assist Devices (VADs) and Total Artificial Heart

Type of Policy: Medical

Prior Approval Date: 01/09/2022

Approval Date: 12/02/2024

Effective Date: 04/01/2025 **Related Polices:** Transplants

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

CPT/HCPCS	Description
33927	Implantation of a total replacement heart system (artificial heart) with
	recipient cardiectomy
33928	Removal and replacement of total replacement heart system (artificial
	heart)
33929	Removal of a total replacement heart system (artificial heart) for heart
	transplantation
33975	Insertion of ventricular assist device; extracorporeal, single ventricle
33976	Insertion of ventricular assist device; extracorporeal, biventricular
33977	Removal of ventricular assist device; extracorporeal, single ventricle
33978	Removal of ventricular assist device; extracorporeal, biventricular
33979	Insertion of ventricular assist device, implantable intracorporeal, single
	ventricle
33981	Replacement of extracorporeal ventricular assist device, single or
	biventricular, pump(s), single or each pump
33982	Replacement of ventricular assist device pump(s); implantable
	intracorporeal, single ventricle, without cardiopulmonary bypass
33983	Replacement of ventricular assist device pump(s); implantable
	intracorporeal, single ventricle, with cardiopulmonary bypass
Q0478	Power adapter for use with electric or electric/pneumatic ventricular
	assist device, vehicle type

MVP Health C	are Medical Policy
Q0479	Power module for use with electric or electric/pneumatic ventricular
	assist device, replacement only
Q0481	Microprocessor control unit for use with electric ventricular assist
	device, replacement only
Q0482	Microprocessor control unit for use with electric/pneumatic
	combination ventricular assist device, replacement onl
Q0483	Monitor/display module for use with electric ventricular assist device,
	replacement only
Q0484	Monitor/display module for use with electric or electric/pneumatic
	ventricular assist device, replacement only
Q0485	Monitor control cable for use with electric ventricular assist device,
	replacement only
Q0486	Monitor control cable for use with electric/pneumatic ventricular assist
	device, replacement only
Q0487	Leads (pneumatic/electrical) for use with any type electric/pneumatic
	ventricular assist device, replacement only
Q0488	Power pack base for use with electric ventricular assist device,
	replacement only
Q0489	Power pack base for use with electric/pneumatic ventricular assist
	device, replacement only
Q0490	Emergency power source for use with electric ventricular assist device,
	replacement only
Q0491	Emergency power source for use with electric/pneumatic ventricular
	assist device, replacement only
Q0492	Emergency power supply cable for use with electric ventricular assist
	device, replacement only
Q0493	Emergency power supply cable for use with electric/pneumatic
	ventricular assist device, replacement only
Q0494	Emergency hand pump for use with electric or electric/pneumatic
	ventricular assist device, replacement only
Q0495	Battery/power pack charger for use with electric or electric/pneumatic
	ventricular assist device, replacement only
Q0496	Battery, other than lithium-ion, for use with electric or
	electric/pneumatic ventricular assist device, replacement only
Q0497	Battery clips for use with electric or electric/pneumatic ventricular assist
	device, replacement only
Q0498	Holster for use with electric or electric/pneumatic ventricular assist
	device, replacement only
Q0499	Belt/vest/bag for use to carry external peripheral components of any
	type ventricular assist device, replacement only
Q0500	Filters for use with electric or electric/pneumatic ventricular assist
	device, replacement only

Q0501	Shower cover for use with electric or electric/pneumatic ventricular assist device, replacement only
00700	· · · · · · · · · · · · · · · · · · ·
Q0502	Mobility cart for pneumatic ventricular assist device, replacement only
Q0503	Battery for pneumatic ventricular assist device, replacement only, each
Q0504	Power adapter for pneumatic ventricular assist device, replacement
	only, vehicle type
Q0507	Miscellaneous supply or accessory for use with an external ventricular
	assist device
Q0508	Miscellaneous supply or accessory for use with an implanted ventricular
	assist device
Q0509	Miscellaneous supply or accessory for use with any implanted
	ventricular assist device for which payment was not made under
	Medicare Part A

Codes Subject to Retrospective Review

CPT/HCPCS	Description
33990	Insertion of ventricular assist device, percutaneous, including
	radiological supervision and interpretation; left heart, arterial access
	only
33991	Insertion of ventricular assist device, percutaneous, including
	radiological supervision and interpretation; left heart, both arterial
	and venous access, with transseptal puncture
33992	Removal of percutaneous left heart ventricular assist device, arterial
	or arterial and venous cannula(s), at separate and distinct session
	from insertion
33993	Repositioning of percutaneous right or left heart ventricular assist
	device with imaging guidance at separate and distinct session from
	insertion

Experimental/Investigational

CPT	Description
33995	Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; right heart, venous access only
33997	Removal of percutaneous right heart ventricular assist device, venous cannula, at separate and distinct session from insertion

Common Diagnosis Codes

ICD-10- CM Diagnosis Codes: I09.81, I11.0, I13.0, I13.2, I13.2, I50.1, I50.9

Common Procedure Codes

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy.

Overview

Left ventricular assist devices (LVADs) have been developed to sustain patients awaiting heart transplantation and to provide short-or long-term circulatory support to allow myocardial recovery in patients suffering from reversible cardiac dysfunction. VADs also have been investigated as permanent or "destination" therapy for patients with end stage heart failure who are not candidates for transplantation. Left ventricular devices (LVADs) are used for short-term cardiac support, as bridges to transplantation or full recovery, and for destination therapy. LVADs can be paracorporeal/extracorporeal (outside the body), or intracorporeal (within the body).

Percutaneous ventricular assist devices (VADs), also referred to as percutaneous circulatory support devices, have been proposed as an alternative to a traditional VAD or intra-aortic balloon pump (IABP) for short-term partial or total hemodynamic support. Percutaneous VADs are minimally invasive and do not require surgical implantation, and unlike IABP, percutaneous VADs provide hemodynamic support independent of left ventricular function. Percutaneous VADs have been proposed for use during emergent procedures for patients in acute heart failure caused by left ventricular dysfunction and/or cardiogenic shock. They have also been proposed as an alternative to IABP for use in high-risk percutaneous coronary intervention (PCI) procedures.

The CentriMag Circulatory Support System (CentriMag CSS) is indicated for temporary circulatory support for up to 30 days for one or both sides of the heart to treat post-cardiotomy patients who fail to wean from cardiopulmonary bypass, providing a bridge to decision when it is unclear whether the patient's heart will recover or whether the patient will need alternative, longer-term therapy.

A total artificial heart is an implantable, pneumatic, biventricular support device that serves as a total replacement for both ventricles of the failing heart. Traditionally, the total artificial heart has been used as a temporary measure to improve the likelihood of survival before and after heart transplantation in patients with end-stage heart failure. The temporary use of an artificial heart is referred to as "bridging" to transplant. There is literature which suggests that a total artificial heart may be considered for permanent use or "destination" therapy in patients with end-stage heart failure who are not candidates for heart transplantation.

Documentation Requirements

- Implantation of a LVAD requires submission of the medical record to ascertain medical necessity and risk of imminent death.
- Extracorporeal LVAD requires submission of the medical record to ascertain use of intra-aortic balloon pump and maximal inotropic doses.
- MVP requires that customers requiring LVAD implantation (paracorporeal) receive this treatment in a contracted transplant center/hospital and after approval by a Medical Director.
- Elective procedures for LVAD implantation (paracorporeal, extracorporeal or implantable) require prior authorization.
- Emergent cases: notification of the implantation must be received by MVP within 24 hours of procedure for retrospective review.
- Documentation should include type of LVAD being used and that the device is FDA approved for the covered indication.
- Implantation of an artificial heart device requires submission of the medical record to ascertain medical necessity, risk of imminent death, hemodynamic insufficiency and use of maximal inotropic doses, and should include type of artificial heart device being used and that the device is FDA approved for the covered indication.

Indications/Criteria

Facility Criteria

LVAD Facility Requirements for MVP customers within the MVP service area. Customers are required to utilize an MVP contracted facility or approved Optum Ventricular Assist Device (VAD) Center of Excellence.

LVAD Facility Requirements for MVP customers outside the MVP service area: Customers are required to utilize an approved Optum Transplant Center

Bridge-to-transplantation (BTT) with severe congestive heart failure indications

- Customer fulfills MVP's criteria for heart transplantation (see Transplants medical policy).
- Customer is approved as a heart transplant candidate by a Medicare approved heart transplant center.
- The device is FDA approved for the covered indication.
- There is an imminent risk of dying before donor heart procurement, as evidenced by:
 - o worsening kidney dysfunction with BUN \geq 40 mg/dl and /or Creatinine \geq 2mg/dl and Urinary Output \leq 0.5ml/kg/hr despite diuretics, **or**
 - o liver dysfunction with T. Bili \geq 2.5mg/dl and/or SGOT \geq 500u/l.
- Hemodynamic criteria (despite inotropic support) include:

- pulmonary wedge pressure > 20 mm Hg combined with:
 - cardiac index < 2 L/min./m²; or
 - systolic blood pressure < 80 mm Hg
- Customer is on an intra-aortic balloon pump prior to implantation (unless contraindicated).

<u>Short-term extracorporeal LVAD use post-cardiotomy for potentially reversible heart failure (no longer than seven days) Indications</u>

- The device is FDA approved for the covered indication.
- Ventricular dysfunction (cardiogenic shock), inability to wean-off cardiopulmonary bypass, must meet one of the hemodynamic abnormalities (despite inotropic support) while on an intraaortic balloon pump (IABP):
 - o cardiac index < 2.0L/min/m2 and PCWP > 18mm Hg; or
 - o SBP < 90mm Hg; or
 - o left atrium pressures > 20mm Hg; or
 - o SVR > 2000.

