


# 2025 MVP Health Care® Pharmacy Policies

Updated August 1st, 2025

## MVP Pharmacy Policies

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**MVP Health Care Medical Policy**

**Abatacept**

| | |
|---|---|
| **Type of Policy:** | Medical Therapy |
| **Prior Approval Date:** | 02/01/2023 |
| **Approval Date:** | 02/01/2024 |
| **Effective Date:** | 04/01/2024 |
| **Related Policies:** | Apremilast, Adalimumab, Infliximab, Risankizumab, Secukinumab, Tofacitinib, Upadacitinib, Ustekinumab, Ozanimod, Golimumab, Tocilizumab, Certolizumab |

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies.

Refer to the MVP website for the Medicare Part B policies for coverage criteria of drugs covered under the medical benefit.

## Drugs Requiring Prior Authorization under the pharmacy benefit

Orencia SQ is non-preferred under the pharmacy benefit

## Drugs Requiring Prior Authorization under the medical benefit

J0129 abatacept, 10mg (Orencia IV)

## Overview

Abatacept is a fully human recombinant fusion protein categorized as a costimulatory or second-signal blocker of T cell activation. It is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis (RA), in patients 2 years of age and older with active psoriatic arthritis (PsA), and in patients 2 years of age and older with moderately to severely active polyarticular juvenile idiopathic arthritis. Abatacept is also indicated as prophylaxis of acute graft versus host disease, in combination with a calcineurin inhibitor and methotrexate, in adults and pediatric patients 2 years of age and older undergoing hematopoietic stem-cell transplantation

from a matched or 1 allele-mismatched unrelated donor. Members should be screened for immunologic and infectious disease prior to initiating therapy.

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**Medicaid Variation:** Medications that are a pharmacy benefit are covered and billed to New York State Fee-For-Service (FFS) program. They are defined as medications that go through a retail or specialty pharmacy, including self administered injectable products. Pharmacy medications are subject to FFS's clinical criteria including (but not limited to) coverage, quantity limit, step therapy, and prior authorization. Pharmacy benefit information can be found here: https://www.emedny.org/info/fullform.pdf

**Indications/Criteria**

A. For all indications, Abatacept SQ (Orencia) is non-formulary and will only be considered for **pharmacy** coverage when:

- Documented failure, contraindication or ineffective response to all preferred/formulary therapies for the specific indication.

B. For all indications, Abatacept IV (Orencia) may be considered for **medical** coverage when:

- Prescribed for an FDA approved indication **AND**
- Ordered by or with consult from a rheumatologist/immunologist **AND**
- Documentation identifies failure of **preferred** self-administered biologic therapies to treat the condition **AND**
- Rationale and documentation are provided identifying why member or caregiver is unable to self-administer
- Site of Care
    - Per the MVP Health Care Pharmacy Management Programs policy, Abatacept IV (Orencia) is subject to Site of Care requirements and must be obtained through a preferred home infusion vendor. Prior Authorization and medical justification is required for Abatacept IV (Orencia) obtained and administered in other outpatient settings such as a provider's office or hospital facility.
    - MVP will allow 60 days after prior authorization approval for members to transfer to a preferred infusion site.
    - This requirement does not apply to MVP Medicare and Medicaid members

C. **Rheumatoid Arthritis**

Abatacept may be considered for coverage for Rheumatoid Arthritis when the above criteria is met **AND**:

- Member has a diagnosis of moderate to severe active adult RA as defined by persistent or recurrent symptoms with documented synovitis and morning stiffness of significant duration to inhibit activities of daily living.
- Chart notes are provided documenting a failure to respond to a three-month trial of methotrexate at a maximally tolerated dose.
    - Failure is demonstrated by documentation of provider assessment without improvement in joint counts and/or physical symptoms and inflammatory markers while on therapy.
    - If the member has a contraindication or significant intolerance to methotrexate
        - Chart notes documenting a failure to respond to at least one other nonbiologic DMARDs at a maximally tolerated dose for at least 3 months **AND** documentation confirming why methotrexate cannot be used is required. If a trial of methotrexate is not appropriate due to alcohol use, chart notes must be provided indicating that the patient has been counseled on the need to abstain from alcohol use while taking methotrexate and is unwilling to abstain from alcohol use.

**Initial approval** for **6 months**.

**Extension requests** will be approved for 12 months if the member has a continued benefit to therapy **AND** there is medical necessity for use of the IV formulation instead of a self-administered formulation.

**Extension requests** where Abatacept did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

D. **Juvenile Idiopathic Arthritis**

Abatacept to treat Juvenile idiopathic arthritis will be reviewed on a case-by-case basis using the American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis.

**Initial approval** for **6 months**.

**Extension requests** will be approved for 12 months if the member has a continued benefit to therapy **AND** there is medical necessity for use of the IV formulation instead of a self-administered formulation.

**Extension requests** where Abatacept IV (Orencia) did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

E. **Psoriatic Arthritis**

Abatacept may be considered for coverage for Psoriatic Arthritis when the above criteria is met **AND**:

- Member has a diagnosis of moderate to severe PsA as defined by three or more tender joints AND three or more swollen joints on two separate occasions at least one month apart
- Chart notes are provided documenting failure of at least one NSAID at maximum tolerated dose unless the member has contraindications to NSAID therapy such as cardiovascular disease, peptic ulcer disease or renal disease **AND**
- Chart notes are provided documenting failure to an adequate trial of at least one of the following nonbiologic disease modifying anti-rheumatic drugs (DMARDs): leflunomide, sulfasalazine, or methotrexate.
    - **Members with pure axial manifestations** do not have to have a trial of nonbiologic disease modifying anti-rheumatic drugs (DMARDs)
    - If a trial of methotrexate is not appropriate due to alcohol use, chart notes must be provided indicating that the patient has been counseled on the need to abstain from alcohol use while taking methotrexate and is unwilling to abstain from alcohol use.

**Initial approval** for **6 months**.

**Extension requests** will be approved for 12 months if the member has a continued benefit to therapy **AND** there is medical necessity for use of the IV formulation instead of a self-administered formulation.

**Extension requests** where Abatacept IV (Orencia) did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

F. **Acute graft versus host disease (GVHD) prophylaxis**

Abatacept may be considered for coverage for GVHD when the above criteria is met **AND** documentation that the member is undergoing hemotopoietic stem-cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated donor.

**Initial approval** for **6 months**.

**Extension requests** will be approved for 12 months if the member has a continued benefit to therapy **AND** there is medical necessity for use of the IV formulation instead of a self-administered formulation.

**Extension requests** where Abatacept did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

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**Exclusions**

The use of Abatacept will not be covered for the following situations:

- Dosing, age, and/or frequency outside of the FDA approved package labeling
- Combination therapy that is not supported by current clinical guidelines

## References


1. Clinical Pharmacology. Abatacept. Revised 12/21/2021. Accessed 01/05/2023.
2. Orencia (abatacept) for injection. Prescribing information. Bristol-Myers Squibb Princeton, NJ. Revised 10/2023.
3. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis & Rheumatology Vol. 71, No. 1, January 2019, pp 5–32 DOI 10.1002/art.40726. 2018 American College of Rheumatology/ National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis
4. 2021 American College of Rheumatology Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Oligoarthritis, Temporomandibular Joint Arthritis, and Systemic Juvenile Idiopathic Arthritis. Arthritis and Rheumatology. Vol 74 No. 4 April 2022, pp553-569. Available at: https://www.rheumatology.org/Portals/0/Files/ACR-JIA%20Guideline-Oligo-TMJ-sJIA-EarlyView.pdf
5. Fraenkel et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care & Research Vol. 73, No. 7, July 2021, pp 924–939 DOI 10.1002/acr.24596. Available at: 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis (contentstack.io).


| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Medicare Gold Giveback | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |

| | |
|---|---|
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D |
| 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).** | |
| *© 2024 MVP Health Plan, Inc. All rights reserved. Descriptions contained within MVP's Medical Policies are not a guarantee of coverage. Each MVP Group or Subscriber Contract contains specific limitations, exclusions and requirements that may affect a Policy. If there is any discrepancy between your Group or Subscriber Contract and a Policy, your Group or Subscriber Contract shall in all cases govern.* | |

***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 |

**MVP Health Care Medical Policy**

**Medicare Part B: Abatacept**

| | |
|---|---|
| **Type of Policy:** | **Medical Therapy** |
| **Prior Approval Date:** | **11/01/2023** |
| **Approval Date:** | **02/01/2024** |
| **Effective Date:** | **04/01/2024** |
| **Related Policies:** | **Infliximab, Risankizumab, Secukinumab, Ustekinumab, Golimumab, Tocilizumab, Certolizumab** |

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies for drugs that may be covered under the Part D benefit.

## Drugs Requiring Prior Authorization under the medical benefit

J0129 abatacept, 10mg (Orencia IV)

## Overview/Summary of Evidence

Abatacept is a fully human recombinant fusion protein categorized as a costimulatory or second-signal blocker of T cell activation. It is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis (RA), in patients 2 years of age and older with active psoriatic arthritis (PsA), and in patients 2 years of age and older with moderately to severely active polyarticular juvenile idiopathic arthritis. Abatacept is also indicated as prophylaxis of acute graft versus host disease, in combination with a calcineurin inhibitor and methotrexate, in adults and pediatric patients 2 years of age and older undergoing hematopoietic stem-cell transplantation from a matched or 1 allele-mismatched unrelated donor. Members should be screened for immunologic and infectious disease prior to initiating therapy.

## Indications/Criteria

A. For all indications, Abatacept IV (Orencia) may be considered for **medical** coverage when:
   - Prescribed for an FDA approved indication **AND**

- Ordered by or with consult from a rheumatologist/immunologist **AND**
- Member has coverage under Medicare Part B and meets the criteria below for a provider administered drug identified in this policy

B. **Rheumatoid Arthritis**

Abatacept may be considered for coverage for Rheumatoid Arthritis when the above criteria is met **AND**:

- Member has a diagnosis of moderate to severe active adult RA as defined by persistent or recurrent symptoms with documented synovitis and morning stiffness of significant duration to inhibit activities of daily living.
- Chart notes are provided documenting a failure to respond to a three-month trial of methotrexate at a maximally tolerated dose.
    - Failure is demonstrated by documentation of provider assessment without improvement in joint counts and/or physical symptoms and inflammatory markers while on therapy.
    - If the member has a contraindication or significant intolerance to methotrexate
        - Chart notes documenting a failure to respond to at least one other nonbiologic DMARDs at a maximally tolerated dose for at least 3 months **AND** documentation confirming why methotrexate cannot be used is required. If a trial of methotrexate is not appropriate due to alcohol use, chart notes must be provided indicating that the patient has been counseled on the need to abstain from alcohol use while taking methotrexate and is unwilling to abstain from alcohol use.

**Initial approval** for **6 months**.

**Extension requests** will be approved for 12 months if the member has a continued benefit to therapy
**Extension requests** where Abatacept did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

C. **Juvenile Idiopathic Arthritis**

Abatacept to treat Juvenile idiopathic arthritis will be reviewed on a case-by-case basis using the American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis.

**Initial approval** for **6 months**.

**Extension requests** will be approved for 12 months if the member has a continued benefit to therapy
**Extension requests** where Abatacept IV (Orencia) did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

D. **Psoriatic Arthritis**
Abatacept may be considered for coverage for Psoriatic Arthritis when the above criteria is met **AND**:

- Member has a diagnosis of moderate to severe PsA as defined by three or more tender joints AND three or more swollen joints on two separate occasions at least one month apart
- Chart notes are provided documenting failure of at least one NSAID at maximum tolerated dose unless the member has contraindications to NSAID therapy such as cardiovascular disease, peptic ulcer disease or renal disease **AND**
- Chart notes are provided documenting failure to an adequate trial of at least one of the following nonbiologic disease modifying anti-rheumatic drugs (DMARDs): leflunomide, sulfasalazine, or methotrexate.
    - **Members with pure axial manifestations** do not have to have a trial of nonbiologic disease modifying anti-rheumatic drugs (DMARDs)
    - If a trial of methotrexate is not appropriate due to alcohol use, chart notes must be provided indicating that the patient has been counseled on the need to abstain from alcohol use while taking methotrexate and is unwilling to abstain from alcohol use.

**Initial approval** for **6 months**.

**Extension requests** will be approved for 12 months if the member has a continued benefit to therapy
**Extension requests** where Abatacept IV (Orencia) did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

E. **Acute graft versus host disease (GVHD) prophylaxis**
Abatacept may be considered for coverage for GVHD when the above criteria is met **AND** documentation that the member is undergoing hemotopoietic stem-cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated donor.

**Initial approval** for **6 months**.

**Extension requests** will be approved for 12 months if the member has a continued benefit to therapy
**Extension requests** where Abatacept did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

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## Exclusions

The use of Abatacept will not be covered for the following situations:

- Dosing, age, and/or frequency outside of the FDA approved package labeling
- Combination therapy that is not supported by current clinical guidelines

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## References


1. Clinical Pharmacology. Abatacept. Revised 12/21/2021. Accessed 01/05/2023.
2. Orencia (abatacept) for injection. Prescribing information. Bristol-Myers Squibb Princeton, NJ. Revised 10/2023.
3. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis & Rheumatology Vol. 71, No. 1, January 2019, pp 5–32 DOI 10.1002/art.40726. 2018 American College of Rheumatology/ National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis
4. 2021 American College of Rheumatology Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Oligoarthritis, Temporomandibular Joint Arthritis, and Systemic Juvenile Idiopathic Arthritis. Arthritis and Rheumatology. Vol 74 No. 4 April 2022, pp553-569. Available at: https://www.rheumatology.org/Portals/0/Files/ACR-JIA%20Guideline-Oligo-TMJ-sJIA-EarlyView.pdf
5. Fraenkel et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care & Research Vol. 73, No. 7, July 2021, pp 924–939 DOI 10.1002/acr.24596. Available at: 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis (contentstack.io).

**MVP Health Care Medical Policy**

**ACL Inhibitors**

| | |
|---|---|
| **Type of Policy:** | **Drug Therapy** |
| **Prior Approval Date:** | **08/01/2023** |
| **Approval Date:** | **08/01/2024** |
| **Effective Date:** | **10/01/2024** |
| **Related Policies:** | **PCSK9 Inhibitors** |

**Drugs Requiring Prior Authorization (covered under the pharmacy benefit)**

Nexletol (Bempedoic acid)

Nexlizet (Bempedoic acid and ezetimibe)

Refer to the MVP website for the Medicare Part D formulary for drugs that may be covered under the Part D benefit.

**Overview**

Nexletol (Bempedoic Acid) is indicated to reduce the risk of myocardial infarction (MI) and coronary revascularization in adults who are unable to take recommended statin therapy (including those not taking a statin with: established cardiovascular disease (CVD) or a high risk for a CVD event but without established CVF. Nexletol is also indicated as an adjunct to diet, in combination with other low-density lipoprotein cholesterol (LDL-C) lowering therapies or alone when concomitant LDL-C lowering therapy is not possible, to reduce LDL-C in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH).

Nexlizet contains bempedoic acid in combination with ezetimibe. Nexlizet is indicated as an adjunct to diet, alone or in combination with other low-density lipoprotein cholesterol (LDL-C) lowering therapies, to reduce LDL-C in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH). Nexlizet is also indicated to reduce the risk of myocardial infarction and coronary revascularization in adults who are unable to take

recommended statin therapy (including those not taking a statin) with: established cardiovascular disease (CVD), or a high risk for a CVD event but without established CVD.

Ezetimibe reduces blood cholesterol by inhibiting the absorption of cholesterol by targeting Niemann-Pick C1-Like 1 (NPC1L1) in the small intestine.[2] NPC1L1 is involved in the intestinal uptake of cholesterol and phytosterols. Ezetimibe inhibits the absorption of cholesterol, leading to a decrease in the delivery of intestinal cholesterol to the liver. This causes a reduction of hepatic cholesterol stores and an increase in clearance of cholesterol from the blood.