Destination Therapy (DT) Indications

Left ventricular assist device as destination therapy is covered when all of the following criteria are met:

- the device is FDA approved for the covered indication; and
- evaluated by an approved heart transplant center but deemed unsuitable for heart transplantation; and
- New York Heart Association (NYHA) Class IV end-stage heart failure; and,
- failure to respond to optimal medical management including dietary salt restriction, diuretics, digitalis, beta blockers, and ACE inhibitors for at least 45 of the last 60 days, or have been balloon pump-dependent for seven (7) days, or IV inotrope-dependent for 14 days; and,
- left ventricular ejection fraction (LVEF) < 25%; and
- functional limitation with a peak oxygen consumption of < 14ml/kg/min; or, continued need for balloon pump or intravenous inotropic therapy due to symptomatic hypotension, or physically unable to perform the test.

CentriMag Circulatory Support System (CentriMag CSS) criteria:

CentriMag CSS is covered for customers that fail to wean from cardiopulmonary bypass when all of the following are met:

For patients being evaluated for left-sided support (LVAD); one of the following:

- o cardiac index < 2.0L/min/m2; or
- o PCWP > 18mm Hg; or
- Pulmonary Artery Diastolic Pressure (PADP) ≥ 18 mmHg; or
- Left Atrial Pressure (LAP) ≥ 18 mmHg.
- For patients being evaluated for Right or Biventricular support (BVAD) one of the following:
 - Central Venous Pressure (CVP) ≥ 15 mmHg; or
 - o Right Atrial Pressure (RAP) ≥ 15 mmHg; or
 - Right Ventricular Stroke Work Index (RVSWI) ≤ 4.1 gm·m2/beat.
- Placement of an intra-aortic balloon pump has been attempted unless contraindicated; and
- All possible measures have been attempted to correct low arterial pH, arterial blood gas abnormalities, electrolytes, hypovolemia, hypervolemia, inadequate cardiac rate, dysrhythmias and residual hypothermia; and
- Cardiac resuscitation using pharmacologic agents, and epicardial pacing (if appropriate and possible) has been attempted; and
- Customer must be able to be treated with an appropriate anticoagulant such as heparin or a comparable alternative.

Percutaneous Ventricular Assist Device:

Impella Recover® LP 2.5 Percutaneous Cardiac Support System, Impella CP, Impella 5.0 catheters, Impella 2.5 Plus Percutaneous Ventricular Assist Devices (Abiomed) or Impella 5.5 (CPT codes 33390, 33991, 33992, 33993) is a percutaneous ventricular assist device (pVAD), used in accordance with the FDA approval, is considered medical necessary for:

- Short term circulatory support in cardiogenic shock; or
- Severe decompensated heart failure with threatening multi-organ failure.

SynCardia temporary Total Artificial Heart

SynCardia temporary Total Artificial Heart, used in accordance with FDA approval, is considered medically necessary as a bridge-to-heart transplantation for customers who meet all of the following criteria [8, 43]:

- have no other reasonable medical or surgical options including unavailability of heart donor; and
- risk of imminent death from biventricular failure; and
- heart transplant eligible (refer to MVP Transplant Policy); and
- New York Heart Association Class IV; and

 have sufficient space in the chest cavity to accommodate the device generally with body size area ≥ 1.7m² and a heart size ≥ 1500cc as measured by chest x-ray or who have a body size area < 1.7m² and an anterior-posterior dimension of 10cm at T-10 by CT scan;

Exclusions

- Not meeting criteria under Indications/Criteria in this policy.
- Left Ventricular Assist Device
 - Chronic irreversible hepatic, renal, or respiratory failure that is anticipated to limit survival to < 2 years
 - Advanced stage of HIV (AIDS) infection
 - o Age >80
 - Severely restricted pulmonary function
 - Major neurological deficit that severely compromises the ability to use and care for external system components or to ambulate and exercise
 - o Long-term high dose corticosteroid use
 - Severe blood dyscrasia
 - o Body surface < 1.5 mm²
 - Severe bacterial infection resistant to therapy
 - Uncorrected valvular disease (due to potential problems with adequate function of the VAD)
 - Active malignancy and a life expectancy of < 2 years
 - Pre-operative risk factors include:
 - o right atrial pressure > 20 mm Hg;
 - o prothrombin time > 16 sec;
 - o right ventricular failure;
 - o re-operation;
 - WBC > 15,000;
 - urine output < 30 ml/hr;
 - mechanical ventilation; or
 - o temperature > $101.5^{\circ} F (38.6^{\circ} C)$.
 - Active alcohol dependency and substance abuse
 - Current pregnancy

- Tandemheart® PTVA® System is not considered medically necessary as the published evidence has not proven a beneficial impact on health outcomes and, therefore, is not covered.
- Impella RP (RVAD- percutaneous right ventricular assist device CPT codes 33995, 33997) is not considered medically necessary as there is insufficient published evidence has not proven a beneficial impact on health outcomes and, therefore, is not covered.
- Medtronic HeartWare left ventricular assist device is excluded from coverage.
- CentriMag Circulatory Support System (CentriMag CSS) is not covered for any other indication.

Medicare Variation

<u>Artificial Hearts as Bridge-to-Transplant or as Destination Therapy:</u>

An artificial heart for bridge-to-transplantation or destination therapy is covered when performed under coverage with evidence development (CED) when a clinical study meets all of the criteria listed below. The clinical study must address at least one of the following questions:

- were there unique circumstances such as expertise available in a particular facility or an unusual combination of conditions in particular patients that affected their outcomes? or
- what will be the average time to device failure when the device is made available to larger numbers of patients? or
- do results adequately give a reasonable indication of the full range of outcomes (both positive and negative) that might be expected from more widespread use?

Centers for Medicare & Medicaid Services. NCD for artificial hearts and related devices (20.9). Effective Date October 30, 2013. Available: https://www.cms.gov/

Centers for Medicare & Medicaid Services. NCD for Ventricular Assist Devices (20.9.1). Effective Date October 30, 2013. Available: https://www.cms.gov/

References (Updated 2024)

- Anderson MB, Goldstein J, Milano C, Morris LD, Kormos RL, Bhama J, Kapur NK, Bansal A, Garcia J, Baker JN, Silvestry S, Holman WL, Douglas PS, O'Neill W. Benefits of a novel percutaneous ventricular assist device for right heart failure: The prospective RECOVER RIGHT study of the Impella RP device. J Heart Lung Transplant. 2015 Dec;34(12):1549-60. Doi: 10.1016/j.healun.2015.08.018. Epub 2015 Sep 8. PMID: 26681124.
- 2. Batsides G, Massaro J, Cheung A, Soltesz E, Ramzy D, Anderson MB. Outcomes of Impella 5.0 in Cardiogenic Shock: A Systematic Review and Meta-analysis. Innovations (Phila). 2018 Jul/Aug;13(4):254-260

- 3. Burkhoff D, Cohen H, Brunckhorst C, O'Neill WW; TandemHeart Investigators Group. A randomized multicenter clinical study to evaluate the safety and efficacy of the TandemHeart percutaneous ventricular assist device versus conventional therapy with intraaortic balloon pumping for treatment of cardiogenic shock. Am Heart J. 2006; 152(3):469.e1-469.e8.
- 4. Burkhoff D, O'Neill W, Brunckhorst C, et al. Feasibility study of the use of the TandemHeart percutaneous ventricular assist device for treatment of cardiogenic shock. Catheter Cardiovasc Interv. 2006;68(2):211-217.
- 5. Centers for Medicare and Medicaid Services. Decision Memo for Artificial Hearts (CAG-00322N). May 1, 2008.
- 6. Centers for Medicare and Medicaid Services. Decision Memo for Ventricular Assist Devices as Destination Therapy (CAG-00119R2) November 9, 2010
- 7. Centers for Medicare & Medicaid Services. NCD for artificial hearts and related devices (20.9). Effective Date October 30, 2013. Available: https://www.cms.gov/
- 8. Centers for Medicare & Medicaid Services. NCD for Ventricular Assist Devices (20.9.1). Effective Date October 30, 2013. Available: https://www.cms.gov/
- 9. Copeland, JG, et al Cardiac replacement with a total artificial heart as a bridge to transplantation. New England Journal of Medicine 2004; 351:859-867. Available: www.nejm.org
- 10. Copeland JG, Copeland H, Gustafson M, Mineburg N, Covington D, Smith RG, Friedman M. Experience with more than 100 total artificial heart implants. J Thorac Cardiovasc Surg. 2012 Mar;143(3):727-34. Epub 2012 Jan 14.
- 11. Copeland JG, Copeland H, Gustafson M, Mineburg N, Covington D, Smith RG, Friedman M. Experience with more than 100 total artificial heart implants. J Thorac Cardiovasc Surg. 2012 Mar;143(3):727-34. Epub 2012 Jan 14.
- 12. Dixon, SR, et al. A prospective feasibility trial investigating use of the Impella 2.5 system in patients undergoing high-risk percutaneous coronary intervention (the PROTECT I Trial); Initial U.S experience. JACC Cardiovascular Intervention 2009; 2(2); 91-96.
- 13. Drakos SG, Kfoury AG, Long JW, Stringham JC, Gilbert EM, Moore SA, et al. Effect of mechanical circulatory support on outcomes after heart transplantation. J Heart Lung Transplant. 2006 Jan;25(1):22-8.
- 14. Frazier, OH, et al. Improved survival after extended bridge to cardiac transplantation. Annals of Thoracic Surgery 1994; 57:1416-1422. Available: www.nlm.nih.gov
- 15. Frazier, OH, et al Multicenter clinical evaluation of the HeartMate vented electrical left ventricular assist system in patients awaiting heart transplantation. Journal of Thoracic and Cardiovascular Surgery 2001; 122:1186-1195.

- 16. Hayes Inc. Hayes Health Clinical Research Response: Impella 5.5 (Abiomed, Inc.) for the Temporary Treatment of Cardiogenic Shock. Hayes © 2021 Hayes, a symplr company. October 1, 2020.
- 17. Hayes Health Technology Assessment. Impella Heart Pumps for Cardiac Support in Patients Undergoing High-Risk Percutaneous Coronary Intervention. HAYES, Inc.; © 2022 Hayes, a symplr company. May 2, 2024.
- 18. Hayes Inc. Hayes Health Emerging Technology Report: Impella RP For Right Heart Failure. Hayes © 2021 Hayes, a symplr company. October 10, 2017
- 19. Hayes Inc. Hayes Health Technology Assessment: Impella 2.5 System (Abiomed Inc.) For Cardiac Support In Patients Undergoing High-Risk Percutaneous Coronary Intervention . Hayes © 2021 Hayes, a symplr company. October 17, 2017. (Annual review 11ecember 2, 2019) Archived October 17, 2020.
- 20. Hayes Inc. Hayes Health Technology Assessment: Impella 2.5 System (Abiomed Inc.) For Emergent Hemodynamic Cardiac Support In Patients With Cardiogenic Shock. Hayes © 2021 Hayes, a symplr company. September 3, 2015. Annual review July 20, 2017.
- 21. <u>Hayes Inc. Hayes</u> Medical Technology Assessment: Impella 5.0 (Abiomed Inc.) For Emergent Hemodynamic Support In Patients With Cardiogenic Shock. Hayes © 2021 Hayes, a symplr company. August 18, 2010. Annual review July 20, 2017.
- 22. Hayes Inc. Hayes Medical Technology Assessment: Left Ventricular Assist Device (LVADs) in Adult Patients with Chronic, End-Stage Heart Failure. Hayes © 2021 Hayes, a symplr company. August 18, 2010. Annual review August 8, 2014
- 23. HAYES Health Technology Assessment: Total Artificial Heart, Temporary Or Permanent, Biventricular Mechanical Circulatory Support Device HAYES, Inc.; © 2021 Hayes, a symplr company. August 18, 2010. May 28, 2015 Annual review June 19, 2019.
- 24. Kapur NK, Paruchuri V, Korabathina R, Al-Mohammdi R, Mudd JO, Prutkin J, Esposito M, Shah A, Kiernan MS, Sech C, Pham DT, Konstam MA, Denofrio D. Effects of a percutaneous mechanical circulatory support device for medically refractory right ventricular failure. J Heart Lung Transplant. 2011 Dec;30(12):1360-7. Doi: 10.1016/j.healun.2011.07.005. Epub 2011 Aug 24. PMID: 21868253.
- 25. Kovacic JC, Nguyen HT, Karajgikar R, Sharma SK, Kini AS. The Impella Recover 2.5 and TandemHeart ventricular assist devices are safe and associated with equivalent clinical outcomes in patients undergoing high-risk percutaneous coronary intervention. *Catheter Cardiovasc Interv*. Epub ahead of print. January 13, 2011.
- 26. Krabatsch T, Netuka I, Schmitto JD, Zimpfer D, Garbade J, Rao V, et al. Heartmate 3 fully magnetically levitated left ventricular assist device for the treatment of

- MVP Health Care Medical Policy advanced heart failure -1 year results from the Ce mark trial. J Cardiothorac Surg. 2017 Apr 4;12(1):23.
- 27. Lauten A, Engström AE, Jung C, et al. Percutaneous left-ventricular support with the Impella-2.5-assist device in acute cardiogenic shock: Results of the Impella-EUROSHOCK-Registry. *Circ Heart Fail.* 2013;6(1):23-30.
- 28. Lee MS, Makkar RR. Percutaneous left ventricular support devices. Cardiol Clin. 2006; 24(2):265-275.
- 29. Levy, WC, et al. Predictors of death and transplant in patients with mechanical circulatory support device: a multi-institutional study. Journal of Heart Lung Transplant 2009 28(1): 44-50.
- 30. Lietz K, Long JW, Kfoury AG, Slaughter MS, Silver MA, Milano CA, et al. Outcomes of left ventricular assist device implantation as destination therapy in the post-REMATCH era: implications for patient selection. Circulation. 2007 Jul 31;116(5):497-505.
- 31. Lima B, Bansal A, Abraham J, Rich JD, Lee SS, Soleimani B, et al; Evolving Mechanical Support Research Group (EMERG). Controversies and Challenges of Ventricular Assist Device Therapy. Am J Cardiol. 2018 May 15;121(10):1219-1224
- 32. Maini B, Naidu SS, Mulukutla S, et al. Real-world use of the Impella 2.5 circulatory support system in complex high-risk percutaneous coronary intervention: the Uspella registry. *Catheter Cardiovasc Interv.* 2012;80:717-725.
- 33. Maybaum S, Mancini D, Xydas S, Starling RC, Aaronson K, Pagani FD, for the LVAD Working Group. Cardiac improvement during mechanical circulatory support: a prospective multicenter study of the LVAD Working Group. Circulation. 2007 May 15;115(19):2497-505.
- 34. O'Neill WW, Kleiman NS, Moses J, et al. A prospective, randomized clinical trial of hemodynamic support with Impella 2.5 versus intra-aortic balloon pump in patients undergoing high-risk percutaneous coronary intervention: the PROTECT II study. *Circulation*. 2012;126(14):1717-1727.
- 35. Oz, Mehmet C., Gelijns, Annetine C., et al. Left Ventricular Assist Devices as Permanent Heart Failure Therapy. Annals of Surgery. (October 2003), Volume 238, pp. 577-585.
- 36. Pagani FD, Miller LW, Russell SD, Aaronson KD, John R, Boyle AJ, e t al.; HeartMate II Investigators. Extended mechanical circulatory support with a continuous-flow rotary left ventricular assist device. J Am Coll Cardiol. 2009 Jul 21;54(4):312-21.
- 37. Potapov EV, Stiller B, Hetzer R. Ventricular assist devices in children: current achievements and future perspectives. Pediatr Transplant. 2007 May;11(3):241-55.
- 38. Rogers JG, Butler J, Lansman SL, et al.; INTrEPID Investigators. Chronic mechanical circulatory support for inotropedependent heart failure patients who are not

- MVP Health Care Medical Policy transplant candidates: results of the INTrEPID Trial. *J Am Coll Cardiol*.2007;50(8):741-747.
- 39. Rose, EA, et al. Randomized Evaluation of Mechanical assistance for the Treatment of Congestive Heart Failure (REMATCH) Study Group. Long-term use of a left ventricular assist device for end-stage heart failure. New England Journal of Medicine 2001; 345:1435-1443.
- 40. Seyfarth M, et al. A randomized clinical trial to evaluate the safety and efficacy of a percutaneous left ventricular assist device versus intra-aortic balloon pumping for treatment of cardiogenic shock caused by myocardial infarction. Journal of the American College of Cardiology 2008; 52(19); 1584-1588.
- 41. Shah R, Thomson A, Atianzar K, et al. Percutaneous left ventricular support for highrisk PCI and cardiogenic shock: who gets what? Cardiovasc Revasc Med. 2012;13(2):101-105.
- 42. Sjauw KD, Konorza T, Erbel R, et al. Supported high-risk percutaneous coronary intervention with the Impella 2.5 device: the Europella registry. J Am Coll Cardiol. 2009;54(25):2430-2434. Available at: http://www.sciencedirect.com/science/article/pii/S0735109709031933.
- 43. Slaughter, MS, et al. HeartMate II Investigators. Advanced heart failure treated with continuous-flow left ventricular assist device. New England Journal of Medicine. 2009 Dec 3; 361 (23):2241-51.
- 44. Slaughter M, Tsui SS, El-Banayosy A, Sun BC, Kormos RL, Mueller DK, at al., on behalf of the IVAD Study Group. Results of a multicenter clinical trial with the Thoratec Implantable Ventricular Assist Device. J Thorac Cardiovasc Surg. 2007 Jun;133(6):1573-80. Erratum in: J Thorac Cardiovasc Surg. 2007 Sep;134(3):A34.
- 45. Takayama H, Naka Y, Kodali SK, Vincent JA, Addonizio LJ, Jorde UP, Williams MR. A novel approach to percutaneous right-ventricular mechanical support. Eur J Cardiothorac Surg. 2012 Feb;41(2):423-6. Doi: 10.1016/j.ejcts.2011.05.041. Epub 2011 Dec 12. PMID: 21737292.
- 46. Thiele H, Lauer B, Hambrecht R, et al. Reversal of cardiogenic shock by percutaneous left atrial-to-femoral arterial bypass assistance. Circulation. 2001; 104(24):2917-2922.
- 47. Thiele H, Sick P, Boudriot E, et al, Randomized comparison of intra-aortic balloon support with a percutaneous left ventricular assist device in patients with revascularized acute myocardial infarction complicated by cardiogenic shock. Eur Heart J. 2005;26(13):1276-1283.
- 48. U.S. Food and Drug Administration (FDA). FDA Alerts Health Care Providers to Stop New Implants of Certain Ventricular Assist Device System. June 3, 2021.
- 49. U.S. Food and Drug Administration (FDA). PMA-Pre-market Approval Syncardia temporary CardioWest total artificial heart. Oct. 2004. Available:

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cftopic/pma/pma.cfm?num=p03 0011

- 50. U.S. Food and Drug Administration (FDA). Summary of Safety and Effectiveness Data (SSED): CentriMag Circulatory Support System. Available: https://www.accessdata.fda.gov/cdrh_docs/pdf17/P170038B.pdf
- 51. Welp H, Sindermann JR, Deschka H, Martens S, Scherer M. Pulmonary Bleeding During Right Ventricular Support After Left Ventricular Assist Device Implantation. J Cardiothorac Vasc Anesth. 2016 Jun;30(3):627-31. Doi: 10.1053/j.jvca.2015.07.012. Epub 2015 Jul 14. PMID: 26460277.