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**Indications/Criteria**

A. For all indication, the following criteria must be met in addition to the specific diagnosis criteria below:

- Prior and current lipid treatments-including dose, duration of treatment, reason for discontinuation, and LDL-C reduction
- Current lipid panel and liver function tests obtained within 30 days of request
- Confirmation the member has been adhering to lifestyle modifications (i.e heart healthy diet, regular exercise)
- Nexletol and Nexlizet must be prescribed by or given in consultation with a cardiologist or endocrinologist
- Nexletol or Nexlizet is being prescribed as adjunct with statin therapy
    - If adjunct statin therapy is not considered medically appropriate, documentation of a contraindication to all statins must be provided OR
    - Documentation of statin intolerance. Statin intolerance is confirmed with one of the following:
        i. Intolerable muscle pain
            1. Other causes/conditions that may cause muscle pain must be ruled out
            2. Pain must significantly improve or resolve upon discontinuation of the statin
        ii. Muscle pain with a CK>5 x ULN
        iii. Hepatic transaminases >3 x ULN
- Confirmation of at least two attempts of different statin re-challenges must be provided (one of the statins must be rosuvastatin (Crestor))

Statin re-challenge is not required if while on statin therapy the member had an elevation of CK level ≥ 10 times ULN or experienced rhabdomyolysis

**B. Risk reduction of myocardial infarction or coronary revascularization**

- Member has a history of ASCVD (must have one of the following):

- MI, angina (stable or unstable), history of stroke or TIA, PTCA, CABG, Peripheral vascular disease, or findings from a CT angiogram or cardiac catheterization consistent with clinical ASCVD

- Must meet one of the following:
  - Current LDL-C level ≥70 mg/dL after a minimum of 3 months of therapy with a high potency statin in combination with ezetimibe 10 mg **OR** highest tolerated statin dose in combination with ezetimibe 10 mg
    - High potency statins include atorvastatin 40 mg, 80 mg, and rosuvastatin 20 mg, 40 mg
    - Member must be adherent with 3 months of high-intensity statin and ezetimibe therapy
    - Claims history will be used to verify adherence
    - The following will be considered a contraindication to ezetimibe: active hepatic disease or unexplained persistent elevations in serum transaminases (3 times ULN), women who are pregnant, or are breastfeeding

**C. Heterozygous Familial Hypercholesterolemia (FH)**

- Member has a confirmed diagnosis of heterozygous FH with **one** of the following met:
  - Genetic testing that indicates LDL-receptor mutation, ApoB defect, or PCSK9 mutation
  - Dutch Lipid Clinic Network total score >8
  - Simon-Broome Diagnostic Criteria
    i. Total cholesterol > 290 mg/dL or LDL-C >190 mg/dL, plus tendon xanthomas in first or second degree relative

- Members without ASCVD must meet one of the following:
  - Current LDL-C level ≥100 mg/dL after a minimum of 3 months of therapy with a high potency statin in combination with ezetimibe 10 mg or highest tolerated statin dose in combination with ezetimibe 10 mg
    - High potency statins include atorvastatin 40 mg, 80 mg, and rosuvastatin 20 mg, 40 mg
    - Member must be compliant with 3 months of high-intensity statin and ezetimibe therapy
    - Claims history will be used to verify compliance
    - The following will be considered a contraindication to ezetimibe: active hepatic disease or unexplained persistent elevations in serum

transaminases (3 times ULN), women who are pregnant, or are breastfeeding

**Initial approval** will be for 3 months.

**Subsequent extensions** will be approved for 12 months if the member meets the criteria below:

- The member meets all criteria specified in the "initiating therapy" section (Section A) above
  **AND**
- Member continues to receive concomitant maximally tolerated statin therapy
  **AND**
- Member continues to demonstrate adherence with ACL inhibitor, statin therapy, and lifestyle modifications. Claims history will be used to verify compliance **AND**
- Current documentation demonstrates the member has had a reduction or maintained a reduction in LDL-C from baseline **OR**
- Reduction below the goal LDL-C level of ≤70 mg/dL for ASCVD or 100 mg/dL for heterozygous FH

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**Exclusions**

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling History of tendon rupture
- Concomitant use with simvastatin greater than 20 mg or pravastatin greater than 40 mg
- Nexlizet: moderate to severe hepatic impairment

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**References**


1. Nexletol (bempedoic acid) [prescribing information]. Ann Arbor, MI: Esperion Therapeutics, Inc; March 2024
2. Nexlizet (bempedoic acid and ezetimibe) [prescribing information]. Ann Arbor, MI: Esperion Therapeutics, Inc; March 2024
3. Ray KK, Bays HE, Catapano AL, et al. Safety and Efficacy of Bempedoic Acid to Reduce LDL Cholesterol. New England Journal of Medicine [Internet]. 2019;380(11):1022–32. Accessed October 2020.
4. Goldberg AC, Leiter LA, Stroes ESG, et al. Effect of Bempedoic Acid vs Placebo Added to Maximally Tolerated Statins on Low-Density Lipoprotein Cholesterol in

Patients at High Risk for Cardiovascular Disease. JAMA [Internet]. 2019 Dec; 322(18):1780. Accessed October 2020.
5. Laufs U, Banach M, Mancini GBJ, et al. Efficacy and Safety of Bempedoic Acid in Patients With Hypercholesterolemia and Statin Intolerance. Journal of the American Heart Association [Internet]. 2019 Feb; 8(7). Accessed October 2020.
6. Ballantyne CM, Banach M, Mancini GJ, et al. Efficacy and safety of bempedoic acid added to ezetimibe in statin-intolerant patients with hypercholesterolemia: A randomized, placebo-controlled study. Atherosclerosis [Internet]. 2018 Jun; 277:195–203. Accessed October 2020.
7. Guidelines for the Management of High Blood Cholesterol - Endotext - NCBI Bookshelf (nih.gov)

| 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 | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Authorization |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Medicare Gold Giveback | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |

| | |
|---|---|
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D |
| 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 | 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

**Acthar**

| | |
|---|---|
| **Type of Policy:** | **Drug/Medical Therapy** |
| **Prior Approval Date:** | **02/01/2024** |
| **Approval Date:** | **02/01/2025** |
| **Effective Date:** | **04/01/2025** |

**Related Policies:**

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies.

**Drugs Requiring Prior Authorization**

J0800 (Injection, corticotropin, up to 40 units)

**Overview**

Acthar® Gel (repository corticotropin injection) is natural source adrenocorticotropic hormone (ACTH) in 16% gelatin that stimulates prolonged hormonal release after intramuscular or subcutaneous injection.

**Indications/Criteria**

**A. Multiple Sclerosis**

Acthar may be considered for coverage in the treatment of acute exacerbations of relapsing-remitting multiple sclerosis when the following criteria is met:

- Prescribed by or in consult with a neurologist
- Member is 18 years of age or older
- The symptoms are severe and impair vision and/or mobility.
- There is a documented severe allergic or hypersensitivity reaction, anaphylaxis, or angioedema to high-dose oral corticosteroids and/or IV methylprednisolone or dexamethasone.
- Prescriber must rule out pseudo-exacerbation from other precipitating factors (i.e. infection, pain, stress, premenstrual syndrome)

- Member is currently being treated with a Disease-Modifying Agent and has been stable within the past 30 days

**Initial approval** will be for one month.

**Extension requests** require clinical documentation indicating response to initial treatment and plan for continued therapy

B. **Nephrotic Syndrome**

Acthar may be considered for coverage in the treatment of nephrotic syndrome if all the following criteria are met:

- Prescribed by or in consult with a nephrologist.
- Proteinuria of at least 3.5 g/24 hours.
- The member has been compliant with a low-protein diet and lipid management
- Member has a documented severe allergic or hypersensitivity reaction, anaphylaxis or angioedema to high-dose oral corticosteroids and/or IV methylprednisolone or dexamethasone
- Member has not responded to high dose corticosteroids (prednisone up to 80 mg/day) for up to 16 weeks

| Idiopathic Type | First- line Therapy Option(s) | Second-line Therapy Option(s) |
|---|---|---|
| Focal Segmental Glomerulonephritis | • Corticosteroids | • Cyclosporine or tacrolimus<br>• Mycophenolate AND dexamethasone |
| IgA Nephropathy | • ACE-inhibitor OR ARB<br>• Corticosteroids | • Cyclophosphamide (crescentic IgAN, only) |
| Membranoproliferative glomerulonephritis | • Cyclophosphamide | • Mycophenolate AND corticosteroids |
| Membranous Nephropathy | • Corticosteroids AND cyclophosphamide | • Cyclosporine OR tacrolimus |

**Note:** A failure is defined as <u>not</u> achieving a complete or partial remission following treatment:

- Complete remission: reduction of proteinuria to less than 300 mg/day
- Partial remission: reduction of proteinuria to 300-3500 mg/day

**C. Infantile Spasms**

Acthar may be considered for coverage in the treatment of infantile spasms if all the following criteria are met:

- Documentation supporting diagnosis of infantile spasms (with hypsarrhythmia) including onset of age, description of symptoms
- Provide dose, frequency, and number of requested vials per month.
- Failure, intolerance, or contraindication of all other available medical treatments (such as vigabatrin and oral steroids).
- Less than 2 years of age.
- Prescribed by or in consult with a neurologist.

Initial approval will be for 6 months

Extension requests require documentation indicating an improvement in spasms within four weeks of initiation of therapy.

**D. Other FDA approved indications:**

For other FDA approved indications Acthar use must meet MVP's Experimental or Investigational Procedures, Behavioral Health Services, Drugs and Treatments, Off-Label use of FDA Approved Drugs and Clinical Trials policy.

## Exclusions

The use of Acthar will not be covered for the following situations:

- Member has not failed all other standard therapies for the disease
- No documented failure of corticosteroid treatment.
- Members with absolute contraindications to Acthar including scleroderma, osteoporosis, systemic fungal infections, ocular herpes simplex, recent surgery, history of or the presence of a peptic ulcer, congestive heart failure, uncontrolled hypertension, adrenal insufficiency, osteoporosis, or sensitivity to proteins of porcine origin.
- Acthar administered intravenously

## References

1. Acthar (corticotropin) injection gel, Prescribing information. Bedminster, NJ: Mallinckrodt Pharmaceuticals; October 2021.

2. Shields DW, Infantile spasms: little seizures, BIG consequences. Epilepsy Curr. 2006 May; 6(3): 63–69. doi: 10.1111/j.1535-7511.2006.00100.x. Retrieved from http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=1464162.

3. Mackay MT, Weiss SK, Adams-Webber T, et al. Practice parameter: Medical treatment of infantile spasms. Report of the American Academy of Neurology and the Child Neurology Society. Neurology 2004;62:1668-1681.

4. Kodner C. Nephrotic syndrome in adults: diagnosis and management. Am Fam Physician. 2009;80(10):1129-1134, 1136.

5. Bomback, Andrew S., Tumlin, James A., Baranski, Joel. Treatment of Nephrotic Syndrome with Adrenocorticotropic Hormone (ACTH) Gel. Drug Design, Development and Therapy. 2011:5 147-153.

6. Goodman, Howard: Baxter, J. The Nephrotic Syndrome: Clinical Observations on Therapy with Prednisone and Other Steroids. JAMA. 1957:165 (14): 1798-1808 id=38244&search=nephritic+syndrome.

7. Kidney Disease: Improving Global Outcomes (KDIGO) Glomerulonephritis Work Group. KDIGO Clinical Practice Guideline for Glomerulonephritis. Kidney inter., Suppl. 2012; 2: 139–274.

8. Cattran DC, Appel GB. Treatment and prognosis of IgA nephropathy. UpToDate Last updated 2014 Nov 12. Available from: http://www.uptodate.com/contents/treatment-and-prognosis-of-iga-nephropathy

9. Kelepouris E, Rovin B. Overview of heavy proteinuria and the nephrotic syndrome. UpToDate (Accessed on January 4, 2016)

| 10. 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Complete Wellness | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D |

| | |
|---|---|
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D |
| USA Care PPO | Refer to the MVP website for the Medicare Part B and Part D |
| 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 | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

**Adakveo**

| | |
|---|---|
| **Type of Policy:** | Drug Therapy |
| **Prior Approval Date:** | 10/01/2023 |
| **Approval Date:** | 12/01/2024 |
| **Effective Date:** | 02/01/2025 |
| **Related Policies:** | N/A |

**Codes Requiring Prior Authorization (covered under the medical benefit)**

J0791- Injection, crizanlizumab-tmca, 5mg (Adakveo)

**Overview**

Red blood cells are normally round and flexible being able to move through the blood vessels with ease. In sickle cell anemia, the red blood cells are rigid and "sticky" taking on the shape of sickles or crescent moons. The red blood cells can cluster together creating blockages throughout the body making blood flow difficult. The blockages can create "vaso-occlusive crises" which are intense episodes of pain.

Adakveo (crizanlizumab-tmca) is indicated to reduce the frequency of vaso-occlusive crises in adults and pediatric members aged 16 years and older with sickle cell disease. Adakveo is a humanized IgG2 kappa monoclonal antibody which inhibits sickled red blood cells from adhering together to create blockages by binding to P-selectin and preventing interaction with P-selectin glycoprotein ligand 1.

Adakveo is administered by intravenous infusion at week 0, week 2 and every 4 weeks thereafter.

**Indications/Criteria**

Adakveo may be considered for coverage when all the following criteria are met:

- Chart notes confirming the diagnosis of sickle cell disease.
- Member is at least 16 years of age or older.
- Baseline vaso-occlusive crises (number of crises within the past one year)
- Chart notes documenting (or documentation of) failure, intolerance, or contraindication to hydroxyurea therapy.
- Site of Care

a. Per the MVP Health Care Pharmacy Management Programs policy, Adakveo is subject to Site of Care requirements and must be obtained through a preferred home infusion vendor. Prior Authorization and medical justification are required for Adakveo obtained and administered in other outpatient settings such as a provider's office or hospital facility.
    i. MVP will allow 60 days after prior authorization approval for members to transfer to a preferred infusion site.
    ii. This requirement does not apply to MVP Medicare and Medicaid members

**Initial approval will be for 6 months**

**Extension requests will be up to one year.** Extension requests require current chart notes documenting improved member status and a decrease in baseline vaso-occlusive crises.

**Medicaid Variation**

Adakveo may be considered for coverage when all the following criteria are met:

1. Chart notes confirming the diagnosis of sickle cell disease
2. Member is at least 16 years of age or older.

**Initial approval** will be for 6 months

**Extension requests will be up to one year.** Extension requests require documentation of a decrease in baseline vaso-occlusive crises.

**Exclusions**

1. Indication, age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling.

**References**

1. Adakveo. Prescribing Information. East Hanover, NJ. Novartis Pharmaceuticals Corporation. Revised 06/2024. https://www.novartis.us/sites/www.novartis.us/files/adakveo.pdf
2. Sickle cell anemia. Mayo Clinic. Available at: https://www.mayoclinic.org/diseases-conditions/sickle-cell-anemia/symptoms-causes/syc-20355876
3. New York State Fee-For-Service Policy and Billing Guidance for Adakveo: New Coverage Criteria and "J" Code. New York State Medicaid Update - May 2020 Volume 36 - Number 10 (ny.gov)
4. Study of Dose Confirmation and Safety of Crizanlizumab in Pediatric Sickle Cell Disease Patients. Clinicaltrials.gov. Available at:

https://clinicaltrials.gov/ct2/show/NCT03474965?term=crizanlizumab&draw=2&rank=1. Last Updated 10/23/2024

| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Complete Wellness | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D |
| USA Care PPO | Refer to the MVP website for the Medicare Part B and Part D |
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| 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 | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

**Adalimumab**

| | |
|---|---|
| **Type of Policy:** | Drug Therapy |
| **Prior Approval Date:** | 12/01/2023 |
| **Approval Date:** | 10/01/2024 |
| **Effective Date:** | 01/01/2025 |
| **Related Policies:** | Aprelimast, Etanercept, Infliximab, Risankizumab, Secukinumab, Tofacitinib, Upadacitinib, Ustekinumab, Ozanimod |

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies.

**Drugs Requiring Prior Authorization under the pharmacy benefit**

Humira (adalimumab)

Adalimumab-adaz

Hyrimoz

**Overview**

Adalimumab is a subcutaneous monoclonal antibody specific for tumor necrosis factor-alpha (TNF-alpha), also known as a TNF-blocker. Adalimumab is indicated in a variety of inflammatory disorders, including adults with rheumatoid arthritis (RA), psoriatic arthritis (PsA), psoriasis, and ankylosing spondylitis (AS), adults and children with Crohn's disease, moderate to severe hidradenitis suppurativa, moderate to severe ulcerative colitis, uveitis, and polyarticular juvenile idiopathic arthritis.

Members should be screened for immunologic and infectious disease prior to initiating therapy.

Lymphomas and other malignancies have been observed in patients treated with TNF blocking agents.

**Medicaid Variation:** Medications that are a pharmacy benefit are covered and billed to New York State Fee-For-Service (FFS) program. They are defined as medications that go through a retail or specialty pharmacy, including self-administered injectable products. Pharmacy medications are subject to FFS's clinical criteria including (but not limited to)

coverage, quantity limit, step therapy, and prior authorization. Pharmacy benefit information can be found here: https://www.emedny.org/info/fullform.pdf

**Indications/Criteria**

**A. For all indications, the following criteria must be met in addition to the specific diagnosis criteria below.**

- Prescription drugs covered under the pharmacy benefit must be self-administered. If office administration is being requested documentation must be provided identifying why the member or caregiver is unable to administer the medication
- Must be ordered by or with consult from an appropriate specialist: rheumatologist, immunologist, dermatologist, gastroenterologist, colorectal surgeon, or ophthalmologist
- Must be prescribed for an FDA approved indication
- Humira, adalimumab-adaz and Hyrimoz are the preferred agents. Requests for other adalimumab biosimilars will only be considered for coverage when:
    - Documented failure, contraindication or ineffective response to all preferred/formulary therapies for the specific indication.