Customer Product	Medical Management Requirements*
New York Products	
HMO	Prior Auth
PPO in Plan	Prior Auth
PPO OOP	Prior Auth
POS in Plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Prior Auth
MVP Child Health Plus	Prior Auth
MVP Harmonious Health Care Plan	Prior Auth
MVP Medicare Complete Wellness	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP Medicare WellSelect PPO	Prior Auth
MVP Medicare WellSelect Plus PPO	Prior Auth
MVP Medicare Patriot Plan PPO	Prior Auth
MVP DualAccess D-SNP HMO	Prior Auth
MVP DualAccess Complete D-SNP HMO	Prior Auth
MVP DualAccess Plus D-SNP HMO	Prior Auth
UVM Health Advantage Select PPO	Prior Auth
USA Care PPO	Potential for Retrospective Review
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	
POS in Plan	Prior Auth
POS OOP	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP VT HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD
	, 300 3. 2

[♦] Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

Revision History:

10/01/2021 - Annual review for the policy. Added indications and criteria for the CentriMag Circulatory Support System. The criteria for the total artificial heart was moved from the artificial heart policy into this policy. Added Impella RP (RVAD- percutaneous right ventricular assist device – CPT codes 33995, 33997) as investigational procedures. A Medicare variation for artificial hearts was added to the policy.

04/01/2023 – Added coverage for percutaneous right ventricular assist devices as indicated in certain circumstances.

04/01/2025 – Annual review. No changes to current criteria.



Vision Therapy (Orthoptics, Eye Exercises)

Type of Policy: Medical

Prior Approval Date: 10/03/2022

Approval Date: 08/07/2023

Effective Date: 10/01/2023

Related Polices: N/A

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

N/A

Codes Subject to Retrospective Review

N/A

Experimental/Investigational

N/A

Common Diagnosis Codes

ICD-10- CM Diagnosis Codes: H50.00, H50.011, H50.012, H50.021, H50.022, H50.031, H50.032, H50.041, H50.042, H50.05, H50.06, H50.07, H50.311, H50.312, H50.32, H50.331, H50.332, H51.11, H53.009, H53.019, H53.29, H53.039

Common Procedure Codes

CPT code

92065 Orthoptic and/or pleoptic training, with continuing medical direction and evaluation 92066 Orthoptic training; under supervision of a physician or other qualified health care professional

Please refer to the product grid for detailed authorization requirements for specific plans. Code lists may not be all inclusive. Codes requiring prior-authorization for some products may be retrospectively reviewed for plans that do not require prior-authorization. Common diagnosis and procedure codes are included for informational purposes. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy.

Overview

Vision therapy involves a range of optometric treatment modalities, including lenses, prisms, filters and other materials, methods, equipment, and procedures, that are used for eye movement and fixation training. The therapeutic goal of vision therapy is to correct or improve specific visual dysfunctions such as amblyopia. Vision therapy is sometimes called visual therapy, visual training, vision training, orthoptics, orthoptic vision therapy, or optometric vision therapy. Some common eye problems are:

- Amblyopia. Decreased vision in one or both eyes without detectable anatomic damage in
 the eye or visual pathways. Usually uncorrectable by eyeglasses or contact lenses. Occlusion
 therapy works by forcing the patient to depend visually on one eye that has diminished
 acuity and allowing the otherwise unaltered experience of seeing to improve the functional
 capability of the amblyopic eye.
- Esotropia, "cross-eyes". Eye misalignment in which one eye deviates inward (toward nose) while the other fixates normally. Prism adaptation may be used prior to surgical treatment. Prism adaptation is commonly studied by having a person put on goggles bearing wedge prisms that laterally displace the visual field, for example, in the rightward direction. The person then interacts with the environment, for example, by pointing toward visual targets. Initially, the person makes pointing errors to the right of a target, but errors disappear in a dozen or so pointing trials, depending upon exposure conditions. The person has adapted to the prismatic displacement.
- Convergence insufficiency is the inability to maintain binocular function (keeping the two eyes working together) while working at a near distance. Typically, one eye will turn outward (intermittent exotropia) when focusing on a word or object at near. In convergence insufficiency, eye misalignment occurs when focusing at near. Occasionally, a well-controlled intermittent exotropia (outward eye turning) will be present at near and distance in a patient with convergence weakness; however, in convergence insufficiency the deviation is symptomatic and occurs spontaneously only when focusing on near objects. Convergence insufficiency can often be treated by practicing convergence through exercises. One method of therapy to resolve convergence insufficiency is the use of baseout prisms which force the system to work harder to converge. They are used only during short periods of time while performing therapy as they are very tiring to the eyes.

Indications/Criteria

Vision therapy is covered for the following indications:

- occlusion administered as treatment for amblyopia;
- prism adaptation prior to surgery administered as treatment for acquired esotropia;
- oculomotor exercises (near-point or prism-convergence) administered as treatment for convergence insufficiency.

Exclusions

Vision therapy is considered investigational for all other indications.

Medicaid Variation

Orthoptic training is covered for MVP Medicaid Managed Care and MVP Harmonious Health Care Plan (HARP). [8] Orthoptic training includes oculomotor exercises, stereoscopes, vectograms, tracing pictures, completing puzzles, patching/occlusion for amblyopia, prisms to compensate for muscle imbalance and surgery of the eye muscles.

Orthoptic training, vision therapy or training and vision perception training are not covered for MVP Child Health Plus plans.

Medicare

There is no Medicare National or Local Coverage Determination for orthoptic training.

References (Reviewed 2023)

- 1. American Academy of Ophthalmology. Esotropia and Exotropia Preferred Practice Pattern®. Updated Nov. 2017. Available: https://www.aao.org/preferred-practice-pattern/esotropia-exotropia-ppp-2017
- 2. American Academy of Ophthalmology. Amblyopia Preferred Practice Pattern®. Nov. 2017 Available: http://one.aao.org/preferred-practice-pattern/amblyopia-ppp--september-2012
- 3. American Academy of Ophthalmology. Learning Disabilities, Dyslexia and Vision. The American Academy of Pediatrics (Section on Ophthalmology, Council on Children with Disabilities), the American Academy of Ophthalmology, the American Association of Pediatric Ophthalmology and Strabismus and the Association of Certified Orthoptists. Pediatrics. 2009 Aug;124(2):837-44. doi: 10.1542/peds.2009-1445. Epub 2009 Jul 27. PMID: 19651597. Reaffirmed 2014.
- American Association for Pediatric Ophthalmology and Strabismus. Convergence Insufficiency. 2012. Available: https://aapos.org/browse/glossary/entry?GlossaryKey=19ea2d8f-a728-40f8-ad7a-5ce0214ebb96
- 5. HAYES Medical Technology Directory™. Vision Therapy for Dyslexia and Other Reading and Learning Disabilities. HAYES, Inc.; ©Winifred S. Hayes, Inc. July 17, 2012. Archived 08/17/2017 Available: www.hayesinc.com/

- 6. Hayes, Inc. Hayes Health Technology Assessment: Vision Therapy For Convergence Insufficiency And Accommodative Dysfunction In Children. Hayes © 2021 Hayes, a symplr company. December 17, 2013. (Annual Review November 13, 2015). Archived January 17, 2017.
- 7. Hayes Evidence Research Brief. Vision Therapy for Amblyopia in Pediatric Patients. ©2022 Hayes, a sympir company. May 20, 2022 Archived June 20, 2023.
- 8. New York State Department of Health Medicaid Program. Vision Care Manual. Available: https://www.emedny.org/ProviderManuals/index.aspx
- 9. Sheryl M. Handler, Walter M. Fierson, the Section on Ophthalmology and Council on Children with Disabilities, American Academy of Ophthalmology, American Association for Pediatric Ophthalmology and Strabismus, and American Association of Certified Orthoptists Pediatrics Mar 2011, 127 (3) e818-e856; DOI: 10.1542/peds.2010-3670
- 10. McConaghy JR, McGuirk R. Amblyopia: detection and treatment. *Am Fam Physician*. 2019;100(12):745-750. Available at: https://www.aafp.org/afp/2019/1215/p745.html
- 11. Milla M, Piñero DP. Characterization, passive and active treatment in strabismic amblyopia: a narrative review. *Int J Ophthalmol*. 2020;13(7):1132-1147. doi:10.18240/ijo.2020.07.18. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7321947/pdf/ijo-13-07-1132.pdf

Customer Product	Medical Management Requirements*
New York Products	
HMO	Potential for Retrospective Review
PPO In Plan	Potential for Retrospective Review
PPO OOP	Potential for Retrospective Review
POS In Plan	Potential for Retrospective Review
POS OOP	Potential for Retrospective Review
Essential Plan	Potential for Retrospective Review
MVP Medicaid Managed Care	Potential for Retrospective Review
MVP Harmonious Health Care Plan	Potential for Retrospective Review
MVP Child Health Plus	Not A Covered Benefit
MVP Medicare Complete Wellness	Potential for Retrospective Review
MVP Medicare Preferred Gold HMO POS	Potential for Retrospective Review
MVP Medicare Secure HMO POS	Potential for Retrospective Review
MVP Medicare WellSelect PPO	Potential for Retrospective Review
MVP Medicare WellSelect Plus PPO	Potential for Retrospective Review
MVP Medicare Patriot Plan (PPO)	Potential for Retrospective Review
MVP DualAccess D-SNP HMO	Potential for Retrospective Review
MVP DualAccess Complete D-SNP HMO	Potential for Retrospective Review
MVP DualAccess Plus D-SNP HMO	Potential for Retrospective Review
UVM Health Advantage Select PPO	Potential for Retrospective Review
USACare PPO	Potential for Retrospective Review
Healthy NY	Potential for Retrospective Review
MVP Secure	Potential for Retrospective Review
MVP EPO	Potential for Retrospective Review
MVP EPO HDHP	Potential for Retrospective Review
MVP PPO	Potential for Retrospective Review
MVP PPO HDHP	Potential for Retrospective Review
Student Health Plans	Potential for Retrospective Review
ASO	See SPD
Vermont Products	
POS In Plan	Potential for Retrospective Review
POS OOP	Potential for Retrospective Review
MVP Medicare Preferred Gold HMO POS	Potential for Retrospective Review
MVP Medicare Secure Plus HMO POS	Potential for Retrospective Review
MVP Medicare WellSelect PPO	Potential for Retrospective Review
MVP VT HMO	Potential for Retrospective Review
MVP VT HDHP HMO	Potential for Retrospective Review
MVP VT Plus HMO	Potential for Retrospective Review
MVP Secure	Potential for Retrospective Review
ASO	See SPD

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. Maybe subject to Retrospective Review

Retro Review Required
Not Covered Service is not a covered benefit.
See SPD See Specific Plan Design

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MVP Health Care Medical Policy Revision History:

12/01/2022 – Annual review, updated format, added H51.11 (Convergence insufficiency) to covered diagnosis codes.

10/01/2023 – Annual review, updated format, no changes to the indications or criteria. Removed references to learning disabilities and left exclusion to all other indications not addressed in the criteria. Added Medicare section. Updated references.



Vitiligo Treatment

Type of Policy: Medical

Prior Approval Date: 11/01/2021

Approval Date: 12/04/2023

Effective Date: 02/01/2024

Related Polices: Phototherapy, Photochemotherapy,

and Excimer Laser Therapy for

Dermatologic Conditions

Cosmetic and Reconstructive Services

Cosmetic Drug Agents

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

N/A

Codes Subject to Retrospective Review

N/A

Experimental/Investigational

N/A

Common Diagnosis Codes

ICD-10- CM Diagnosis Codes: L80

Common Procedure Codes

N/A

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are

Vitiligo Treatment Page 1 of 5

subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy.

Overview

Vitiligo is a pigmentation disorder that results in the loss of melanocytes (the cells that make pigment) in the skin, mucus membranes and the retina. As a result, white patches of skin appear on different parts of the body. The cause of vitiligo is unknown, but it appears to be more common in people with autoimmune diseases. It can be a focal, generalized or segmented pattern. The disorder may be acquired or inherited. It is usually progressive.

There are several types of medical and surgical treatments available to treat this disorder, but treatment is considered to be cosmetic in nature.

Policy Criteria

Treatment for vitiligo is considered to be cosmetic and, therefore, not medically necessary.

Exclusions

N/A

Medicare Variation

Part D drugs indicated for the treatment of psoriasis, acne, rosacea, or vitiligo are not considered cosmetic.

References (Reviewed 2023)

- 1. Ashraf AZ, et al. The effectiveness of home-based phototherapy for vitiligo: A systematic review of randomized controlled trials. Photodermatol Photoimmunol Photomed 2022; 11:1-9.
- 2. Bacigalupi RM, Postolova A, Davis RS. Evidence-based, non-surgical treatments for vitiligo: A review. Am J Clin Dermatol. 2012;13(4):217-237.
- 3. Batchelor JM, et al. Home-based narrowband UVB, topical corticosteroid or combination for children and adults with vitiligo: HI-Light Vitiligo three-arm RCT. Health Technology Assessment 2020 Nov; 24 (64):1-5.
- Centers for Medicare & Medicaid Services (CMS). Medicare Prescription Drug Benefit Manual. Chapter 6. Part D Drugs and Formulary Requirements. (Rev.18,01/15/2016). Available: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals
- 5. Hayes, Inc. Evidence Analysis Research Brief. Home ultraviolet B phototherapy for vitiligo. Hayes ©2021 Hayes, a sympire company. Published July 23, 2020.

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- 6. Hayes, Inc. Health Technology Brief (ARCHIVED). Excimer laser therapy (ELT) for vitiligo. Hayes ©2021 Hayes, a sympire company. Published November 24, 2008. Updated October 28, 2010.
- 7. Hayes, Inc. Medical Technology Directory (ARCHIVED). Ultraviolet B phototherapy for vitiligo. Hayes ©2021 Hayes, a sympire company. Published February 26, 2010. Updated February 28, 2014.
- 8. Hayes, Inc. Evidence Analysis Research Brief. Excimer laser Therapy for Treatment of Vitiligo. Hayes ©2021 Hayes, a sympire company. Published May 9, 2023.
- 9. Khandpur S, et al. Narrow-band ultraviolet B comb as an effective home-based phototherapy device for limited or localized non-segmental vitiligo: A pilot, open-label, single-arm clinical study. Indian Journal of Dermatology, Venereology, and Leprology 2020 May-Jun;86 (3): 298-301.
- 10. UpToDate, Inc. Vitiligo: management and prognosis. http://www.uptodate.com. Updated July 2020.
- 11. Whitton, M.E., Ashcroft, D.M., Barrett, C. W., Gonzalez, U. Interventions for vitiligo. *The Cochrane Database of Systematic Reviews* 2006, Issue 1. Art. No.: CD003263. DOI: 10.1002/14651858.CD003263.pub3.
- 12. Whitton ME, Pinart M, Batchelor J, et al. Interventions for vitiligo. Cochrane Database Syst Rev. 2010;(1):CD003263.

Vitiligo Treatment Page 3 of 5

Customer Product	Medical Management Requirements*
New York Products	
HMO	Potential for Retrospective Review Cosmetic
PPO in Plan	Potential for Retrospective Review Cosmetic
PPO OOP	Potential for Retrospective Review Cosmetic
POS in Plan	Potential for Retrospective Review Cosmetic
POS OOP	Potential for Retrospective Review Cosmetic
Essential Plan	Potential for Retrospective Review Cosmetic
MVP Medicaid Managed Care	Potential for Retrospective Review Cosmetic
MVP Child Health Plus	Potential for Retrospective Review Cosmetic
MVP Harmonious Health Care Plan	Potential for Retrospective Review Cosmetic
MVP Medicare Compete Wellness	Potential for Retrospective Review Cosmetic
MVP Medicare Preferred Gold HMO POS	Potential for Retrospective Review Cosmetic
MVP Medicare Secure HMO POS	Potential for Retrospective Review Cosmetic
MVP Medicare Secure Plus HMO POS	Potential for Retrospective Review Cosmetic
MVP Medicare WellSelect PPO	Potential for Retrospective Review Cosmetic
MVP Medicare WellSelect Plus PPO	Potential for Retrospective Review Cosmetic
MVP Medicare Patriot Plan PPO	Potential for Retrospective Review Cosmetic
MVP DualAccess D-SNP HMO	Potential for Retrospective Review Cosmetic
MVP DualAccess Complete D-SNP HMO	Potential for Retrospective Review Cosmetic
MVP DualAccess Plus D-SNP HMO	Potential for Retrospective Review Cosmetic
UVM Health Advantage Select PPO	Potential for Retrospective Review Cosmetic
USA Care PPO	Potential for Retrospective Review
Healthy NY	Potential for Retrospective Review Cosmetic
MVP Premier	Potential for Retrospective Review Cosmetic
MVP Premier Plus	Potential for Retrospective Review Cosmetic
MVP Premier Plus HDHP	Potential for Retrospective Review Cosmetic
MVP Secure	Potential for Retrospective Review Cosmetic
MVP EPO	Potential for Retrospective Review Cosmetic
MVP EPO HDHP	Potential for Retrospective Review Cosmetic
MVP PPO	Potential for Retrospective Review Cosmetic
MVP PPO HDHP	Potential for Retrospective Review Cosmetic
Student Health Plans	Potential for Retrospective Review Cosmetic
ASO	See SPD
Vermont Products	
POS in Plan	Potential for Retrospective Review Cosmetic
POS OOP	Potential for Retrospective Review Cosmetic
MVP Medicare Preferred Gold HMO POS	Potential for Retrospective Review Cosmetic
MVP Medicare Secure Plus HMO POS	Potential for Retrospective Review Cosmetic
MVP VT HMO	Potential for Retrospective Review Cosmetic
MVP VT HDHP HMO	Potential for Retrospective Review Cosmetic
MVP VT Plus HMO	Potential for Retrospective Review Cosmetic
MVP VT Plus HDHP HMO	Potential for Retrospective Review Cosmetic
MVP Secure	Potential for Retrospective Review Cosmetic
ASO	See SPD

♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro ReviewRetrospective Review RequiredNot CoveredService is not a covered benefit.See SPDSee Specific Plan Design

Vitiligo Treatment Page 4 of 5

Revision History:

02/01/2022 – Annual review with no changes to the policy criteria.