**B. Rheumatoid arthritis (RA)**

Adalimumab may be considered for coverage for RA when the following criteria is met:

- Member has a diagnosis of moderate to severe active adult RA as defined by persistent or recurrent symptoms with documented synovitis and morning stiffness of significant duration to inhibit activities of daily living.
- Chart notes are provided documenting a failure to respond to a three-month trial of methotrexate at a maximally tolerated dose.
    - Failure is demonstrated by documentation of provider assessment without improvement in joint counts and/or physical symptoms and inflammatory markers while on therapy.
    - If the member has a contraindication or significant intolerance to methotrexate
        - Chart notes documenting a failure to respond to at least one other nonbiologic DMARDs at a maximally tolerated dose for at least 3 months **AND** documentation confirming why methotrexate cannot be used is required. If a trial of methotrexate is not appropriate due to

alcohol use, chart notes must be provided indicating that the member has been counseled on the need to abstain from alcohol use while taking methotrexate and is unwilling to abstain from alcohol use.

- Adalimumab may be used without prior methotrexate trial if the member has an acute, aggressive, very rapidly progressive intense inflammatory symmetrical arthritis disease as defined by their rheumatologist.

  **Initial approval** will be for 6 months.

  **Extension requests** will be approved for up to 12 months if the member has a continued benefit to therapy. Extension requests where adalimumab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

### C. Psoriatic arthritis (PsA)

Adalimumab may be considered for coverage for PsA when the following criteria is met:

- Member has a diagnosis of moderate to severe PsA as defined by three or more tender joints AND three or more swollen joints on two separate occasions at least one month apart **AND**
- Chart notes documenting failure of at least one NSAID at maximum tolerated dose unless the member has contraindications to NSAID therapy such as cardiovascular disease, peptic ulcer disease or renal disease **AND**
- Chart notes documenting failure to an adequate trial of at least one of the following nonbiologic disease modifying anti-rheumatic drugs (DMARDs): leflunomide, sulfasalazine, or methotrexate.
  - **Members with pure axial manifestations** do not have to have a trial of nonbiologic disease modifying anti-rheumatic drugs (DMARDs)
  - If a trial of methotrexate is not appropriate due to alcohol use and **both** leflunomide and sulfasalazine are not clinically appropriate, chart notes must be provided indicating that the member has been counseled on the need to abstain from alcohol use while taking methotrexate and is unwilling to abstain from alcohol use.

    **Initial approval** will be for 6 months.

    **Extension requests** will be approved for up to 12 months if the member has a continued benefit to therapy. Extension requests where adalimumab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

### D. Plaque Psoriasis

Adalimumab may be considered for coverage for psoriasis when the following criteria is met:

- The medication is ordered by or in consultation with a dermatologist
- A diagnosis of moderate to severe chronic plaque psoriasis and one of the following:
    - Crucial body areas (e.g. hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected OR
    - At least 10% of the body surface area (BSA) is affected OR
    - At least 3% of the body surface area (BSA) is affected AND the member meets any of the following criteria:
        - Member has had an inadequate response or intolerance to either phototherapy (e.g. UVB, PUVA) OR
        - Member has had an inadequate response or intolerance to pharmacologic treatment with methotrexate, cyclosporine, or acitretin

      **Initial approval** will be for 6 months.

      **Extension requests** will be approved for up to 12 months if the member has a continued benefit to therapy. Extension requests where adalimumab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

### E. Ankylosing Spondylitis (AS)

Adalimumab may be considered for coverage for AS when the following criteria is met:

- Member has a diagnosis of moderate to severe AS
- Chart notes documenting failure of at least one NSAID at maximum tolerated dose unless the member has contraindications to NSAID therapy such as cardiovascular disease, peptic ulcer disease or renal disease AND
- Chart notes are provided documenting significant clinical symptoms such as fatigue, spinal pain, arthralgia, inflammation of joints and tendons, morning stiffness duration and therapy AND
- Chart notes are provided documenting an insufficient response to at least one local corticosteroid injection in patients with symptomatic peripheral arthritis

**Initial approval** will be for 6 months.

**Extension requests** will be approved for up to 12 months if the member has a continued benefit to therapy. Extension requests where adalimumab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

## F. Crohn's Disease

Adalimumab may be considered for coverage for Crohn's Disease when the following criteria is met:

- Diagnosis of moderate to severe active Crohn's disease confirmed by endoscopy (or capsule endoscopy when appropriate)
- Documentation including the assessment of growth, nutrition, extraintestinal complications, therapy-induced complications and functional ability and any clinical signs and symptoms outlined in Crohn's Disease Activity Index (CDAI) such as frequent liquid stools >4/day, severity grade and frequency of abdominal pain, presence of an abdominal mass, general well-being, extra-intestinal symptoms (arthralgia, uveitis, erythema, stomatitis, abscess, fever >37.5 in the last week), taking opiates or diphenoxylate/atropine for diarrhea, anemia, and weight loss >10%

**Initial approval** will be for 6 months.

**Extension requests** will be approved for up to 12 months if the member has a continued benefit to therapy. Extension requests where adalimumab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

## G. Hidradenitis Suppurativa

Adalimumab may be considered for coverage for hidradenitis suppurativa when the following criteria is met:

- Diagnosis of moderate to severe disease (Hurley State II or III)
- An appropriate trial with two of the following was not effective or contraindicated
    - Oral antibiotic therapy (tetracycline, clindamycin)
    - Hormonal therapy with antiandrogenic agents (drospirenone containing oral contraceptives, spironolactone, finasteride, dutasteride)

- Oral retinoids

**Initial approval** will be for 6 months.

**Extension requests** will be approved for up to 12 months if the member has a continued benefit to therapy with documentation of at least 50% improvement in clinical signs/symptoms. Extension requests where adalimumab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

**H. Uveitis**

Adalimumab may be considered for coverage for Uveitis when the following criteria is met:

- Diagnosis of non-infectious intermediate, posterior and panuveitis uveitis
- Documentation that the member has received an adequate course of an oral corticosteroid and is unable to taper without worsening of disease or that there is a contraindication to use of an oral corticosteroid.
- Documentation that the member has failed therapy with or has a contraindication to the use of one of the following immunosuppressive drugs- methotrexate, azathioprine, mycophenolate mofetil, cyclosporine or tacrolimus.

**Initial approval** will be for 6 months.

**Extension requests** will be approved for up to 12 months if the member has a documentation to support no development of new inflammatory chorioretinal and/or inflammatory retinal vascular lesions, increased anterior chamber cell grade or vitreous haze grade, and decrease in best corrected visual acuity. Extension requests where adalimumab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

**I. Polyarticular juvenile idiopathic arthritis**

Adalimumab may be considered for coverage for Polyarticular juvenile idiopathic arthritis on a case- by-case basis using the American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis.

**Initial approval** will be for 6 months.

**Extension requests** will be approved for up to 12 months if the member has a continued benefit to therapy. Extension requests where adalimumab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

### J. Ulcerative Colitis

Adalimumab may be considered for coverage for ulcerative colitis when the following criteria is met:

- Diagnosis of moderate to severe ulcerative colitis
- Chart notes are provided documenting an inadequate response, intolerance or contraindication to conventional therapy for maintenance of remission (i.e. anti-inflammatory aminosalicylates [e.g., mesalamine (5-ASA), sulfasalazine], 6-mercaptopurine, and azathioprine).
    - If conventional therapy is not considered medically appropriate, documentation must be provided

**Initial approval** will be for 6 months.

**Extension requests** will be approved for up to 12 months if the member has a continued benefit to therapy. Extension requests where adalimumab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

### K. Pyoderma Gangrenosum with coexisting inflammatory bowel disease and refractory Wegener's Granulomatosis

- Requests will be reviewed on a case-by-case basis

## Exclusions

Adalimumab will not be covered for the following situations:

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling
- Combination therapy that is not supported by current clinical guidelines

## References

1. Humira™ (adalimumab) Injection. Prescribing Information. North Chicago, IL: Abbott Laboratories; February 2024.

2. ACG Clinical Guideline: Ulcerative Colitis in Adults. The American Journal of Gastroenterology: March 2019 - Volume 114 - Issue 3 - p 384-413 doi: 10.14309/ajg.0000000000000152. Accessed: ACG Clinical Guideline: Ulcerative Colitis in Adults : Official journal of the American College of Gastroenterology | ACG (lww.com)

3. AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis. Gastroenterology 2020;158:1450–1461; Published:January 13,2020 DOI:https://doi.org/10.1053/j.gastro.2020.01.006.

4. Guidelines for the Use of Anti-TNF Therapy in Patients with Ankylosing Spondylitis: Overview of ASAS (Assessments in Ankylosing Spondylitis Working Group) and SPARTAN (Spondylitis Research and Treatment network). Available: On-line: www.spondylitis.org/MedicalResearch/spartanguideline.aspx.

5. Ward Michael, Atul Deodhar et al. 2019 Update of the American College of Rheumatology/ Spondylitis Association of America/Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. Arthritis and Rheumatology. Vol 71 (No. 10). October 2019, pp 1599-1613. Available at: https://www.rheumatology.org/Portals/0/Files/AxialSpA-Guideline-2019.pdf

6. Ringold S, Weiss PF, et al. 2013 Update of the 2011 American College of Rheumatology Recommendations for the Treatment of Juvenile Idiopathic Arthritis. Arthritis Rheum. 2013;65:2499-2512

7. Rosenbaum J. Uveitis: Treatment. Last updated May 19, 2017. UpToDate. Retrieved June 21, 2017 from https://www-uptodate-com.ezproxy./contents/uveitis-treatment?source=search_result&search=uveitis%20treatment&selectedTitle=1~150#H6

8. Lichtenstein, Gary R MD, FACG[1]; Loftus, Edward V MD, FACG[2]; Isaacs, Kim L MD, PhD, FACG[3]; Regueiro, Miguel D MD, FACG[4]; Gerson, Lauren B MD, MSc, MACG (GRADE Methodologist)[5,†]; Sands, Bruce E MD, MS, FACG[6]. ACG Clinical Guideline: Management of Crohn's Disease in Adults. American Journal of Gastroenterology: April 2018 - Volume 113 - Issue 4 - p 481-517 doi: 10.1038/ajg.2018.27

9. Fraenkel, L., Bathon, J., England, B., et al. (2021). 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Vol. 73. July 2021, pg 924-939. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis (contentstack.io)

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United States and Canadian Hidradenitis Suppurativa Foundations. North American clinical management guidelines for hidradenitis suppurativa: A publication from the United States and Canadian Hidradenitis Suppurativa Foundations - PMC (nih.gov)

11. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. *Journal of Psoriasis and Psoriatic Arthritis*. 2019;4(1):31-58. doi:10.1177/2475530318812244

12. Menter, A., Strober, B., Kaplan, D., et al. (2019). Journal of the American Academy of Dermatology. Volume 80, Issue 4, P1029-1072. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics - Journal of the American Academy of Dermatology (jaad.org)

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| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Medicare Gold Giveback | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |

| | |
|---|---|
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D |
| 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 | 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).** | |
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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 |

**MVP Health Care Medical Policy**

**Agents for Female Sexual Dysfunction**

**Type of Policy: Drug Therapy**
**Prior Approval Date: 11/01/2023**
**Approval Date: 11/01/2024**
**Effective Date: 01/01/2025**
**Related Policies:** N/A

**Drugs Requiring Prior Authorization (covered under the pharmacy benefit)**
Addyi® (flibanserin) oral tablets
Vyleesi (bremelanotide) solution for injection

Refer to the MVP website for the Medicare Part D formulary for drugs that may covered under the Part D benefit.

**Overview**

Addyi® (flibanserin) is a postsynaptic 5-HT1A agonist, 5-HT2A antagonist non-hormonal treatment for hypoactive sexual desire disorder (HSDD) in premenopausal women. Vyleesi is a melanocortin receptor agonist administered subcutaneously for the treatment of HSDD in premenopausal females. Assessment of a patient presenting for possible treatment involves readily discernable factors including:

- Degree of dissatisfaction with her current level of sexual desire or interest
- Change from her previous level of sexual desire or interest
- Whether that change is causing her distress, and
- Whether there are alternative explanations for the lack of desire such as dissatisfaction with relationship or partner, concomitant medication or medical condition causing sexual dysfunction, pregnancy, recent childbirth, or other pre-existing sexual dysfunction

**Indications/Criteria**

Addyi and Vyleesi may be considered for coverage if the following criteria are met:

- Member has a confirmed diagnosis of acquired or generalized hypoactive sexual desire disorder (HSDD) by a mental health professional or gynecologist
- Low sexual desire is **not** related to:
    - co-existing medical or psychiatric condition
    - The effects of a medication or other drug substance
        - Medications may include antipsychotics, antiepileptic drugs, beta-blockers or SSRIs
    - Problems with relationship
- Secondary causes of HSDD such as chronic illness, emotional issues, gynecologic issues, hormone changes, major life events have been evaluated
- For Vyleesi:
    - provider attestation that the member has been assessed for cardiovascular risk and their blood pressure is under control
- For Addyi
    - Provider attestation that the member is not concomitantly on moderate or strong CYP3A4 inhibitors (i.e. fluconazole, itraconazole, ketoconazole, verapamil, ritonavir, ciprofloxacin, clarithromycin, diltiazem).

**Initial approval** will be for 6 months

**Extension requests** will be approved for up to 12 months if **all** the following must be met:

- Documentation identifies that medication has improved HSDD
- Prescription history must show compliance as defined by a medication possession ratio of at least 80%.
- Member's cardiovascular risk is assessed, and blood pressure is under control for Vyleesi.

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**Exclusions**

- Member is postmenopausal
- Low sexual desire due to a medical or psychiatric condition

- Exclusions associated with REMS criteria
- Use to enhance sexual performance
- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling

## References


1. Addyi (flibanserin) tablets. Prescribing Information. Raleigh, NC: Sprout Pharmaceuticals. June 2016. Revised September 2021.
2. Vyleesi (bremelanotide injection), for subcutaneous use. Prescribing Information. Waltham, MA: AMAG Pharmaceuticals, Inc. June 2019. Revised February 2021.
3. New York State Department of Health. Guidance on the Coverage of Prescription PDE5 Inhibitors, and Other Prescription Drugs Indicated for Treatment of Sexual and Erectile Dysfunction. September 2019.


| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Complete Wellness | Refer |
| 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 | 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 | Not Covered |
| MVP Medicare Secure Plus HMO POS | Not Covered |
| 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).** | |
| *© 2025 MVP Health Plan, Inc. All rights reserved. Descriptions contained within MVP's Medical Policies are not a guarantee of coverage. Each MVP Group or Subscriber Contract contains specific limitations, exclusions and requirements that may affect a Policy. If there is any discrepancy between your Group or Subscriber Contract and a Policy, your Group or Subscriber Contract shall in all cases govern.* | |

***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 |

**MVP Health Care Medical Policy**

**Amtagvi (Lifileucel)**

| | |
|---|---|
| **Type of Policy:** | Medical Therapy (administered by the pharmacy department) |
| **Prior Approval Date:** | NA |
| **Approval Date:** | 06/01/2024 |
| **Effective Date:** | 06/01/2024 |
| **Related Policies:** | CAR T-Cell Therapy |

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies.

## Drugs Requiring Prior Authorization under the medical benefit

J999 Amtagvi (Lifileucel)

## Overview

Lifileucel is a tumor-derived autologous T-cell immunotherapy indicated for the treatment of adult patients with unresectable or metastatic melanoma previously treated with a PD-1 blocking antibody, and if BRAF V600 mutation positive, a BRAF inhibitor with or without a MEK inhibitor. This indication is approved under accelerated approval based on objective response rate (ORR). Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

**Medicaid Variation:** Medications that are a pharmacy benefit are covered and billed to New York State Fee-For-Service (FFS) program. They are defined as medications that go through a retail or specialty pharmacy, including self-administered injectable products. Pharmacy medications are subject to FFS's clinical criteria including (but not limited to) coverage, quantity limit, step therapy, and prior authorization. Pharmacy benefit information can be found here: https://www.emedny.org/info/fullform.pdf

## Indications/Criteria

### Unresectable or metastatic melanoma

Amtagvi may be considered for coverage when ALL the following criteria are met:

- Prescribed by or in consultation with an oncologist
- Chart notes confirming a diagnosis of unresectable or metastatic melanoma
- Chart notes confirming the member has been previously treated with a PD-1 blocking antibody (such as Opdivo, Keytruda etc.). Documentation must include dates of use.
- For members with a positive BRAF V600 mutation, chart notes confirming the member has **also** been previously treated with a BRAF inhibitor (such as Zelboraf, Tafinlar, Braftovi, etc) with or without a MEK inhibitor (such as Mekinist, Cotellic, Mektovi, etc). Documentation must include dates of use.
- Documentation that the member will receive a lymphodepleting regimen of cyclophosphamide and fludarabine before Amtagvi infusion.
- Documentation that member has not received live vaccines 28 days prior to Amtagvi infusion
- Provider attestation that the member is eligible to receive post-lifileucel aldeskeukin (IL-2) therapy
- Documentation that the member does not have signs and symptoms of acute renal failure prior to therapy.
- Member is ≥ 18 years old
- For female members, a negative serum pregnancy test must be confirmed
- Member has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 1.
- Hospitals administering Amtagvi must be appropriately certified to do so. Please see the link for certified treatment centers: AMTAGVI Now Approved Official Site
- Criteria and use of this agent must follow the FDA package label and the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. MVP reserves the right to deviate from the NCCN guidelines if new safety information becomes available prior to updated NCCN guidelines. The NCCN guidelines may be accessed at www.nccn.org

Amtagvi will be approved as a one-time dose within 6 months. Requests for replacement due to lost or damaged product will not be covered. Coverage is contingent on eligibility at the time of infusion.