02/01/2024 - Annual review with no changes to the policy criteria.

Vitiligo Treatment Page 5 of 5



Wheelchairs (Manual)

Type of Policy: DME

Prior Approval Date: 10/21/2024

Approval Date: 12/02/2024

Effective Date: 04/01/2025

Related Polices: Wheelchairs (Electric) and Power

Scooters

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

MVP list of Durable Medical Equipment (DME) that requires Prior Authorization, go to https://www.mvphealthcare.com/providers/reference-library/#utilization

Codes Subject to Retrospective Review:

HCPCS Code	
E2230	Manual wheelchair accessory, manual standing system

Experimental/Investigational

N/A

Common Diagnosis Codes

N/A

Common Procedure Codes

HCPCS Codes: E0970, E1085, E1086, E1089, E1090, E1130, E1140, E1250, E1260, E1285, E1290

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has

been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

A manual wheelchair is considered to be durable medical equipment known as mobility assistive equipment and is used by patients in the home who have a personal mobility deficit sufficient to impair their participation in mobility-related activities of daily living such as toileting, feeding, dressing, grooming, and bathing in customary locations in the home.

Indications/Criteria

Documentation Requirements

When prescribing a manual wheelchair, the physician or other treating practitioner who performed the face-to-face examination must submit the written prescription accompanied by documentation supporting medical necessity of the device. The examination should be tailored to the individual patient's conditions. The medical history should contain a well-documented description of the patient's functional abilities and limitations on a typical day. It should contain as much objective data as possible. The physical examination should be focused on the body systems that are responsible for the patient's ambulatory difficulty or impact on the patient's ambulatory ability. Included in all exams must be a detailed description of the patient's observed ability or inability to transfer and/or walk.

This should include pertinent parts of the medical record and include the documentation of the beneficiary's face-to-face examination including information such as the history, physical examination, diagnostic tests, summary of findings, diagnoses, and treatment plans. The patient's medical records include the physician's office records, hospital records, nursing home records, home health agency records, records from other health care professionals, or test reports.

The physician may refer the beneficiary to a licensed/certified medical professional (LCMP), such as a physical therapist (PT) or occupational therapist (OT), who has experience and training in mobility evaluations to perform part of the face-to-face examination. This person may have no financial relationship with the supplier. If all or some of the medical examination is completed by another medical professional, the ordering physician must sign off on the report and incorporate it into their records. The report of the physician's visit shall state concurrence or any disagreement with the LCMP examination.

Medical record documentation should be sufficient to:

 delineate the history of events that led to the request for the manual wheelchair;

Wheelchairs (Manual) Page 2 of 14

- identify the mobility deficits to be corrected by the manual wheelchair;
- establish that other treatments do not obviate the need for the manual wheelchair (walkers, crutches);
- establish that the beneficiary lives in an environment that supports the use of the manual wheelchair;
- establish that the beneficiary or caregiver is capable of operating the manual wheelchair; and

In most cases, the information recorded at the face-to-face examination will be sufficient. However, there may be some cases where the physician or treating practitioner has treated a patient for an extended period of time and the information recorded at the face-to-face examination refers to previous notes in the medical record. In this instance, those previous notes would also be needed.

Home Assessment

The supplier or practitioner must perform an on-site evaluation of the patient's home to verify that the patient can adequately maneuver the device that is provided considering physical layout, doorway width, doorway thresholds, and surfaces. There must be a written report of this evaluation provided in the request.

Replacement of a manual wheelchair at the end of its five-year useful lifetime requires a complete reassessment following the same rules as if a new initial device was being provided.

General Coverage Criteria

A manual wheelchair for use inside the home (E1037-E1039, E1161, K0001-K0009, E1231-E1238) is covered if:

- Criteria A, B, C, D, and E are met; and
- Criterion F or G is met.
 - A. The beneficiary has a mobility limitation that significantly impairs his/her ability to participate in one or more mobility-related activities of daily living (MRADLs) such as toileting, feeding, dressing, grooming, and bathing in customary locations in the home. A mobility limitation is one that:
 - 1. Prevents the beneficiary from accomplishing an MRADL entirely, or
 - 2. Places the beneficiary at reasonably determined heightened risk of morbidity or mortality secondary to the attempts to perform an MRADL; or
 - 3. Prevents the beneficiary from completing an MRADL within a reasonable timeframe.

Wheelchairs (Manual) Page 3 of 14

- B. The beneficiary's mobility limitation cannot be sufficiently resolved by the use of an appropriately fitted cane or walker.
- C. The beneficiary's home provides adequate access between rooms, maneuvering space, and surfaces for use of the manual wheelchair that is provided.
- D. Use of a manual wheelchair will significantly improve the beneficiary's ability to participate in MRADLs and the beneficiary will use it on a regular basis in the home.
- E. The beneficiary has not expressed an unwillingness to use the manual wheelchair that is provided in the home.
- F. The beneficiary has sufficient upper extremity function and other physical and mental capabilities needed to safely self-propel the manual wheelchair that is provided in the home during a typical day. Limitations of strength, endurance, range of motion, coordination, presence of pain, or deformity or absence of one or both upper extremities are relevant to the assessment of upper extremity function.
- G. The beneficiary has a caregiver who is available, willing, and able to provide assistance with the wheelchair.

ADDITIONAL CRITERIA FOR SPECIFIC MANUAL WHEELCHAIRS (E1037, E1038, E1039, E1161, K0002 – K0008)

In addition to the general manual wheelchair criteria above, the specific criteria below must be met for each manual wheelchair. If the specific criteria are not met, the manual wheelchair will be denied as not reasonable and necessary.

A transport chair (E1037, E1038 or E1039) is covered as an alternative to a standard manual wheelchair (K0001) and if basic coverage criteria A-E and G above are met.

A standard hemi-wheelchair (K0002) is covered when the beneficiary requires a lower seat height (17" to 18") because of short stature or to enable the beneficiary to place his/her feet on the ground for propulsion.

A lightweight wheelchair (K0003) is covered when a beneficiary meets both criteria (1) and (2):

- 1. Cannot self-propel in a standard wheelchair in the home; and
- 2. The beneficiary can and does self-propel in a lightweight wheelchair.

A high-strength lightweight wheelchair (K0004) is covered when a beneficiary meets the criteria in (1) or (2):

1. The beneficiary self-propels the wheelchair while engaging in frequent activities in the home that cannot be performed in a standard or lightweight wheelchair.

Wheelchairs (Manual) Page 4 of 14

2. The beneficiary requires a seat width, depth, or height that cannot be accommodated in a standard, lightweight, or hemi-wheelchair, and spends at least two hours per day in the wheelchair.

A high-strength lightweight wheelchair is rarely reasonable and necessary if the expected duration of need is less than three months (e.g., post-operative recovery).

An ultra-lightweight manual wheelchair (K0005) is covered for a beneficiary if criteria one or two is met, and three and four are met:

- 1. The beneficiary must be a full-time manual wheelchair user.
- 2. The beneficiary must require individualized fitting and adjustments for one or more features such as, but not limited to, axle configuration, wheel camber, or seat and back angles, and which cannot be accommodated by a K0001 through K0004 manual wheelchair.
- 3. The beneficiary must have a specialty evaluation that was performed by a licensed/certified medical professional (LCMP), such as a PT or OT, or physician who has specific training and experience in rehabilitation wheelchair evaluations and that documents the medical necessity for the wheelchair and its special features (see Documentation Requirements section). The LCMP may have no financial relationship with the supplier.
- 4. The wheelchair is provided by a Rehabilitative Technology Supplier (RTS) that employs a RESNA-certified Assistive Technology Professional (ATP) who specializes in wheelchairs and who has direct, in-person involvement in the wheelchair selection for the patient.

Documentation of the medical necessity for a K0005 must include a description of the beneficiary's routine activities. This may include the types of activities the beneficiary frequently encounters and whether the beneficiary is fully independent in the use of the wheelchair. Describe the features of the K0005 base which are needed compared to the K0004 base.

A heavy-duty wheelchair (K0006) is covered if the beneficiary weighs more than 250 pounds or the beneficiary has severe spasticity.

An extra heavy-duty wheelchair (K0007) is covered if the beneficiary weighs more than 300 pounds.

A manual wheelchair with tilt in space (E1161) is covered if the beneficiary meets the general coverage criteria for a manual wheelchair above, and if both criteria are met:

1. The beneficiary must have a specialty evaluation that was performed by a licensed/certified medical professional (LCMP), such as a PT or OT, or physician who has specific training and experience in rehabilitation wheelchair evaluations and that documents the medical necessity for the wheelchair and its special

Wheelchairs (Manual) Page 5 of 14

- features (see Documentation Requirements section). The LCMP may have no financial relationship with the supplier.
- 2. The wheelchair is provided by a Rehabilitative Technology Supplier (RTS that employs a RESNA-certified Assistive Technology Professional (ATP) who specializes in wheelchairs and who has direct, in-person involvement in the wheelchair selection for the patient.

A pediatric folding or rigid manual wheelchair (E1235 – E1238) is covered if the beneficiary meets the general coverage criteria for manual wheelchairs above and both criteria below:

- 1. The beneficiary must have a specialty evaluation that was performed by a licensed/certified medical professional (LCMP), such as a PT or OT, or physician who has specific training and experience in rehabilitation wheelchair evaluations and that documents the medical necessity for the wheelchair and its special features (see Documentation Requirements section). The LCMP may have no financial relationship with the supplier.
- 2. The wheelchair is provided by a Rehabilitative Technology Supplier (RTS) that employs a RESNA-certified Assistive Technology Professional (ATP) who specializes in wheelchairs and who has direct, in-person involvement in the wheelchair selection for the patient.

A pediatric manual wheelchair with tilt in space (E1231-E1234) is covered if the beneficiary meets the general coverage criteria for a manual wheelchair above and all the criteria below:

- 1. The beneficiary must have a specialty evaluation that was performed by a licensed/certified medical professional (LCMP, such as a PT or OT, or physician who has specific training and experience in rehabilitation wheelchair evaluations and that documents the medical necessity for the wheelchair and its special features (see Documentation Requirements section). The LCMP may have no financial relationship with the supplier.
- 2. The wheelchair is provided by a Rehabilitative Technology Supplier (RTS) that employs a RESNA-certified Assistive Technology Professional (ATP) who specializes in wheelchairs and who has direct, in-person involvement in the wheelchair selection for the patient.
- 3. The customer is not independent with transfers.
 - The customer has a plan of care that addresses the medical need for frequent positioning changes (e.g., for pressure reduction or poor/absent trunk control) that do not always include a tilt position.

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A combination of manual tilt-in-space along with manual recline option is covered when the customer meets the coverage criteria for both components and when provided alone, one function will not meet their seating and positioning needs.

Custom Manual Wheelchair base (K0008)

A custom manual wheelchair base (K0008) is covered if, in addition to the general coverage criteria above, the specific configuration required to address the beneficiary's physical and/or functional deficits cannot be met using one of the standard manual wheelchair bases plus an appropriate combination of wheelchair seating systems, cushions, options, or accessories (prefabricated or custom fabricated), such that the individual construction of a unique individual manual wheelchair base is required.

Documentation must include a description of the beneficiary's unique physical and functional characteristics that require a customized manual wheelchair base. This must include a detailed description of the manufacturing of the wheelchair base, including types of materials used in custom fabricating or substantially modifying it, and the construction process and labor skills required to modify it. The record must document that the needs of the beneficiary cannot be met using another manual wheelchair base that incorporates seating modifications or other options or accessories (prefabricated and/or custom). The documentation must demonstrate that the K0008 is so different from another wheelchair base that the two items cannot be grouped together for pricing purposes.

Other Manual Wheelchair/Base (K0009/E1229)

Other manual wheelchair/base (K0009/E1229) is to be used for beneficiaries with medical needs for features in addition to those indicated for the wheelchair and/or accessory codes listed. Custom-made wheelchairs feature a wheelchair frame that is uniquely constructed or substantially modified for a specific beneficiary and is covered if the feature needed is not available in an already manufactured wheelchair or accessory. The assembly of a wheelchair from modular components and the use of customized options do not meet the requirements for a custom-made wheelchair.

A custom/other (K0008, K0009) manual wheelchair will be considered not medically necessary if the expected duration of need is less than three months (e.g., post-operative recovery).

Miscellaneous

If the manual wheelchair will be used inside the home and the coverage criteria are not met, it will be considered not medically necessary. If the manual wheelchair base is not covered, then related accessories will be considered not medically necessary.

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 Push-rim activated power assist option for a manual wheelchair (E0986). Only one unit of service should be billed per manual wheelchair. Please see the Power Mobility Devices Medical Policy for criteria.

Backup Wheelchairs

Backup chairs are denied as not reasonable and necessary.

Options and Accessories

Options and accessories must meet all of the following criteria:

- the patient has a wheelchair that meets all of the criteria listed in this policy; and
- the options/accessories are necessary for the patient to function in the home and to perform mobility related activities of daily living.

Wheelchair Options and Accessories

 All options and accessories (e.g., tilt and/or recline seating, adjustable arm trough, elevating leg rests, etc.) must meet medical necessity criteria as indicated in the Medicare National Coverage Policy L33792 Wheelchair Options and Accessories.

Wheelchair Seating (E2603 - E2610, E2613 - E2617, E2620 - E2625)

 Positioning and skin protection seat and back cushions must meet medical necessity criteria as indicated in the Medicare National Coverage Policy L33312 Wheelchair Seating.

MVP uses the Medicare Local Coverage Policy on Wheelchair Options and Accessories and Wheelchair Seating criteria for these items. For coverage criteria go to: https://med.noridianmedicare.com/web/jadme/policies/lcd/active

Exclusions

- Not meeting criteria listed in the Indications/Criteria of this policy.
- The beneficiary has not demonstrated that he/she has the ability to safely and effectively operate Mobility Assistive Equipment (MAE) in the home environment.
- There are conditions that limit the beneficiary's ability to participate in mobility related activities of daily living at home such as impairment of cognition or judgment and/or vision such that the provision of mobility assistive equipment (MAE) might not enable a customer to participate in mobility related activities of daily living if the co-morbidity prevents effective use of the wheelchair or reasonable completion of the tasks even with MAE.
- The beneficiary's home does not provide adequate access, maneuvering space, and surfaces for the operation of a wheelchair.

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- If a power operated vehicle (POV) is covered, a manual wheelchair provided at the same time or subsequently will usually be denied as not medically necessary.
- Options that are beneficial primarily in allowing the patient to perform leisure or recreational activities will be denied as not medically necessary.
- The wheelchair is primarily for use outdoors.
- An additional wheelchair to be used as back-up is considered to be a convenience and is considered to be not medically necessary.
- Hi-Lo Positioning systems (eg, Special Tomato seating system, Rifton activity chair, Squiggles seating system), including feeding chairs or highchairs for children who use other mobility devices (eg, wheelchair) with positioning or support attachments are considered a duplication of service.
- An add-on to convert a manual wheelchair to a joystick-controlled power mobility device or to a tiller-controlled power mobility device will be denied as not medically necessary. (A power add-on is used to convert a manual wheelchair to a motorized wheelchair.)
- Wheelchair options and accessories are covered when the individual meets coverage criteria for a wheelchair and the options/accessories are required for the individual to function successfully in the home for activities of daily living. Any option or accessory that is primarily for the purpose of allowing the individual to perform leisure or recreational activities, or is considered to be a convenience, is considered not medically necessary. The following items are considered to be not medically necessary:
 - auto carriers;
 - baskets, bags, pouches;
 - gloves;
 - o ramps;
 - snow tires for wheelchairs;
 - canopies;
 - o clothing guards to protect clothing from dirt, mud, or water thrown up by the wheels (similar to mud flaps for cars);
 - crutch or cane holder;
 - o identification devices such as labels, license plates, name plates;
 - shock absorbers;
 - tie-down restraints (transit option);

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warning devices, such as horns and backup signals.

Medicaid Variation

A statement from the licensed/certified medical professional (LCMP) of the alternatives considered or attempted (e.g., manual versus power, single versus multiple power option) and why these alternatives do not meet the customer's medical needs is required.

Wheelchairs for home and/or community use are considered, however there must be a secure storage space documented when community use is part of the request. A transit option may be considered for separate reimbursement if community use/transportation is cited as a need.

Back-up manual wheelchairs are covered when:

- (a) the customer meets the criteria for a power mobility device; and
- (b) the customer meets the criteria for the rented or purchased back-up manual wheelchair; and
- (c) the customer is unable to complete MRADLs without a back-up manual wheelchair; and
- (d) the backup wheelchair accommodates the seating and positioning components (SPC) on the primary wheelchair.

NOTE: Ultra-lightweight wheelchairs (K0005) should not be dispensed as back-up manual wheelchairs unless due to the required dimensions not being available in less costly alternatives (e.g., pediatric size and growth options).

Manual tilt-in-space wheelchairs (E1161, E1233, and E1234) are covered when:

- (a) The customer is not independent with transfers, and
- (b) The customer has a plan of care that addresses the medical need for frequent positioning changes (e.g., for pressure reduction or poor/absent trunk control) that do not always include a tilt position.
- Pediatric tilt-in-space wheelchairs satisfy future growth capability, attendant or user controlled tilt, multi position tilt, transit system, attendant handles, 10-18" width, 13-18" depth and standard back heights.
- Adult tilt-in-space wheelchairs feature attendant or user-controlled tilt, multi position tilt, transit system, attendant handles, 10-19" width and standard depth and back height.
- A combination of manual tilt-in-space along with manual recline option is covered when the customer meets the coverage criteria for both components

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and when provided alone, one function will not meet their seating and positioning needs.

Stroller-style Mobility Devices only (E1236)

- Code includes all accessories, parts and seating. Wheelchair accessory codes are not to be used at initial issue or for replacement parts.
- Strollers (E1236) are covered when supporting documentation:
 - (a) illustrates why a manual wheelchair (E1161, E1233, E1234, K0001-K0009) would not meet the customer's medical needs in their customary environments;
 - (b) selection is not based solely on caregiver convenience but on medical need of the customer.
 - (c) confirms there is no presence of severe, fixed postural deviations or contractures.

Medicare Variation

There is a Medicare National Coverage Determination (NCD) for Mobility Assistive Equipment. For full coverage details please refer to: Centers for Medicare & Medicaid Services National Coverage Determination (NCD) 280.15 (Effective Date 7/5/2005); NCD for Mobility Assistive Equipment; Available on-line: www.cms.gov.