## Exclusions

The use of Amtagvi will not be covered for the following situations:

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling
- Member has been previously treated with Amtagvi
- Members with active systemic infections
- Members with any of the following as these were excluded in clinical trials:
    - Uncontrolled brain metastases
    - Organ allograft or prior cell transfer
    - Melanoma of uveal or ocular origin
    - Current systemic steroid therapy
    - Left ventricular ejection fraction (LVEF) less than 45% or New York Heart Association (NYHA) functional classification greater than Class 1
    - Forced expiratory volume in one second (FEV1) of less than or equal to 60%.
- Prescribed in combination with other CAR T-Cell therapy
- Previously treated with other CAR T-Cell therapy

## References

1. Highlights of prescribing information ... [Internet]. Iovance Biotherapeutics ; 2024 [cited 2024 Apr 11]. Available from: https://www.iovance.com/AMTAGVI_USPI/
2. National Comprehensive Cancer Network. NCCN Guidelines Version 2.2024 Melanoma: Cutaneous cutaneous_melanoma.pdf (nccn.org)

| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Medicare Gold Giveback | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |

| | |
|---|---|
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

**Medicare Part B: Amtagvi (Lifileucel)**

| | |
|---|---|
| **Type of Policy:** | Medical Therapy (administered by the pharmacy department) |
| **Prior Approval Date:** | NA |
| **Approval Date:** | 06/01/2024 |
| **Effective Date:** | 06/01/2024 |
| **Related Policies:** | CAR T-Cell Therapy |

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies.

## Drugs Requiring Prior Authorization under the medical benefit

J999 Amtagvi (Lifileucel)

## Overview

Lifileucel is a tumor-derived autologous T-cell immunotherapy indicated for the treatment of adult patients with unresectable or metastatic melanoma previously treated with a PD-1 blocking antibody, and if BRAF V600 mutation positive, a BRAF inhibitor with or without a MEK inhibitor. This indication is approved under accelerated approval based on objective response rate (ORR). Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

**Medicaid Variation:** Medications that are a pharmacy benefit are covered and billed to New York State Fee-For-Service (FFS) program. They are defined as medications that go through a retail or specialty pharmacy, including self-administered injectable products. Pharmacy medications are subject to FFS's clinical criteria including (but not limited to) coverage, quantity limit, step therapy, and prior authorization. Pharmacy benefit information can be found here: https://www.emedny.org/info/fullform.pdf

## Indications/Criteria

### Unresectable or metastatic melanoma

Amtagvi may be considered for coverage when ALL the following criteria are met:

- Prescribed by or in consultation with an oncologist
- Chart notes confirming a diagnosis of unresectable or metastatic melanoma
- Chart notes confirming the member has been previously treated with a PD-1 blocking antibody (such as Opdivo, Keytruda etc.). Documentation must include dates of use.
- For members with a positive BRAF V600 mutation, chart notes confirming the member has **also** been previously treated with a BRAF inhibitor (such as Zelboraf, Tafinlar, Braftovi, etc) with or without a MEK inhibitor (such as Mekinist, Cotellic, Mektovi, etc). Documentation must include dates of use.
- Documentation that the member will receive a lymphodepleting regimen of cyclophosphamide and fludarabine before Amtagvi infusion.
- Documentation that member has not received live vaccines 28 days prior to Amtagvi infusion
- Provider attestation that the member is eligible to receive post-lifileucel aldeskeukin (IL-2) therapy
- Documentation that the member does not have signs and symptoms of acute renal failure prior to therapy.
- Member is ≥ 18 years old
- For female members, a negative serum pregnancy test must be confirmed
- Member has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 1.
- Hospitals administering Amtagvi must be appropriately certified to do so. Please see the link for certified treatment centers: AMTAGVI Now Approved Official Site
- Criteria and use of this agent must follow the FDA package label and the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. MVP reserves the right to deviate from the NCCN guidelines if new safety information becomes available prior to updated NCCN guidelines. The NCCN guidelines may be accessed at www.nccn.org

Amtagvi will be approved as a one-time dose within 6 months. Requests for replacement due to lost or damaged product will not be covered. Coverage is contingent on eligibility at the time of infusion.

## Exclusions

The use of Amtagvi will not be covered for the following situations:

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling
- Member has been previously treated with Amtagvi
- Members with active systemic infections
- Members with any of the following as these were excluded in clinical trials:
    - Uncontrolled brain metastases
    - Organ allograft or prior cell transfer
    - Melanoma of uveal or ocular origin
    - Current systemic steroid therapy
    - Left ventricular ejection fraction (LVEF) less than 45% or New York Heart Association (NYHA) functional classification greater than Class 1
    - Forced expiratory volume in one second (FEV1) of less than or equal to 60%.
- Prescribed in combination with other CAR T-Cell therapy
- Previously treated with other CAR T-Cell therapy

## References

1. Highlights of prescribing information ... [Internet]. Iovance Biotherapeutics ; 2024 [cited 2024 Apr 11]. Available from: https://www.iovance.com/AMTAGVI_USPI/
2. National Comprehensive Cancer Network. NCCN Guidelines Version 2.2024 Melanoma: Cutaneous cutaneous_melanoma.pdf (nccn.org)

**MVP Health Care Medical Policy**

# Apremilast

**Type of Policy:** Drug Therapy
**Prior Approval Date:** 10/01/2023
**Approval Date:** 10/01/2024
**Effective Date:** 01/01/2025
**Related Policies:** Adalimumab
Etanercept
Infliximab
Risankizumab
Secukinumab
Tofacitinib
Upadacitinib
Ustekinumab
Ozanimod

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies.

## Drugs Requiring Prior Authorization under the pharmacy benefit

Otezla (apremilast)

## Overview

Apremilast is an oral phosphodiesterase-4 (PDE4) inhibitor and is considered a targeted synthetic DMARD. The drug is indicated for use in adults with oral ulcers associated with

Behcet's Disease, plaque psoriasis in patients who are candidates for phototherapy or systemic therapy, and for adults with active psoriatic arthritis (PsA).

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## Indications/Criteria

**A. For all indications, the following criteria must be met in addition to the specific diagnosis criteria below.**

- Must be ordered by or with consult from an appropriate specialist: rheumatologist/immunologist/dermatologist
- Must be prescribed for an FDA approved indication

**B. Behçet's Disease (oral ulcers)**

Apremilast may be considered for coverage for oral ulcers associated with Behcet's Disease when the following criteria is met:

- Chart notes documenting a failure, adverse effects and/or contraindication to topical corticosteroids (or documentation supporting that topical corticosteroid use is inappropriate due to disease severity and/or area affected).

**Initial approval** will be for 12 months.

**Extension requests** will be approved for up to 3 years if the member has a continued benefit to therapy. Extension requests where apremilast did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

**C. Plaque Psoriasis**

Apremilast may be considered for coverage for plaque psoriasis when one the following criteria is met:

- Member has previously received a biologic indicated for the treatment of plaque psoriasis OR
- Member has had an inadequate response or intolerance to ONE of the following: phototherapy (e.g., UVB, PUVA) OR topical therapies (e.g. medium or higher potency topical corticosteroids, calcineurin inhibitors, vitamin D analogs) OR

    - Member has a contraindication or clinical reason to avoid BOTH of the following: phototherapy (e.g., UVB, PUVA) AND topical therapies (topical corticosteroids, calcineurin inhibitors, vitamin D analogs) OR
- Member has had an inadequate response to or intolerance to pharmacological treatment with ONE of the following medications: methotrexate, cyclosporine, or acitretin OR
    - Member has a clinical reason to avoid pharmacological treatment with ALL the following medications: methotrexate, cyclosporine, and acitretin.

**Initial approval** will be for 12 months.

**Extension requests** will be approved for up to 3 years if the member has a continued benefit to therapy. Extension requests where apremilast did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

**D. Psoriatic arthritis (PsA)**

Apremilast may be considered for coverage for PsA when the following criteria is met:

- Member has a diagnosis of moderate to severe psoriatic arthritis as indicated by three or more tender joints AND three or more swollen joints on two separate occasions at least one month apart.
- Chart notes documenting a failure of at least one NSAID at maximum tolerated dose unless the member has contraindications to NSAID therapy such as cardiovascular disease, peptic ulcer disease or renal disease.
- Chart notes documenting a failure to an adequate trial of at least one of the following nonbiologic disease modifying anti-rheumatic drugs (DMARDs): leflunomide, sulfasalazine, or methotrexate.
- If a trial of methotrexate is not appropriate due to alcohol use and both leflunomide and sulfasalazine are not clinically appropriate, chart notes must be provided indicating that the patient has been counseled on the need to abstain from alcohol use while taking methotrexate and is unwilling to abstain from alcohol use.

**Initial approval** will be for 12 months.

**Extension requests** will be approved for up to 3 years if the member has a continued benefit to therapy. Extension requests where apremilast did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

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## Exclusions

The use of apremilast will not be covered for the following situations:

- Age, dose, frequency of dosing and/or duration of therapy outside of FDA approved package labeling.
- Combination therapy that is not supported by current clinical guidelines

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## References


1. Otezla (apremilast) package insert. Thousand Oaks, CA:Amgen, Inc; April 2024.
2. Rosenbaum J. Uveitis: Treatment. Last updated May 19, 2017. UpToDate. Retrieved June 21, 2017 from https://www-uptodate-com.ezproxy./contents/uveitis-treatment?source=search_result&search=uveitis%20treatment&selectedTitle=1~150#H6
3. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. *Journal of Psoriasis and Psoriatic Arthritis*. 2019;4(1):31-58. doi:10.1177/2475530318812244Menter, A., Strober, B., Kaplan, D., et al. (2019). Journal of the American Academy of Dermatology. Volume 80, Issue 4, P1029-1072. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics - Journal of the American Academy of Dermatology (jaad.org)
4. Alpsoy E, Leccese P, Emmi G, Ohno S. Treatment of Behçet's Disease: An Algorithmic Multidisciplinary Approach. Front Med (Lausanne). 2021 Apr 28;8:624795. doi: 10.3389/fmed.2021.624795. PMID: 33996847; PMCID: PMC8115406.


| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Medicare Gold Giveback | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP VT HMO | |
| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

**Antibiotic/Antiviral (oral) Prophylaxis**

**Type of Policy:** **Drug Therapy**
**Prior Approval Date:** **12/01/2023**
**Approval Date:** **12/01/2024**
**Effective Date:** **02/01/2025**
**Related Policies:** **NA**

## Codes Requiring Prior Authorization

HCPC Codes: N/A

Refer to the Medicare Part D formulary for drugs that may be covered under the Part D benefit.

## Overview

Antibiotics and antivirals are used for treatment and prophylaxis of disease. The Center for Disease Control (CDC) and state health departments offer guidance on the appropriate use of antibiotics and antivirals. Antibiotics and antivirals should not be prescribed for members to stockpile for future use.

## Indications/Criteria

The Vice President, Health and Pharmacy Management, in conjunction with the Chief Medical Officer, will determine such limits as required on antibiotic and antiviral usage to prevent inappropriate utilization and/or stockpiling. These limits will be presented to and approved by the Pharmacy & Therapeutics (P&T) Committee at the first scheduled meeting immediately following the determination.

The prescription drug rider is required for coverage.

Quantity limits will be enforced at the pharmacy on antibiotics and antivirals with the potential for inappropriate stockpiling or use for prophylaxis following national public health alerts and/or warnings. These limits shall be in effect for such time as deemed necessary by the P&T committee.

Overrides may be allowed pursuant to information supplied to MVP from a participating provider that exposure has occurred, and antibiotic or antiviral prophylaxis is medically necessary.

## Exclusions

- Members who do not meet above criteria.
- Members who do not have a prescription drug rider.

## References

1. Centers for Disease Control and Prevention (CDC). Antiviral Medications for the treatment and chemoprophylaxis of influenza: recommendations of the Advisory Committee on Immunization Practices (ACIP), 2011. MMWR 2011;60 (RR01);1-24.
2. Centers for Disease Control and Prevention (CDC). Antibiotic / Antimicrobial Resistance. Available: http://www.cdc.gov/drugresistance/index.htm.
3. New York State Department of Health. Seasonal Influenza (Flu) Available: http://www.health.state.ny.us/diseases/communicable/influenza/.

New York State Department of Health. Antibiotic Resistance: Preserve Antibiotics Protect the Future.
https://www.health.ny.gov/professionals/protocols_and_guidelines/antibiotic_resistance/

| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Complete Wellness | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| USA Care PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

**Baricitinib**

| | |
|---|---|
| **Type of Policy:** | Drug Therapy (administered by the pharmacy department) |
| **Prior Approval Date:** | NA |
| **Approval Date:** | 04/01/2024 |
| **Effective Date:** | 06/01/2024 |
| **Related Policies:** | Cosmetic Drug Agents, Ritlecitinib |

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies.

## Drugs Requiring Prior Authorization under the pharmacy benefit

Baricitinib (Olumiant)

## Overview

Baricitinib is an oral Janus kinase (JAK) inhibitor and is considered a targeted synthetic disease-modifying antirheumatic drug (tsDMARD). Janus kinases are intracellular enzymes that transmit signals arising from cytokine interactions on the cellular membrane to influence cellular processes of immune cell function. Baricitinib is FDA approved for the treatment of moderately to severely active rheumatoid arthritis in persons who have had an inadequate response to tumor necrosis factor (TNF) inhibitors. It is also FDA approved to treat severe alopecia areata, a disease when the immune system attacks hair follicles and causes hair loss.

## Indications/Criteria

**Medicaid Variation:** Medications that are a pharmacy benefit are covered and billed to New York State Fee-For-Service (FFS) program. They are defined as medications that go through a retail or specialty pharmacy, including self administered injectable products. Pharmacy medications are subject to FFS's clinical criteria including (but not limited to)

coverage, quantity limit, step therapy, and prior authorization. Pharmacy benefit information can be found here: https://www.emedny.org/info/fullform.pdf

## A. Rheumatoid Arthritis (RA)

Baricitinib may be considered for coverage for Rheumatoid Arthritis when all the following criteria below are met:

- Member has a diagnosis of moderate to severe active adult **rheumatoid arthritis** as defined by persistent or recurrent symptoms with documented synovitis and morning stiffness of significant duration to inhibit activities of daily living
- Chart notes are provided documenting a failure to respond to a three-month trial of methotrexate at a maximally tolerated dose.
    - Failure is demonstrated by documentation of provider assessment without improvement in joint counts and/or physical symptoms and inflammatory markers while on therapy.
    - If the member has a contraindication or significant intolerance to methotrexate
        - Chart notes documenting failure to respond to at least one other nonbiologic DMARD at a maximally tolerated dose for at least 3 months AND documentation confirming why methotrexate cannot be used is required. If a trial of methotrexate is not appropriate due to alcohol use, chart notes must be provided indicating that the patient has been counseled on the need to abstain from alcohol use while taking methotrexate and is unwilling to abstain from alcohol use.
- Chart notes are provided documenting a failure, contraindication, intolerance or ineffective response to all preferred/formulary therapies and must include TNF inhibitor.