Home Assessment:

For manual wheelchairs, the home assessment may be done directly by visiting the customer's home or indirectly based upon information provided by the customer or their designee. Regardless of the method used for the home assessment, issues such as the physical layout of the home, surfaces to be traversed, and obstacles to the use of the selected manual wheelchair must be addressed by and documented in the home assessment. Information from the customer's medical record and the supplier's records must be available upon request.

There is a Medicare Local Coverage Determination (LCD) for Manual Wheelchair Bases For full coverage details please refer to: Noridian Healthcare Solutions, LLC Durable Medical Equipment Medicare Administrative Contractor, LCD and Policy Article for Manual Wheelchair Bases (L33788 & A52497), Revision Effective Date 07/01/2024. Available: https://med.noridianmedicare.com/web/jddme/policies/lcd/active

There is a Medicare Local Coverage Determination (LCD) for Wheelchair Options/Accessories For full coverage details please refer to: Noridian Healthcare Solutions, LLC Durable Medical Equipment Medicare Administrative Contractor, LCD for LCD for Wheelchair Options/Accessories (L33792), Revision Effective Date 01/01/2020. Available: https://med.noridianmedicare.com/web/jddme/policies/lcd/active

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There is a Medicare Local Coverage Determination (LCD) for Wheelchair Seating For full coverage details please refer to: Noridian Healthcare Solutions, LLC Durable Medical Equipment Medicare Administrative Contractor, LCD for Wheelchair Seating (L33312), Revision Effective Date 01/01/2020. Available:

https://med.noridianmedicare.com/web/jddme/policies/lcd/active

References (Updated 2024)

- Centers for Medicare & Medicaid Services NCD 280.15 (Revision Effective Date 07/26/2006); NCD for Mobility Assistive Equipment; Available on-line: www.cms.gov
- 2. Noridian Healthcare Solutions, LLC Durable Medical Equipment Medicare Administrative Contractor, LCD for Manual Wheelchair Bases (L33788), Revision Effective Date 01/01/2020. Available: https://med.noridianmedicare.com/web/jddme/policies/lcd/active
- 3. Noridian Healthcare Solutions, LLC Durable Medical Equipment Medicare Administrative Contractor, LCD for LCD for Wheelchair Options/Accessories (L33792), Revision Effective Date 01/01/2020. Available: https://med.noridianmedicare.com/web/jddme/policies/lcd/active
- 4. Noridian Healthcare Solutions, LLC Durable Medical Equipment Medicare Administrative Contractor, LCD for Wheelchair Seating (L33312), Revision Effective Date 01/01/2020. Available: https://med.noridianmedicare.com/web/jddme/policies/lcd/active
- 5. New York State Department of Health. Provider Manual. DME Manual. Procedure Codes. 2015. Available: https://www.emedny.org/ProviderManuals/DME/index.aspx

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Prior Auth
Prior Auth
Potential for Retrospective Review
Prior Auth
See SPD
Prior Auth
See SPD

[♦] Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

*Medical Management Requirements

Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review

Retro ReviewRetrospective Review RequiredNot CoveredService is not a covered benefitSee SPDSee Specific Plan Design

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Revision History:

10/01/2021 – updated wording for how options and accessories are covered; added criteria to the Medicaid Managed Care variation for coverage of pediatric wheelchairs.

06/01/2023 –positioning systems added as an exclusion.

07/01/2024 – added variation for Medicare home assessments.

04/01/2025 – Completed formal review of changes effective 07/01/2024.

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Whole Exome Sequencing (New York State Medicaid)

Type of Policy: Medical

Prior Approval Date: 01/10/2025

Approval Date: 03/28/2025

Effective Date: 06/01/2025

Related Polices: Genetic and Molecular Diagnostic

Testing

Codes Requiring Prior Authorization

Prior authorization may vary by plan which means the codes listed below may be specific to one product or all products. Please refer to the product grid found at the end of this policy for detailed authorization requirements for specific plans.

N/A

Codes Requiring Retrospective Review

81415 Exome (eg, unexplained constitutional or heritable disorder or syndrome); sequence analysis; (WES)

81417 Exome (eg, unexplained constitutional or heritable disorder or syndrome); reevaluation of previously obtained exome sequence (eg, updated knowledge or unrelated condition/syndrome) (WES)

Experimental/Investigational

N/A

Common Diagnosis Codes

N/A

Common Diagnosis Codes associated with this policy have been provided for informational purposes only. The list of codes may not be all-inclusive and may be updated to reflect any applicable revisions to the ICD-10 code set and/or medical necessity quidelines applied in this policy.

Common Procedure Codes

N/A

Not Covered Procedure Codes:

81416, 81425, 81426, 81427

Please refer to the product grid for detailed authorization requirements for specific plans. Codes requiring prior-authorization for some products may require retrospective review for plans that do not require prior-authorization. Common diagnosis codes are included for informational purposes only and every attempt has been made to update and keep these codes accurate. These codes may not be all inclusive. CPT codes are subject to change as replacement codes are adopted by CMS. Any codes related to CMS updates will be adopted and applied to this policy by MVP.

Overview

Whole exome sequencing is a genetic test that uses next generation sequencing that is used to identify genetic variations that may cause genetic disorders.

This policy is specific to coverage only for Medicaid Managed Care Plans as required by New York State Department of Health.

For all other genomic testing please refer to the Genetic and Molecular Diagnostic Testing Medical Policy.

Indications/Criteria

Whole exome Sequencing is covered for members 18 years or younger for the evaluation of unexplained neurodevelopmental, neurological or congenital disorders when all of the following criteria are met:

- Clinical presentation and history of the customer suggests a genetic etiology;
- Clinical presentation does not fit a well-defined syndrome;
- Clinical presentation cannot be attributed to an environmental exposure, injury, infection, or other nongenetic etiology;
- Prior genetic testing for specific disorders has failed to yield a diagnosis;
- No additional genetic tests are being ordered concurrently;
- The individual has been evaluated and the test ordered by a physician specializing in clinical genetics or with extensive experience evaluating patients with suspected genetic syndromes; and
- Testing is expected to inform management decisions and/or avoid additional diagnostic tests, which may be unnecessary, expensive, and/or uncomfortable.

Exclusions

For all other genomic testing please refer to the Genetic and Molecular Diagnostic Testing Medical Policy.

Whole Exome Sequencing for prenatal/fetal screening or diagnosis is not covered by NYS Medicaid.

Whole Genome Sequencing ((WGS) 81425, 81426, 81427) looks at both the coding and noncoding regions of chromosomal DNA and will not be covered by NYS Medicaid.

Exome sequence analysis using a comparator exome from a healthy family member (e.g., parents, siblings) (81416) is not covered by New York State Medicaid.

References (2025)

- New York State Medicaid Program Fee-For Service Laboratory Procedure Codes and Coverage Guidelines Manual. Version 1/2025. Available: <u>Laboratory Procedure Codes.pdf</u>
- Manickam K, McClain MR, Demmer LA, Biswas S, Kearney HM, Malinowski J, Massingham LJ, Miller D, Yu TW, Hisama FM; ACMG Board of Directors. Exome and genome sequencing for pediatric patients with congenital anomalies or intellectual disability: an evidence-based clinical guideline of the American College of Medical Genetics and Genomics (ACMG). Genet Med. 2021 Nov;23(11):2029-2037.

Member Product	Medical Management Requirements*
New York Products	
HMO	NA
PPO in Plan	NA
PPO OOP	NA
POS in Plan	NA
POS OOP	NA
Essential Plan	NA
MVP Medicaid Managed Care	Retro Review
MVP Child Health Plus	Retro Review
MVP Harmonious Health Care Plan	Retro Review
MVP Medicare Complete Wellness	NA
MVP Medicare Preferred Gold HMO POS	NA
MVP Medicare Secure HMO POS	NA
MVP Medicare Secure Plus HMO POS	NA
MVP Medicare WellSelect PPO	NA
MVP Medicare WellSelect Plus PPO	NA
MVP Medicare Patriot Plan (PPO)	NA NA
USA Care PPO	Potential for Retrospective Review
MVP DualAccess D-SNP HMO	NA
MVP DualAccess Complete D-SNP HMO	NA NA
MVP DualAccess Plus D-SNP HMO	NA NA
UVM Health Advantage Select PPO	NA NA
Healthy NY	NA
MVP Premier	NA
MVP Premier Plus	NA
MVP Premier Plus HDHP	NA
MVP Secure	NA
MVP EPO	NA
MVP EPO HDHP	NA
MVP PPO	NA
MVP PPO HDHP	NA
Student Health Plans	NA
ASO	NA
Vermont Products	
POS in Plan	NA
POS OOP	NA
MVP Medicare Preferred Gold HMO POS POS	NA
MVP Medicare Secure Plus HMO POS	NA
MVP VT HMO	NA
MVP VT HDHP HMO	NA NA
MVP VT Plus HMO	NA
MVP VT Plus HDHP HMO	NA
MVP Secure	NA NA
ASO	NA

[♦] Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).

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*Medical Management Requirements

Prior Auth Prior Authorization Required

Potential for Retrospective Review No Prior Authorization Required. May be subject to Retrospective Review.

Retro ReviewRetrospective Review RequiredNot CoveredService is not a covered benefit.See SPDSee Specific Plan Design

Revision History:

02/01/2025 - New policy effective.

06/01/2025 –Formal review of current policy completed.