**Initial approval** for 6 months
**Extension requests** will be approved for up to 12 months if the member has a continued benefit to therapy. Extension requests where baricitinib did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

## B. Alopecia areata

Baricitinib may be considered for coverage for alopecia areata when all the following criteria below are met:

- Prescribed by or in consultation with a dermatologist
- Chart notes documenting a diagnosis of severe alopecia areata
- Chart notes documenting that other causes of hair loss have been ruled out
- Chart notes documenting a failure of another systemic therapy such as corticosteroids, methotrexate, prednisone and/or cyclosporine
- Member's current episode of alopecia areata has lasted ≥ 6 months
- Member has a ≥ 50% scalp hair loss

**Initial approval** for 6 months
**Extension requests** will be approved for up to 12 months if the member has a continued benefit to therapy. Extension requests where baricitinib did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

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**Exclusions**

The use of Baricitinib will not be covered for the following situations:

- Dosing, age, and/or frequency exceeding the FDA approved package labeling.
- Combination therapy that is not supported by current guidelines
- Avoid using baricitinib in members that may be at increased risk of thrombosis and thromboembolism; use with caution in those with thromboembolic disease
- Cosmetic use
- Member has a current active, serious or opportunistic infection

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**References**

1. National Institute of Arthritis and Musculoskeletal and Skin Diseases. Alopecia Areata - Hair loss Causes & Living With It | NIAMS (nih.gov). Accessed January 2024.

2. Baricitinib. Clinical Pharmacology. Revised April 21, 2023. Accessed January 29, 2024.

3. Olumiant. Prescribing Information. Eli Lilly and Company. September 2022.

4. American Academy of Dermatology Association. Revised August 30, 2023. Accessed January 29, 2024. Hair loss types: Alopecia areata diagnosis and treatment (aad.org)

| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
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| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
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| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

**Beqvez**

| | |
|---|---|
| **Type of Policy:** | Drug Therapy (administered by the pharmacy department |
| **Prior Approval Date:** | N/A |
| **Approval Date:** | 08/01/2024 |
| **Effective Date:** | 01/01/2025 |
| **Related Policies:** | Hemophilia Factor, Hemophilia Gene Therapy |

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies.

**Drugs Requiring Prior Authorization under the medical benefit**

J3590 fidanacogene elaparvovec (Beqvez)

**Overview**

Fidanacogene elaparvovec is an adeno-associated virus vector-based gene therapy indicated for the treatment of moderate to severe hemophilia B (congenital factor IX deficiency) in those who currently use factor IX prophylaxis therapy, have current or historical life-threatening hemorrhage, have repeated, or serious spontaneous bleeding episodes and who do not have neutralizing antibodies to adeno-associated virus serotype Rh74var (AAVRh74var) capsid as detected by an FDA-approved test. Elevated hepatic enzymes have been reported with fidanacogene elaparvovec, and integration of liver-targeting AAV vector DNA into the genome may carry the theoretical risk of hepatocellular carcinoma development.

**Indications/Criteria**

**A. Moderate to severe hemophilia B**

Beqvez will be considered for coverage for moderate to severe hemophilia B when ALL the following criteria is met:

- Beqvez is prescribed by a board-certified hematologist or hemophilia specialist physician
- Member is biologically male
- Member has not received prior gene therapy for hemophilia B
- The member meets one of the following indication criteria:
    - Documentation that the member is currently using Factor IX prophylaxis therapy for at least 50 days OR
    - Chart notes documenting that the member has a current or historical life-threatening hemorrhage OR
    - The member has had repeated, serious spontaneous bleeding episodes requiring episodic factor IX treatment or prophylactic factor IX infusions AND
- Chart notes documenting that the member does not have neutralizing antibodies to adeno-associated virus serotype Rh74var (AAVRh74var) capsid as detected by an FDA -approved test.
- Documentation that the following testing is performed prior to infusion
    - Factor IX (FIX) inhibitor test within 30 days
        - Beqvez cannot be administered to members with a positive test (≥0.6 Bethesda Units [BU] or a prior history for factor IX inhibitor)
    - HIV testing
        - Documentation that the member is not HIV positive OR member is HIV positive and is virally suppressed with anti-viral therapy
            - Beqvez cannot be administered to members with either CD4+ cell count < 200mm$^3$ or viral load ≥20 copies/mL
    - Liver Function test to rule out liver abnormalities
        - alanine transaminase [ALT]
        - aspartate transaminase [AST]
        - alkaline phosphatase [ALP]
        - bilirubin
        - albumin
    - Transient Liver Elastography  for advanced liver fibrosis.
    - Laboratory tests for active hepatitis B or C.
        - Documentation that the member is negative for Hepatitis B and Hepatitis C

Beqvez will be approved as a one-time dose within 6 months. Requests for replacement due to lost or damaged product will not be covered. Coverage is contingent on eligibility at the time of infusion.

## Exclusions

The use of Beqvez will not be covered for the following situations:

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling
- Member has received prior gene therapy
- Positive tests for antibodies to AAVRh74var
- Known hypersensitivity to factor IX replacement product
- Members with current liver-related coagulopathy, hypoalbuminemia, persistent jaundice or cirrhosis
- Active hepatitis C or hepatitis B

## References


1. Beqvez. Clinical Pharmacology. Updated June 27, 2024.

2. Pfizer. (July 29, 2019- ). A Study to Evaluate the Efficacy and Safety of Factor IX Gene Therapy With PF-06838435 in Adult Males With Moderately Severe to Severe Hemophilia B (BENEGENE-2). NCT03861273. Study Details | A Study to Evaluate the Efficacy and Safety of Factor IX Gene Therapy With PF-06838435 in Adult Males With Moderately Severe to Severe Hemophilia B | ClinicalTrials.gov

3. Pfizer. (November 18, 2015 to April 8, 2019). A Gene Therapy Study for Hemophilia B. NCT02484092. Study Results | A Gene Therapy Study for Hemophilia B | ClinicalTrials.gov


| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |

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|---|---|
| MVP Medicare Gold Giveback | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

**Medicare Part B: Beqvez**

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|---|---|
| **Type of Policy:** | Medical |
| **Prior Approval Date:** | N/A |
| **Approval Date:** | 12/01/2024 |
| **Effective Date:** | 02/01/2025 |
| **Related Polices:** | Hemophilia Factor Medicare Part B, Hemophilia Gene Therapy Medicare Part B |

## Codes Requiring Prior Authorization

J3590 fidanacogene elaparvovec (Beqvez)

## Overview

Fidanacogene elaparvovec is an adeno-associated virus vector-based gene therapy indicated for the treatment of moderate to severe hemophilia B (congenital factor IX deficiency) in those who currently use factor IX prophylaxis therapy, have current or historical life-threatening hemorrhage, have repeated, or serious spontaneous bleeding episodes and who do not have neutralizing antibodies to adeno-associated virus serotype Rh74var (AAVRh74var) capsid as detected by an FDA-approved test. Elevated hepatic enzymes have been reported with fidanacogene elaparvovec, and integration of liver-targeting AAV vector DNA into the genome may carry the theoretical risk of hepatocellular carcinoma development.

**Please refer to relevant CMS LCDs/NCDs/Policy Articles for most up to date Medicare Part B guidance if available.**

## Indications/Criteria

### A. Moderate to severe hemophilia B

Beqvez will be considered for coverage for moderate to severe hemophilia B when ALL the following criteria is met:

- Beqvez is prescribed by a board-certified hematologist or hemophilia specialist physician
- Member is biologically male
- Member has not received prior gene therapy for hemophilia B
- The member meets one of the following indication criteria:
    - Documentation that the member is currently using Factor IX prophylaxis therapy for at least 50 days OR
    - Chart notes documenting that the member has a current or historical life-threatening hemorrhage OR
    - The member has had repeated, serious spontaneous bleeding episodes requiring episodic factor IX treatment or prophylactic factor IX infusions AND
- Chart notes documenting that the member does not have neutralizing antibodies to adeno-associated virus serotype Rh74var (AAVRh74var) capsid as detected by an FDA -approved test.
- Documentation that the following testing is performed prior to infusion
    - Factor IX (FIX) inhibitor test within 30 days
        - Beqvez cannot be administered to members with a positive test (≥0.6 Bethesda Units [BU] or a prior history for factor IX inhibitor)
    - HIV testing
        - Documentation that the member is not HIV positive OR member is HIV positive and is virally suppressed with anti-viral therapy
            - Beqvez cannot be administered to members with either CD4+ cell count < 200mm$^3$ or viral load ≥20 copies/mL
    - Liver Function test to rule out liver abnormalities
        - alanine transaminase [ALT]
        - aspartate transaminase [AST]
        - alkaline phosphatase [ALP]
        - bilirubin
        - albumin
    - Transient Liver Elastography for advanced liver fibrosis.
    - Laboratory tests for active hepatitis B or C.
        - Documentation that the member is negative for Hepatitis B and Hepatitis C

**Beqvez will be approved as a one-time dose within 6 months**. Requests for replacement due to lost or damaged product will not be covered. Coverage is contingent on eligibility at the time of infusion.

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**Exclusions**

The use of Beqvez will not be covered for the following situations:

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling
- Member has received prior gene therapy
- Positive tests for antibodies to AAVRh74var
- Known hypersensitivity to factor IX replacement product
- Members with current liver-related coagulopathy, hypoalbuminemia, persistent jaundice or cirrhosis
- Active hepatitis C or hepatitis B

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**References**


1. Beqvez. Clinical Pharmacology. Updated June 27, 2024.
2. Pfizer. (July 29, 2019- ). A Study to Evaluate the Efficacy and Safety of Factor IX Gene Therapy With PF-06838435 in Adult Males With Moderately Severe to Severe Hemophilia B (BENEGENE-2). NCT03861273. Study Details | A Study to Evaluate the Efficacy and Safety of Factor IX Gene Therapy With PF-06838435 in Adult Males With Moderately Severe to Severe Hemophilia B | ClinicalTrials.gov
3. Pfizer. (November 18, 2015 to April 8, 2019). A Gene Therapy Study for Hemophilia B. NCT02484092. Study Results | A Gene Therapy Study for Hemophilia B | ClinicalTrials.gov

**MVP Health Care Medical Policy**

**CAR-T Cell Therapy**

**Type of Policy:** Medical Therapy (administered by the pharmacy department)
**Prior Approval Date:** 11/01/2023
**Approval Date:** 07/01/2024
**Effective Date:** 09/01/2024

**Related Policies:**

Experimental or Investigational Procedures, Behavioral Health Services, Drugs and Treatments, Off-Label use of FDA Approved Drugs, and Clinical Trials

Amtagvi

**Codes Requiring Prior Authorization (covered under the medical benefit)**

Q2042 Kymriah (tisagenlecleucel)
Q2041 Yescarta (axicabtagene ciloleucel)
Q2053 Tecartus (brexucabtagene autoleucel)
Q2054 Breyanzi (lisocabtagene maraleucel)
Q2055 Abecma (idecabtagene vicleucel)
Q2056 Carvykti (ciltacabtagene autoleucel)

Refer to the MVP website for the Medicare Part D formulary for drugs that may be covered under the Part D benefit.

Refer to the MVP website for the Medicare Part B policies for coverage criteria of drugs covered under the medical benefit.

**Overview**

Chimeric antigen receptor (CAR) T-cell therapy is a CD19-directed immunotherapy that works by using a member's own genetically altered immune cells to kill B-cell cancer cells in the blood. Kymriah (tisagenlecleucel) is the first Immunotherapy approved by the FDA, followed by Yescarta (axicabtagene ciloleucel) Tecartus (brexucabtagene autoleucel) Breyanzi (lisocabtagene maraleucel) and Abecma (idecabtagene vicleucel).

All products are available through a restricted REMS (Risk Evaluation and Mitigation Strategy) program.

## 1. Kymriah

Kymriah may be considered for coverage when ALL of the following criteria are met [1,3, 5, 7]:

- Prescribed by or in consultation with an oncologist
- Chart notes confirming a diagnosis of one of the following
    - CD19-positive B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse (≥2 relapses) in members up to 25 years of age
- Adult members with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy
    - Includes diffuse large B-cell lymphoma (DLBC) not otherwise specified, high-grade B-cell lymphoma and DLBCL arising from follicular lymphoma
- Adult members with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy
    - This indication is approved under accelerated approval based on response rate and duration of response. Continued approval of this indication contingent upon verification and description of clinical benefit in confirmatory trials
- Relapsed disease is defined as the reappearance of leukemia cells in the bone marrow or peripheral blood after the attainment of a complete remission with chemotherapy and/or allogeneic cell transplant
- Refractory disease is defined as failure to obtain complete response with induction therapy, i.e., failure to eradicate all detectable leukemia cells (<5% blasts) from the bone marrow and blood with subsequent restoration of normal hematopoiesis (>25% marrow cellularity and normal peripheral blood counts)

- If the member has Philadelphia Chromosome positive (Ph+) ALL, documentation of a trial and failure, or an intolerance/contraindication to at least 2 tyrosine kinase inhibitors (TKI) must be provided
- Documentation that the member will receive treatment course with fludarabine and cyclophosphamide within two weeks preceding Kymriah infusion
    - Alternate lymphodepleting chemotherapy for DLBLC: bendamustine
- Documentation that the member has been screened for HBV, HCV and HIV before collection of cells for manufacturing

- Documentation that the memberhas not received any live vaccines in the two weeks prior to lymphodepleting chemotherapy and during Kymriah treatment
- ECOG score ≤ 2

- Provider attestation that Kymriah will be infused within 9 months of leukapheresis
- Criteria and use of this agent must follow the FDA package label and the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. MVP reserves the right to deviate from the NCCN guidelines if new safety information becomes available prior to updated NCCN guidelines. The NCCN guidelines may be accessed at www.nccn.org
- Hospital administering Kymriah must be appropriately certified to do so. Please see link for treatment centers below: https://www.us.kymriah.com/treatment-center-locator

Kymriah will be approved as a one-time dose within 6 months. Requests for replacement due to lost or damaged product will not be covered. Coverage is contingent on eligibility at the time of infusion.

## 2. Yescarta

Yescarta may be considered for coverage when ALL of the following criteria are met [2,4, 6, 8]:

- Prescribed by or in consultation with an oncologist
- Chart notes confirming a diagnosis of an FDA approved labeled indication:
    - CD19-positive relapsed or refractory large B-cell lymphoma. This includes diffuse large B-cell lymphoma (DLBCL) not otherwise specified, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma and DLBCL arising from follicular lymphoma. **OR**
    - Relapsed/Refractory Follicular Lymphoma
- Chart notes documenting a failure of two or more lines of systemic therapy
    - For CD19-positive relapsed or refractory large B-cell lymphoma: must have included an anthracycline and an anti-CD20 monoclonal antibody, unless tumor is CD20-negative
    - For Relapsed/Refractory Follicular Lymphoma must include the combination of an anti-CD20 monoclonal antibody and an alkylating agent.
- Relapse or refractory is defined as one of the following:

    - Relapse within 1 year after autologous hematopoietic stem cell transplantation
    - Refractory disease, progressive or stable disease as the best response to the most recent therapy
- Member is 18 years of age or older
- Documentation that member will receive cyclophosphamide and fludarabine on the fifth, fourth and third day before infusion of Yescarta
- Documentation that member has been screened for HBV, HCV and HIV before collection of cells for manufacturing
- Documentation that member has not received any live vaccines for at least 6 weeks prior to the start of lymphodepleting chemotherapy and during Yescarta treatment
- ECOG score ≤ 2
- Current documentation of renal and hepatic function tests
    - Creatinine clearance ≥60ml/min
    - Hepatic transaminases less than 2.5 times the upper limit of normal
- Current documentation that cardiac ejection fraction is ≥50%
- Current documentation that absolute lymphocyte count is ≥100 cells/mcL
- Provider attestation that Yescarta will be infused within 1 year of leukapheresis
- Criteria and use of this agent must follow the FDA package label and the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. MVP reserves the right to deviate from the NCCN guidelines if new safety information becomes available prior to updated NCCN guidelines. The NCCN guidelines may be accessed at www.nccn.org
- Hospitals administering Yescarta must be appropriately authorized to do so. Please see link for treatment centers below: YESCARTA® (axicabtagene ciloleucel) Authorized Treatment Centers | HCP (yescartahcp.com)

Yescarta will be approved as a one-time dose within 6 months. Requests for replacement due to lost or damaged product will not be covered. Coverage is contingent on eligibility at the time of infusion.

### 3. Tecartus

- Prescribed by or in consultation with an oncologist
- Chart notes confirming a diagnosis of refractory or relapsed Mantle Cell Lymphoma (MCL)
    - Documentation of failure with prior therapy including an anthracycline or bendamustine containing chemotherapy, an anti-CD20 antibody (such as

rituximab) and a Bruton tyrosine kinase inhibitor (BTKi such as ibrutinib or acalabrutinib).

- Chart notes confirming a diagnosis of relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL).
    - Relapsed or refractory after second line or higher therapy **OR**
    - Relapsed or refractory ALL at least 100 days after allogeneic stem cell transplantation (HSCT).
- Member is 18 years of age or older
- Documentation that the member has not received any live vaccines for at least 6 weeks prior to the start of lymphodepleting chemotherapy and during Tecartus treatment.
- Documentation that the member will receive cyclophosphamide and fludarabine on days 5, 4 and 3 before infusion of Tecartus
- Documentation that the member has been screened for HBV, HCV and HIV before collection of cells for manufacturing
- Criteria and use of this agent must follow the FDA package label and the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. MVP reserves the right to deviate from the NCCN guidelines if new safety information becomes available prior to updated NCCN guidelines. The NCCN guidelines may be accessed at www.nccn.org
- Hospitals administering Tecartus must be appropriately authorized to do so. Please see link for treatment centers below:
    - TECARTUS® Authorized Treatment Centers (tecartushcp.com)

Tecartus will be approved as a one-time dose within 6 months. Requests for replacement due to lost or damaged product will not be covered. Coverage is contingent on eligibility at the time of infusion.

**4. Breyanzi**

- Prescribed by or in consultation with an oncologist
- Chart notes confirming a diagnosis of one of the following:
    - Large B-cell lymphoma (LBCL)
        - This includes diffuse large B-cell lymphoma (DLBCL) not otherwise specified (including DLBCL arising from indolent lymphoma), high-grade B-Cell lymphoma, primary mediastinal large B-cell lymphoma and follicular lymphoma grade 3B who have:
            - refractory disease to first line chemoimmunotherapy or relapse within 12 months of first line chemoimmunotherapy OR

        - refractory disease to first line chemoimmunotherapy or relapse after first line chemoimmunotherapy and are not eligible for hematopoietic stem cell transplantation (HSCT) due to comorbities or age. OR
        - relapsed or refractory disease after two or more lines of systemic therapy
    - Relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) who have received at least 2 prior lines of therapy, including a Bruton tyrosine kinase (BTK) inhibitor and a B-cell lymphoma 2 (BCL-2) inhibitor.
    - This indication is approved under accelerated approval based on response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).Relapsed or refractory follicular lymphoma (FL) who have received 2 or more prior lines of systemic therapy
        - This indication is approved under accelerated approval based on response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).
    - Relapsed or refractory Mantle Cell Lymphoma (MCL) who have received at least 2 prior lines of systemic therapy, including a Bruton tyrosine kinase (BTK) inhibitor.
- Member is 18 years of age or older
- Documentation that the member has been screened for HBV, HCV and HIV before collection of cells for manufacturing
- ECOG score ≤ 2
- Documentation that the member has not received any live vaccines for at least 6 weeks prior to the start of lymphodepleting chemotherapy and during Breyanzi treatment
- Current documentation of the following labs:
    - Left Ventricular Ejection Fraction ≥40%
    - ALT ≤5 times the upper limit of normal,
    - Total bilirubin <2 mg/dL
    - Creatinine clearance >30mL/min
- Documentation that the member will receive cyclophosphamide and fludarabine concurrently for 3 days before infusion of Breyanzi
- Criteria and use of this agent must follow the FDA package label and the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. MVP reserves the right to deviate from the NCCN guidelines if new safety information becomes available prior to updated NCCN guidelines. The NCCN guidelines may be accessed at www.nccn.org

- Hospitals administering Breyanzi must be appropriately authorized to do so. Please see link for treatment centers below: https://www.breyanzihcp.com/treatment-centers/

Breyanzi will be approved as a one-time dose within 6 months. Requests for replacement due to lost or damaged product will not be covered. Coverage is contingent on eligibility at the time of infusion.

**5. Abecma**

- Prescribed by or in consultation with an oncologist
- Chart notes confirming a diagnosis of relapse or refractory multiple myeloma
- Chart notes documenting a failure of twoor more prior lines of therapy including an immunomodulatory agent, a proteasome inhibitor and an anti-CD38 monoclonal antibody
- Member is 18 years of age or older
- Documentation that the member has been screened for HBV, HCV and HIV before collection of cells for manufacturing
- ECOG score ≤ 2
- Current documentation of the following labs:
    - Creatinine clearance ≥ 45 mL/min
    - Alanine aminotransferase less than 2.5 times the upper limit of normal
    - Left ventricular ejection fraction greater than 45%
    - Platelet count greater than 50,000/$mm^3$
    - Absolute neutrophil count greater than 1000 cells/$mm^3$

- Documentation that the member has not received any live vaccines for at least 6 weeks prior to the start of lymphodepleting chemotherapy and during Abecma treatment
- Documentation that the member will receive cyclophosphamide and fludarabine concurrently for 3 days before infusion of Abecma
- Criteria and use of this agent must follow the FDA package label and the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. MVP reserves the right to deviate from the NCCN guidelines if new safety information becomes available prior to updated NCCN guidelines. The NCCN guidelines may be accessed at www.nccn.org
- Hospitals administering Abecma must be appropriately authorized to do so. Please see link for treatment centers: Treatment Center Location (abecma.com)

Abecma will be approved as a one-time dose within 6 months. Requests for replacement due to lost or damaged product will not be covered. Coverage is contingent on eligibility at the time of infusion.

**6. Carvykti**

- Prescribed by or in consultation with an oncologist
- Chart notes confirming a diagnosis of relapse or refractory relapsed or refractory multiple myeloma
- Chart notes documenting a failure of one prior lines of therapy including a proteasome inhibitor and an immunomodulatory agent and are refractory to lenalidomide.
- Member is 18 years of age or older
- Member has been screened for HBV, HCV and HIV before collection of cells for manufacturing
- ECOG score ≤ 2
- Current documentation of the following labs:
    - Creatinine clearance ≥40mL/min
    - Absolute neutrophil count ≥750 cells/ $mm^3$
    - Platelet count ≥ 50,000/ $mm^3$
    - Hepatic transaminases less than 3 times the upper limit of normal
    - Left Ventricular Ejection Fraction ≥45%
- Member has not received any live vaccines for at least 6 weeks prior to the start of lymphodepleting chemotherapy and during Carvykti treatment
- Member will receive cyclophosphamide and fludarabine concurrently for 3 days before infusion of Carvykti
- Criteria and use of this agent must follow the FDA package label and the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. MVP reserves the right to deviate from the NCCN guidelines if new safety information becomes available prior to updated NCCN guidelines. The NCCN guidelines may be accessed at www.nccn.org
- Hospitals administering Carvykti must be appropriately authorized to do so. Please see link for treatment centers below:
- Find A CARVYKTI® (ciltacabtagene autoleucel) Treatment Center

Carvykti will be approved as a one-time dose within 6 months. Requests for replacement due to lost or damaged product will not be covered. Coverage is contingent on eligibility at the time of infusion.

**Exclusions**

- Age, dose, frequency of dosing and/or duration of therapy outside of the FDA approved package labeling
- Member has been previously treated with CAR T-Cell Therapy
- Prescribed in combination with other CAR T-Cell therapy
- Member is pregnant
- Primary central nervous system lymphoma
- Active infection
- Inflammatory disorders

In addition to the exclusions above, the following drug-specific exclusions also apply:

- Kyrmiah
    - Burkitt lymphoma/leukemia
    - Grade 2 to 4 graft versus host disease
    - Concomitant genetic syndrome, such as Fanconi anemia, Kostmann syndrome, Schwachman syndrome, or any other BM failure syndrome (members with Down syndrome are NOT excluded)
    - Received allogeneic cellular therapy, such as donor lymphocyte infusion, within 6 weeks prior to Kymriah infusion
    - Radiation therapy
        - Within two weeks at non-CNS site
        - Within eight weeks at CNS-directed radiation
    - Received allogeneic cellular therapy, i.e., donor lymphocyte infusion, within 6 weeks prior to Kymriah infusion
- Yescarta
    - Member with history of CNS disorder (such as seizure or cerebrovascular ischemia) or autoimmune disease requiring systemic immunosuppression
    - Prior allogeneic hematopoietic stem cell transplantation (HSCT)
    - Bridging chemotherapy between leukapheresis and lymphodepleting chemotherapy
- Tecartus
    - Prior allogeneic hematopoietic stem cell transplantation (HSCT) with the exception of a confirmed diagnosis of ALL

Members with a history of CNS lymphoma or CNS disorders

## **References**

1. Kymriah (tisagenlecleucel) suspension for intravenous infusion. Prescribing Information. East Hanover, NJ. Novartis Pharmaceuticals Corporation. August 2017. Revised April 2024.

2. Yescarta (axicabtagene ciloleucel) suspension for intravenous infusion. Prescribing Information. Santa Monica, CA. Kite Pharma, Inc. October 2017.
3. National Comprehensive Cancer Network. Acute Lymphoblastic Leukemia. Version 1.2018. https://www.nccn.org/professionals/physician_gls/pdf/all.pdf. Accessed April 2, 2018. Revised November 2022.
4. National Comprehensive Cancer Network. B-Cell Lymphomas. Version 2.2018. https://www.nccn.org/professionals/physician_gls/pdf/b-cell_blocks.pdf. Accessed April 2, 2018.
5. Maude, S., Laetsch, T., Buechner, S., et al. Tisagenlecleucel in Children and Young Adults with B-Cell Lymphoblastic Leukemia. N Engl J Med. 2018; 378: 439-48.
6. Neelapu, S., Locke, F., Bartlett, L., et al. Axicabtagene Ciloleucel CAR T-cell Therapy in Refractory Large B-Cell Lymphoma. N Eng J Med 2017; 377:2531-44.
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| 18. 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Medicare Gold Giveback | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D |
| 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).** | |
| *© 2024 MVP Health Plan, Inc. All rights reserved. Descriptions contained within MVP's Medical Policies are not a guarantee of coverage. Each MVP Group or Subscriber Contract contains specific limitations, exclusions and requirements that may affect a Policy. If there is any discrepancy between your Group or Subscriber Contract and a Policy, your Group or Subscriber Contract shall in all cases govern.* | |

***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 |

**MVP Health Care Medical Policy**

**Casgevy (Exagamglogene Autotemcel)**

| | |
|---|---|
| **Type of Policy:** | Medical Therapy (administered by the pharmacy department) |
| **Prior Approval Date:** | NA |
| **Approval Date:** | 06/01/2024 |
| **Effective Date:** | 06/01/2024 |
| **Related Policies:** | Lyfgenia, Adakveo |

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies.

## Drugs Requiring Prior Authorization under the medical benefit

J3590 Casgevy (Exagamglogene Autotemcel)

## Overview

Casgevy (Exagamglogene Autotemcel)as is an autologous genome edited hematopoietic stem cell-based gene therapy for patients with sickle cell disease suffering from vaso-occlusive crisis and transfusion dependent beta-thalassemia. A vaso occlusive crisis is a potentially life-threatening complication caused when sickled red blood cells hinder blood flow causing pain, and lack of oxygen delivery to tissue. Transfusion-dependent beta thalassemia is a blood disorder in which an individual has two missing or defective beta-globin genes which leads to low hemoglobin levels and ultimately a lack of oxygen supply to tissues. Individuals with this condition require lifelong blood transfusions and over time, an influx of iron-containing hemoglobin from chronic blood transfusions can lead to liver, heart, and hormone problems. Casgevy is manufactured specifically for an individual using their own blood stem cells. The treatment course consists of multiple phases including cell mobilization and apheresis to collect CD34+ cells to be edited by CRISPR/Cas9 technology, myeloablative conditioning, and the modified cells are returned to the patient via IV infusions. The

modified cells engraft in the bone marrow resulting in reduced BCL11A expression, increased fetal hemoglobin, and reduced adult hemoglobin. The modified cells prevents red blood cells from sickling and causing vaso-occlusive crises and allows for patients with transfusion dependent beta-thalassemia to potentially become transfusion independent.

**Medicaid Variation:** Medications that are a pharmacy benefit are covered and billed to New York State Fee-For-Service (FFS) program. They are defined as medications that go through a retail or specialty pharmacy, including self-administered injectable products. Pharmacy medications are subject to FFS's clinical criteria including (but not limited to) coverage, quantity limit, step therapy, and prior authorization. Pharmacy benefit information can be found here: https://www.emedny.org/info/fullform.pdf

**Indications/Criteria**

**A. For all indications, the following criteria must be met in addition to the specific diagnosis criteria below**

- Prescribed by a board-certified hematologist
- Hospitals administering Casgevy must be appropriately authorized to do so. Please see link for treatment centers: CASGEVY™ (exagamglogene autotemcel) Authorized Treatment Centers | Official HCP Website (casgevyhcp.com)
- Member has not received previous gene therapy for SCD or TDT (such as Lyfgenia)
- Documentation that that the member has not received a prior allogeneic or autologous HSC transplant AND is not being considered for other gene or investigational therapies for SCD or TDT.

**B. Sickle Cell Disease (SCD) with recurrent vaso-occlusive crises**

Casgevy will be considered for coverage for SCD with recurrent vaso-occlusive crises when ALL of the following criteria is met:

- Member has failed to match with a human leukocyte antigen (HLA) match related hematopoietic stem cell donor
- Member is ≥ 12 years old
- Chart notes documenting a diagnosis of sickle cell disease (SCD)
- Chart notes documenting ≥ 4 severe vaso-occlusive crises in the 2 years prior to screening while adhering to previous SCD therapy, defined as:

    - Acute pain requiring a visit to a medical facility and administration of pain medications (opioid or IV non-steroidal anti-inflammatory drugs [NSAIDs]) or RBC transfusion
    - Acute chest syndrome
    - Priapism lasting >2 hours and requiring visit to a medical facility
    - Splenic sequestration
- Chart notes documenting that the member does not have liver or renal impairment which is documented with current renal and liver function tests
    - Renal impairment (defined as creatinine clearance ≤60mL/min/1.73m$^2$)
    - Examples of advanced liver impairment
        - Alanine transaminase > 3 times upper limit of normal
        - Direct bilirubin value > 2.5 times upper limit of normal
        - Baseline prothrombin time (international normalized ratio [INR]) > 1.5 times upper limit of normal
        - Cirrhosis
        - Bridging fibrosis
        - Active hepatitis
- Chart notes documenting that the member has tried and failed other sickle cell disease treatment (such as hydroxyurea, Adakveo, Oxbryta, Endari) ) up to the maximally indicated dose for ≥6 months. Documentation must include dates of use.
- Provider confirmation that full myeloablative conditioning would occur prior to Casgevy administration
- For female members, a negative serum pregnancy test must be confirmed
- Documented provider attestation confirming that the member is an appropriate candidate for hematopoietic stem cell (HSC) transplantation
- Chart notes documenting that the member has a current negative screening for the following: HIV-1, HIV-2, HBV, or HCV. Documentation must indicate that the member does not have active HIV-1, HIV-2, HBV, or HCV.
- Members aged 12 – 16 years old must have documented normal transcranial doppler (TCD)
- Current documentation that the member does not have any active bacterial, viral, fungal, or parasitic infection(s)
- Treatment centers administering Casgevy must be appropriately certified to do so. Please see link for treatment centers: CASGEVY™

(exagamglogene autotemcel) Authorized Treatment Centers | Official HCP Website (casgevyhcp.com)

Casgevy will be approved as a one-time dose within 6 months. Requests for replacement due to lost or damaged product will not be covered. Coverage is contingent on eligibility at the time of infusion.

**C. Transfusion Dependent β-Thalassemia (TDT)**

Casgevy will be considered for coverage for TDT when ALL of the following criteria is met:

- Chart notes documenting a confirmed diagnosis of Transfusion Dependent β- Thalassemia (TDT)
- Documentation that the member does not have a 10/10 human leukocyte antigen-matched donor
- Member is ≥ 12 years old
- Member is eligible for autologous hematopoietic stem cell transplantation (HSCT)
- Chart notes documenting that the member has a history of requiring ≥100 mL/kg/year or ≥10 units/year of red blood cell transfusions in the previous 2 years
- Provider confirmation that full myeloablative conditioning would occur prior to Casgevy administration
- Member does not have liver or renal impairment which is documented with current renal and liver function tests:
    - Left ventricular ejection fraction >45%
    - Liver Function tests
        - AST or ALT >3 times the upper limit of normal (ULN)
        - Direct bilirubin value >2.5 x ULN
        - Bridging Fibrosis or Cirrhosis
- For female members, a negative serum pregnancy test must be confirmed
- Documented provider attestation confirming that the member is an appropriate candidate for hematopoietic stem cell (HSC) transplantation
- Chart notes documenting that the member has a current negative screening for the following: HIV-1, HIV-2, HBV, or HCV. Documentation must indicate that the member does not have active HIV-1, HIV-2, HBV, or HCV.

- Current documentation that the member does not have any active bacterial, viral, fungal, or parasitic infection(s)
- Treatment centers administering Casgevy must be appropriately certified to do so. Please see link for treatment centers: CASGEVY™ (exagamglogene autotemcel) Authorized Treatment Centers | Official HCP Website (casgevyhcp.com)

Casgevy will be approved as a one-time dose within 6 months. Requests for replacement due to lost or damaged product will not be covered. Coverage is contingent on eligibility at the time of infusion.

---

**Exclusions**

The use of Casgevy will not be covered for members with **Sickle Cell Disease** in the following situations:

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling
- Use in combination with other autologous genome edited hematopoietic stem cell-based gene therapies such as Lyfgenia
- Members with renal deficiency
- Members with hepatic deficiency
- Member is pregnant or planning on becoming pregnant
- Member not an appropriate candidate for hematopoietic stem cell transplantation
- Member has received prior allogeneic or autologous HSC transplant
- Member has tested positive for or has active HIV-1, HIV-2, HBV,or HCV
- Members with active bacterial, viral, fungal, or parasitic infections
- Members with history of untreated Moyamoya disease or presence of Moyomoya disease that puts the patient at risk for bleeding
- Members aged 12 – 18 years old with abnormal TCD

The use of Casgevy will not be covered for members with **Transfusion Dependent β-Thalassemia** in the following situations:

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling
- Use in combination with other autologous genome edited hematopoietic stem cell-based gene therapies such as Lyfgenia

- Members with renal deficiency
- Members with hepatic deficiency
- Member is pregnant or planning to become pregnant
- Member not an appropriate candidate for hematopoietic stem cell transplantation
- Member has received prior allogeneic or autologous HSC transplant
- Member has tested positive for or has active HIV-1, HIV-2, HBV,or HCV
- Members with active bacterial, viral, fungal, or parasitic infections
- Sickle cell β-thalassemia variant or associated α-thalassemia and >1 alpha deletion or alpha multiplications
- Severely elevated iron in the heart (ie, patients with cardiac T2* less than 10 msec by MRI or LVEF <45% by echocardiogram) or advanced liver disease*

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## References


1. Angelicapeebles. (2023, December 8). *U.S. approves first gene-editing treatment, Casgevy, for sickle cell disease*. CNBC. https://www.cnbc.com/2023/12/08/casgevy-first-crispr-gene-editing-treatment-approved-in-us.html
2. Commissioner, O. of the. (n.d.). *FDA approves first gene therapies to treat patients with sickle cell disease*. U.S. Food and Drug Administration. https://www.fda.gov/news-events/press-announcements/fda-approves-first-gene-therapies-treat-patients-sickle-cell-disease
3. *Study design for CASGEVYTM (exagamglogene autotemcel): Official HCP website*. CASGEVY. (n.d.). https://www.casgevyhcp.com/sickle-cell-disease/trial-design
4. Vertex Pharmaceuticals. (2024, January). Casgevy (Exagamglogene Autotemcel) Package Insert. https://pi.vrtx.com/files/uspi_exagamglogene_autotemcel.pdf


| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |

| | |
|---|---|
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Medicare Gold Giveback | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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).** | |
| *© 2024 MVP Health Plan, Inc. All rights reserved. Descriptions contained within MVP's Medical Policies are not a guarantee of coverage. Each MVP Group or Subscriber Contract contains specific limitations, exclusions and requirements that may affect a Policy. If there is any discrepancy between your Group or Subscriber Contract and a Policy, your Group or Subscriber Contract shall in all cases govern.* | |

***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 |

**MVP Health Care Medical Policy**

**Medicare Part B: Casgevy (Exagamglogene Autotemcel)**

| | |
|---|---|
| **Type of Policy:** | Medical Therapy (administered by the pharmacy department) |
| **Prior Approval Date:** | NA |
| **Approval Date:** | 06/01/2024 |
| **Effective Date:** | 06/01/2024 |
| **Related Policies:** | Lyfgenia, Adakveo |

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies.

## Drugs Requiring Prior Authorization under the medical benefit

J3590 Casgevy (Exagamglogene Autotemcel)

## Overview

Casgevy (Exagamglogene Autotemcel)as is an autologous genome edited hematopoietic stem cell-based gene therapy for patients with sickle cell disease suffering from vaso-occlusive crisis and transfusion dependent beta-thalassemia. A vaso occlusive crisis is a potentially life-threatening complication caused when sickled red blood cells hinder blood flow causing pain, and lack of oxygen delivery to tissue. Transfusion-dependent beta thalassemia is a blood disorder in which an individual has two missing or defective beta-globin genes which leads to low hemoglobin levels and ultimately a lack of oxygen supply to tissues. Individuals with this condition require lifelong blood transfusions and over time, an influx of iron-containing hemoglobin from chronic blood transfusions can lead to liver, heart, and hormone problems. Casgevy is manufactured specifically for an individual using their own blood stem cells. The treatment course consists of multiple phases including cell mobilization and apheresis to collect CD34+ cells to be edited by CRISPR/Cas9 technology, myeloablative conditioning, and the modified cells are returned to the patient via IV infusions. The

modified cells engraft in the bone marrow resulting in reduced BCL11A expression, increased fetal hemoglobin, and reduced adult hemoglobin. The modified cells prevents red blood cells from sickling and causing vaso-occlusive crises and allows for patients with transfusion dependent beta-thalassemia to potentially become transfusion independent.

**Medicaid Variation:** Medications that are a pharmacy benefit are covered and billed to New York State Fee-For-Service (FFS) program. They are defined as medications that go through a retail or specialty pharmacy, including self-administered injectable products. Pharmacy medications are subject to FFS's clinical criteria including (but not limited to) coverage, quantity limit, step therapy, and prior authorization. Pharmacy benefit information can be found here: https://www.emedny.org/info/fullform.pdf

**Indications/Criteria**

**A. For all indications, the following criteria must be met in addition to the specific diagnosis criteria below**

- Prescribed by a board-certified hematologist
- Hospitals administering Casgevy must be appropriately authorized to do so. Please see link for treatment centers: CASGEVY™ (exagamglogene autotemcel) Authorized Treatment Centers | Official HCP Website (casgevyhcp.com)
- Member has not received previous gene therapy for SCD or TDT (such as Lyfgenia)
- Documentation that that the member has not received a prior allogeneic or autologous HSC transplant AND is not being considered for other gene or investigational therapies for SCD or TDT.

**B. Sickle Cell Disease (SCD) with recurrent vaso-occlusive crises**

Casgevy will be considered for coverage for SCD with recurrent vaso-occlusive crises when ALL of the following criteria is met:

- Member has failed to match with a human leukocyte antigen (HLA) match related hematopoietic stem cell donor
- Member is ≥ 12 years old
- Chart notes documenting a diagnosis of sickle cell disease (SCD)
- Chart notes documenting ≥ 4 severe vaso-occlusive crises in the 2 years prior to screening while adhering to previous SCD therapy, defined as:

    - Acute pain requiring a visit to a medical facility and administration of pain medications (opioid or IV non-steroidal anti-inflammatory drugs [NSAIDs]) or RBC transfusion
    - Acute chest syndrome
    - Priapism lasting >2 hours and requiring visit to a medical facility
    - Splenic sequestration
- Chart notes documenting that the member does not have liver or renal impairment which is documented with current renal and liver function tests
    - Renal impairment (defined as creatinine clearance ≤60mL/min/1.73m$^2$)
    - Examples of advanced liver impairment
        - Alanine transaminase > 3 times upper limit of normal
        - Direct bilirubin value > 2.5 times upper limit of normal
        - Baseline prothrombin time (international normalized ratio [INR]) > 1.5 times upper limit of normal
        - Cirrhosis
        - Bridging fibrosis
        - Active hepatitis
- Chart notes documenting that the member has tried and failed other sickle cell disease treatment (such as hydroxyurea, Adakveo, Oxbryta, Endari) ) up to the maximally indicated dose for ≥6 months. Documentation must include dates of use.
- Provider confirmation that full myeloablative conditioning would occur prior to Casgevy administration
- For female members, a negative serum pregnancy test must be confirmed
- Documented provider attestation confirming that the member is an appropriate candidate for hematopoietic stem cell (HSC) transplantation
- Chart notes documenting that the member has a current negative screening for the following: HIV-1, HIV-2, HBV, or HCV. Documentation must indicate that the member does not have active HIV-1, HIV-2, HBV, or HCV.
- Members aged 12 – 16 years old must have documented normal transcranial doppler (TCD)
- Current documentation that the member does not have any active bacterial, viral, fungal, or parasitic infection(s)
- Treatment centers administering Casgevy must be appropriately certified to do so. Please see link for treatment centers: CASGEVY™

(exagamglogene autotemcel) Authorized Treatment Centers | Official HCP Website (casgevyhcp.com)

Casgevy will be approved as a one-time dose within 6 months. Requests for replacement due to lost or damaged product will not be covered. Coverage is contingent on eligibility at the time of infusion.

**C. Transfusion Dependent β-Thalassemia (TDT)**

Casgevy will be considered for coverage for TDT when ALL of the following criteria is met:

- Chart notes documenting a confirmed diagnosis of Transfusion Dependent β- Thalassemia (TDT)
- Documentation that the member does not have a 10/10 human leukocyte antigen-matched donor
- Member is ≥ 12 years old
- Member is eligible for autologous hematopoietic stem cell transplantation (HSCT)
- Chart notes documenting that the member has a history of requiring ≥100 mL/kg/year or ≥10 units/year of red blood cell transfusions in the previous 2 years
- Provider confirmation that full myeloablative conditioning would occur prior to Casgevy administration
- Member does not have liver or renal impairment which is documented with current renal and liver function tests:
    - Left ventricular ejection fraction >45%
    - Liver Function tests
        - AST or ALT >3 times the upper limit of normal (ULN)
        - Direct bilirubin value >2.5 x ULN
        - Bridging Fibrosis or Cirrhosis
- For female members, a negative serum pregnancy test must be confirmed
- Documented provider attestation confirming that the member is an appropriate candidate for hematopoietic stem cell (HSC) transplantation
- Chart notes documenting that the member has a current negative screening for the following: HIV-1, HIV-2, HBV, or HCV. Documentation must indicate that the member does not have active HIV-1, HIV-2, HBV, or HCV.

- Current documentation that the member does not have any active bacterial, viral, fungal, or parasitic infection(s)
- Treatment centers administering Casgevy must be appropriately certified to do so. Please see link for treatment centers: CASGEVY™ (exagamglogene autotemcel) Authorized Treatment Centers | Official HCP Website (casgevyhcp.com)

Casgevy will be approved as a one-time dose within 6 months. Requests for replacement due to lost or damaged product will not be covered. Coverage is contingent on eligibility at the time of infusion.

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**Exclusions**

The use of Casgevy will not be covered for members with **Sickle Cell Disease** in the following situations:

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling
- Use in combination with other autologous genome edited hematopoietic stem cell-based gene therapies such as Lyfgenia
- Members with renal deficiency
- Members with hepatic deficiency
- Member is pregnant or planning on becoming pregnant
- Member not an appropriate candidate for hematopoietic stem cell transplantation
- Member has received prior allogeneic or autologous HSC transplant
- Member has tested positive for or has active HIV-1, HIV-2, HBV,or HCV
- Members with active bacterial, viral, fungal, or parasitic infections
- Members with history of untreated Moyamoya disease or presence of Moyomoya disease that puts the patient at risk for bleeding
- Members aged 12 – 18 years old with abnormal TCD

The use of Casgevy will not be covered for members with **Transfusion Dependent β-Thalassemia** in the following situations:

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling
- Use in combination with other autologous genome edited hematopoietic stem cell-based gene therapies such as Lyfgenia

- Members with renal deficiency
- Members with hepatic deficiency
- Member is pregnant or planning to become pregnant
- Member not an appropriate candidate for hematopoietic stem cell transplantation
- Member has received prior allogeneic or autologous HSC transplant
- Member has tested positive for or has active HIV-1, HIV-2, HBV,or HCV
- Members with active bacterial, viral, fungal, or parasitic infections
- Sickle cell β-thalassemia variant or associated α-thalassemia and >1 alpha deletion or alpha multiplications
- Severely elevated iron in the heart (ie, patients with cardiac T2* less than 10 msec by MRI or LVEF <45% by echocardiogram) or advanced liver disease*

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**References**


1. Angelicapeebles. (2023, December 8). *U.S. approves first gene-editing treatment, Casgevy, for sickle cell disease*. CNBC. https://www.cnbc.com/2023/12/08/casgevy-first-crispr-gene-editing-treatment-approved-in-us.html
2. Commissioner, O. of the. (n.d.). *FDA approves first gene therapies to treat patients with sickle cell disease*. U.S. Food and Drug Administration. https://www.fda.gov/news-events/press-announcements/fda-approves-first-gene-therapies-treat-patients-sickle-cell-disease
3. *Study design for CASGEVYTM (exagamglogene autotemcel): Official HCP website*. CASGEVY. (n.d.). https://www.casgevyhcp.com/sickle-cell-disease/trial-design
4. Vertex Pharmaceuticals. (2024, January). Casgevy (Exagamglogene Autotemcel) Package Insert. https://pi.vrtx.com/files/uspi_exagamglogene_autotemcel.pdf

**MVP Health Care Medical Policy**

**C. Difficile Drug Therapy**

| | |
|---|---|
| **Type of Policy:** | Drug Therapy |
| **Prior Approval Date:** | 07/01/2023 |
| **Approval Date:** | 10/01/2024 |
| **Effective Date:** | 01/01/2025 |
| **Related Policies:** | Zinplava (bezlotoxumab) |

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies.

**Drugs Requiring Prior Authorization under the pharmacy benefit**

Vowst (Fecal Microbiota, Live)

**Drugs Requiring Prior Authorization under the medical benefit**

Rebyota (Fecal Microbiota, Live, suspension)

**Overview**

Fecal microbiota, live is a bacterial spore suspension in capsules for oral administration and a rectal microbiota suspension indicated for the prevention of recurrence of *C. difficile* infection (CDI) after antibiotic treatment for recurrent CDI (rCDI). Recurrence of CDI is defined as a relapse of CDI symptoms within 2 - 8 weeks of successful treatment of the initial episode. It is not indicated for the treatment of CDI. Fecal microbiota, live is manufactured from human fecal matter sourced from qualified donors. Rectal fecal microbiota, live is administered 24 to 72 hours after the conclusion of antibiotic treatment for CDI with oral antibiotics being avoided for up to 8 weeks after use. Oral fecal microbiota, live is administered 48 to 96 hours after the conclusion of antibiotic treatment for CDI with antibiotics to be avoided during use.

## Indications/Criteria

**Vowst** may be considered for coverage when:

- Member has a diagnosis of **recurrent** C. difficile infection (rCDI) confirmed with the following:
    - Positive C.difficile stool sample **AND**
    - Recurrent C. difficile infection (rCDI) defined as ≥ 3 episodes of CDI within 12 months
- Chart notes or claims history shows standard of care antibacterial therapy (i.e. vancomycin, fidaxomicin) for the primary episode
- Prescriber confirmation that Vowst is being used for secondary C. difficile infection **prophylaxis** after antibiotic treatment for recurrent C. difficile infection (rCDI)
- Prescriber confirmation that antibacterial treatment for rCDI is completed 2-4 days prior to initiation of Vowst and member has access to magnesium citrate or polyethylene glycol electrolyte solution
- Quantity limit per episode:
    - Vowst: four (4) capsules once daily for 3 days

**Initial approval** of 12 capsules per episode within 2 months

**Subsequent approval for a new episode of rCDI** will be reviewed on a case by cases basis and must include documentation of previous response and clinical benefit

**Rebyota** may be considered for coverage when:

- Member has a diagnosis of **recurrent** C. difficile infection (rCDI) defined as **either**:
    - Had at least 2 episodes of severe CDI resulting in hospitalization within the last year OR
    - At least one recurrence after a primary episode and had completed at least 1 round of standard-of-care (SOC) oral antibiotic therapy (e.g., vancomycin, fidaxomicin)
- Documentation of a positive C.difficile stool sample
- Chart notes or claims history shows standard of care antibacterial therapy (i.e. vancomycin, fidaxomicin) for the primary episode and presenting rCDI
- Prescriber confirmation that Rebyota is being used for secondary C. difficile infection **prophylaxis** after antibiotic treatment for recurrent C. difficile infection (rCDI)
- Prescriber confirmation that antibacterial treatment for rCDI is completed 24 to 72 hours prior to starting Rebyota
- Quantity limit per episode:

- Rebyota: 150ml as a single dose

**Initial approval** of 150ml per episode within 2 months
**Subsequent approval for a new episode of rCDI** will be reviewed on a case by cases basis and must include documentation of previous response and clinical benefit.
**Maximum of a one-time repeat dose**

**Medicare Part B Variation**: members may step through Part D drugs prior to obtaining approval for Rebyota. Please refer to the MVP website for the Medicare Part D formulary for a full list of covered drugs.

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## Exclusions

The use of Vowst and Rebyota will not be covered for the following situations:

- Treatment of CDI
- Indication, age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling

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## References


1. Rebyota (fecal microbiota, live). Clinical Pharmacology. Revised April 27, 2023. Accessed May 30, 2023. 9009000002_REBYOTA-PI_11-2022.pdf (ferringusa.com)
2. Vowst. Prescribing Information. Seres Therapeutics, Inc. Cambridge, MA. Revised April 2023. Microsoft Word - Final-VOWST-PI labeling-text-26April23 (serestherapeutics.com)
3. Centers for Disease Control and Prevention. C.dff (clostridioides difficile). FAQs for Clinicians about D.Diff. FAQs for Clinicians about C. diff | CDC. October 25, 2022. Accessed on June 5, 2023
4. Clinical Practice Guidelines for Clostridium difficile Infection in Adults and Children: 2017 Update by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA) - PMC (nih.gov)
5. Study Details | ECOSPOR III - SER-109 Versus Placebo in the Treatment of Adults With Recurrent Clostridium Difficile Infection | ClinicalTrials.gov
6. AGA Clinical Practice Guideline on Fecal Microbiota–Based Therapies for Select Gastrointestinal Diseases - Gastroenterology (gastrojournal.org)


| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Medicare Gold Giveback | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

**Medicare Part B: C. Difficile Drug Therapy**

**Type of Policy:** **Drug Therapy**
**Prior Approval Date:** **11/01/2024**
**Approval Date:** **10/01/2024**
**Effective Date:** **12/01/2024**

**Related Policies:** **Zinplava (bezlotoxumab)**

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies.

## Drugs Requiring Prior Authorization under the medical benefit

Rebyota (Fecal Microbiota, Live, suspension)

## Overview/Summary of Evidence

Fecal microbiota, live is a bacterial spore suspension in capsules for oral administration and a rectal microbiota suspension indicated for the prevention of recurrence of *C. difficile* infection (CDI) after antibiotic treatment for recurrent CDI (rCDI). Recurrence of CDI is defined as a relapse of CDI symptoms within 2 - 8 weeks of successful treatment of the initial episode. It is not indicated for the treatment of CDI. Fecal microbiota, live is manufactured from human fecal matter sourced from qualified donors. Rectal fecal microbiota, live is administered 24 to 72 hours after the conclusion of antibiotic treatment for CDI with oral antibiotics being avoided for up to 8 weeks after use. Oral fecal microbiota, live is administered 48 to 96 hours after the conclusion of antibiotic treatment for CDI with antibiotics to be avoided during use.

## Indications/Criteria

**Rebyota** may be considered for coverage when:

- Member has a diagnosis of recurrent C. difficile infection (rCDI) defined as **either**:
    - Had at least 2 episodes of severe CDI resulting in hospitalization within the last year OR
    - At least one recurrence after a primary episode and had completed at least 1 round of standard-of-care oral antibiotic (SOC) therapy (e.g., vancomycin, fidaxomicin)
- Documentation of a positive C.difficile stool sample
- Chart notes or claims history shows standard of care antibacterial therapy (i.e. vancomycin, fidaxomicin) for the primary episode and presenting rCDI
- Prescriber confirmation that Rebyota is being used for secondary C. difficile infection **prophylaxis** after antibiotic treatment for recurrent C. difficile infection (rCDI)
- Prescriber confirmation that antibacterial treatment for recurrent CDI is completed 24 to 72 hours prior to starting Rebyota
- Quantity limit per episode:
    - Rebyota: 150ml as a single dose

**Initial approval of 150ml per episode within 2 months**
**Subsequent approval for a new episode of rCDI** will be reviewed on a case by cases basis and must include documentation of previous response and clinical benefit.
**Maximum of a one-time repeat dose**

Members may step through Part D drugs prior to obtaining approval for Rebyota. Please refer to the MVP website for the Medicare Part D formulary for a full list of covered drugs.

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## Exclusions

The use of Rebyota will not be covered for the following situations:

- Treatment of CDI
- Indication, age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling

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## References

1. Rebyota (fecal microbiota, live). Clinical Pharmacology. Revised April 27, 2023. Accessed May 30, 2023. 9009000002_REBYOTA-PI_11-2022.pdf (ferringusa.com)

2. Vowst. Prescribing Information. Seres Therapeutics, Inc. Cambridge, MA. Revised April 2023. Microsoft Word - Final-VOWST-PI labeling-text-26April23 (serestherapeutics.com)

3. Centers for Disease Control and Prevention. C.dff (clostridioides difficile). FAQs for Clinicians about D.Diff. FAQs for Clinicians about C. diff | CDC. October 25, 2022. Accessed on June 5, 2023

4. Clinical Practice Guidelines for Clostridium difficile Infection in Adults and Children: 2017 Update by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA) - PMC (nih.gov)

5. Study Details | ECOSPOR III - SER-109 Versus Placebo in the Treatment of Adults With Recurrent Clostridium Difficile Infection | ClinicalTrials.gov

6. AGA Clinical Practice Guideline on Fecal Microbiota–Based Therapies for Select Gastrointestinal Diseases - Gastroenterology (gastrojournal.org)

**MVP Health Care Medical Policy**

**Certolizumab**

| | |
|---|---|
| **Type of Policy:** | **Medical Therapy** |
| **Prior Approval Date:** | **02/01/2024** |
| **Approval Date:** | **02/01/2025** |
| **Effective Date:** | **04/01/2025** |
| **Related Policies:** | **Apremilast, Adalimumab , Infliximab, Risankizumab, Secukinumab, Tofacitinib, Upadacitinib, Ustekinumab, Ozanimod, Abatacept, Golimumab, Tocilizumab** |

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies.

## Drugs Requiring Prior Authorization under the pharmacy benefit

Cimzia SQ (certolizumab pegol) prefilled syringe is non-preferred under the pharmacy benefit

## Drug Requiring Prior Authorization under the medical benefit

J0717 Cimzia SQ (certolizumab pegol) powder for injection, physician administered, is non-preferred under the medical benefit

## Overview

Certolizumab pegol is a TNF-alpha blocker (TNF-blocker) conjugated to polyethylene glycol for subcutaneous use. It is FDA approved to treat Crohn's Disease, rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and non-radiographic axial spondylarthritis. Members should be screened for immunologic and infectious disease prior to initiating therapy.

**Medicaid Variation:** Medications that are a pharmacy benefit are covered and billed to New York State Fee-For-Service (FFS) program. They are defined as medications that go through a retail or specialty pharmacy, including self-administered injectable products. Pharmacy medications are subject to FFS's clinical criteria including (but not limited to) coverage, quantity limit, step therapy, and prior authorization. Pharmacy benefit information can be found here: https://www.emedny.org/info/fullform.pdf

**Indications/Criteria**

A. **For all indications,** Certolizumab pegol SQ is non-formulary and will only be considered for **pharmacy** coverage when:
   - Documented failure, contraindication or ineffective response to all preferred/formulary therapies for the specific indication.
   - Must be prescribed for an FDA approved indication **AND**
   - Must be ordered by or with consult from a rheumatologist/immunologist unless otherwise specified below **AND**
   - Documentation identifies failure of **preferred** self-administered biologic therapies to treat the condition

Certolizumab pegol powder for injection (physician administered) is non-formulary and will only be considered for **medical** coverage when:

   - Above criteria is met **AND**
   - Rationale and documentation is provided identifying why member or caregiver is unable to self-administer **OR**
   - Member has coverage under Medicare Part B and meets the criteria below for a provider administered drug identified in this policy

B. **Crohn's disease**
   Certolizumab may be considered for coverage for Crohn's Disease when the above criteria is met **AND**:
   - Diagnosis of moderate to severe active Crohn's disease confirmed by endoscopy (or capsule endoscopy when appropriate)
   - Must be ordered by or with consult from a gastroenterologist/colorectal surgeon
   - Documentation should include:
     - Assessment of growth, nutrition, extraintestinal complications, therapy-induced complications and functional ability.
     - Any clinical signs and symptoms outlined in Crohn's disease Activity Index (CDAI) such as frequent liquid stools >4/day, severity grade and frequency of abdominal pain, presence of an abdominal mass, general

well-being, extra-intestinal symptoms (arthralgia, uveitis, erythema, stomatitis, absess, fever >37.5 in the last week), taking opiates or diphenoxylate/atropine for diarrhea, anemia, and weight loss >10%.

**Initial approval** for **6 months**.

**Extension requests** will be approved for 12 months if the member has a continued benefit to therapy **AND** if it is a continuation for physician-administered therapy, there is continued medical necessity for use of the physician-administered formulation instead of a self-administered formulation. Extension requests where certolizumab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

C. **Rheumatoid arthritis**
Certolizumab may be considered for coverage for Rheumatoid Arthritis when the above criteria is met **AND**:

- Member has a diagnosis of moderate to severe active adult RA as defined by persistent or recurrent symptoms with documented synovitis and morning stiffness of significant duration to inhibit activities of daily living.
- Chart notes are provided documenting a failure to respond to a three-month trial of methotrexate at a maximally tolerated dose.
    - Failure is demonstrated by documentation of provider assessment without improvement in joint counts and/or physical symptoms and inflammatory markers while on therapy.
    - If the member has a contraindication or significant intolerance to methotrexate
        - Chart notes documenting a failure to respond to at least one other nonbiologic DMARDs at a maximally tolerated dose for at least 3 months **AND** documentation confirming why methotrexate cannot be used is required. If a trial of methotrexate is not appropriate due to alcohol use, chart notes must be provided indicating that the patient has been counseled on the need to abstain from alcohol use while taking methotrexate and is unwilling to abstain from alcohol use.

**Initial approval** for **6 months**.

**Extension requests** will be approved for 12 months if the member has a continued benefit to therapy **AND** if it is a continuation for physician-administered therapy, there

is continued medical necessity for use of the physician administered formulation instead of a self-administered formulation.
Extension requests where certolizumab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

D. **Psoriasis**

Certolizumab may be considered for coverage for psoriasis when the above criteria is met **AND**:

- The medication is ordered by or in consultation with a dermatologist
- A diagnosis of moderate to severe chronic plaque psoriasis and one of the following:
    - Crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected **OR**
    - At least 10% of the body surface area (BSA) is affected **OR**
    - At least 3% of the body surface area (BSA) is affected AND the member meets any of the following criteria:
        - Member has had an inadequate response or intolerance to either phototherapy (e.g., UVB, PUVA) **OR**
        - Member has had an inadequate response or intolerance to pharmacologic treatment with methotrexate, cyclosporine, or acitretin

**Initial approval** for **6 months**.

**Extension requests** will be approved for 12 months if the member has a continued benefit to therapy **AND** if it is a continuation for physician-administered therapy, there is continued medical necessity for use of the physician-administered formulation instead of a self-administered formulation.
Extension requests where certolizumab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

E. **Psoriatic arthritis**

Certolizumab may be considered for coverage for Psoriatic Arthritis when the above criteria is met **AND**:

- Member has a diagnosis of moderate to severe PsA as defined by three or more tender joints AND three or more swollen joints on two separate occasions at least one month apart

- Chart notes documenting failure of at least one NSAID at maximum tolerated dose unless the member has contraindications to NSAID therapy such as cardiovascular disease, peptic ulcer disease or renal disease **AND**
- Chart notes documenting failure to an adequate trial of at least one of the following nonbiologic disease modifying anti-rheumatic drugs (DMARDs): leflunomide, sulfasalazine, or methotrexate.
    - **Members with pure axial manifestations** do not have to have a trial of nonbiologic disease modifying anti-rheumatic drugs (DMARDs)
    - If a trial of methotrexate is not appropriate due to alcohol use, chart notes must be provided indicating that the patient has been counseled on the need to abstain from alcohol use while taking methotrexate and is unwilling to abstain from alcohol use.
- Members with a documented diagnosis of severe PsA do not require failure of NSAID or DMARD

**Initial approval** for **6 months**.

**Extension requests** will be approved for 12 months if the member has a continued benefit to therapy **AND** if it is a continuation for IV therapy, there is continued medical necessity for use of the physician administered formulation instead of a self-administered formulation.
Extension requests where certolizumab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

F. **Ankylosing Spondylitis**
Certolizumab may be considered for coverage for Ankylosing Spondylitis when the above criteria is met **AND**:
    - Member has a diagnosis of moderate to severe AS
    - Chart notes documenting failure of at least one NSAID at maximum tolerated dose AND documented significant clinical symptoms such as fatigue, spinal pain, arthralgia, inflammation of joints and tendons, morning stiffness duration and therapy AND insufficient response to at least one local corticosteroid injection in patients with symptomatic peripheral arthritis
        - **For members with pure axial manifestations** do not have to have a trial of nonbiologic disease modifying anti-rheumatic drugs (DMARDs)

**Initial approval** for **6 months**.

**Extension requests** will be approved for 12 months if the member has a continued benefit to therapy **AND** if it is a continuation for IV therapy, there is continued medical

necessity for use of the physician administered formulation instead of a self-administered formulation.
Extension requests where certolizumab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

G. **Non-radiographic axial spondylarthritis**
Certolizumab may be considered for coverage for non-radiographic axial spondylarthritis when the above criteria is met **AND** member meets all the criteria for Ankylosing Spondylitis.

**Initial approval** for **6 months**.

**Extension requests** will be approved for 12 months if the member has a continued benefit to therapy **AND** if it is a continuation for IV therapy, there is continued medical necessity for use of the physician administered formulation instead of a self-administered formulation.
Extension requests where certolizumab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

H. Juvenile idiopathic arthritis
Requests for certolizumab treat Juvenile idiopathic arthritis will be reviewed on a case-by-case basis using the American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis.

**Initial approval** will be for 6 months

**Extensions requests** will be approved **up to 12 months** if the member has a continued benefit to therapy. Extension requests where the certolizumab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

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**Exclusions**

The use of certolizumab will not be covered for the following situations:

- Diagnosis of multiple sclerosis

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling
- Combination therapy that is not supported by current clinical guidelines

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## References


1. Clinical Pharmacology. Certolizumab. Revised 10/26/2021. Accessed 01/05/2023.
2. Cimzia (certolizumab pegol) for injection, for subcutaneous use. Prescribing information. Smyrna, GA. UCB, Inc. April 2022.
3. Torres J, Bonovas S, Doherty G, et al. ECCO Guidelines on Therapeutics in Crohn's Disease: Medical Treatment. J Crohns Colitis. 2020;14(1):4-22.
4. Lichtenstein G, Loftus E, Issacs K, et al. ACG Clinical Guideline: Management of Crohn's Disease in Adults. 2018;113(4):481-517.
5. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care Res (Hoboken). 2021;73(7):924-939.
6. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol. 2019;80(4):1029-1072.
7. Singh JA, Guyatt G, Ogdie A, et al. Special Article: 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis Rheumatol. 2019;71(1):5-32.
8. Ward MM, Deodhar A, Gensler LS, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. Arthritis Care Res (Hoboken). 2019;71(10):1285-1299.


| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Complete Wellness | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |

| | |
|---|---|
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| USA Care PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

**Medicare Part B: Certolizumab**

| | |
|---|---|
| **Type of Policy:** | **Medical Therapy** |
| **Prior Approval Date:** | **02/01/2024** |
| **Approval Date:** | **02/01/2025** |
| **Effective Date:** | **04/01/2025** |
| **Related Policies:** | **Abatacept, Golimumab, Infliximab, Risankizumab, Tocilizumab, Ustekinumab** |

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies for drugs that may be covered under the Part D benefit.

## Drug Requiring Prior Authorization under the medical benefit

J0717 Cimzia SQ (certolizumab pegol) powder for injection, physician administered, is non-preferred under the medical benefit

## Overview/Summary of Evidence

Certolizumab pegol is a TNF-alpha blocker (TNF-blocker) conjugated to polyethylene glycol for subcutaneous use. It is FDA approved to treat Crohn's Disease, rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and non-radiographic axial spondylarthritis. Members should be screened for immunologic and infectious disease prior to initiating therapy.

## Indications/Criteria

A. For all indications, Certolizumab pegol powder for injection (physician administered) will only be considered for **medical** coverage when:

- Must be prescribed for an FDA approved indication **AND**

- Must be ordered by or with consult from a rheumatologist/immunologist unless otherwise specified below **AND**
- Member has coverage under Medicare Part B and meets the criteria below for a provider administered drug identified in this policy

B. **Crohn's disease**

Certolizumab may be considered for coverage for Crohn's Disease when the above criteria is met **AND**:

- Diagnosis of moderate to severe active Crohn's disease confirmed by endoscopy (or capsule endoscopy when appropriate)
- Must be ordered by or with consult from a gastroenterologist/colorectal surgeon
- Documentation should include:
    - Assessment of growth, nutrition, extraintestinal complications, therapy-induced complications and functional ability.
    - Any clinical signs and symptoms outlined in Crohn's disease Activity Index (CDAI) such as frequent liquid stools >4/day, severity grade and frequency of abdominal pain, presence of an abdominal mass, general well-being, extra-intestinal symptoms (arthralgia, uveitis, erythema, stomatitis, absess, fever >37.5 in the last week), taking opiates or diphenoxylate/atropine for diarrhea, anemia, and weight loss >10%.
- Documentation identifying inadequate response to or an intolerance to conventional therapy (i.e.: corticosteroids, anti-inflammatory aminosalicylates [e.g., mesalamine (5-ASA), sulfasalazine], 6-mercaptopurine, and azathioprine).

**Initial approval** for **6 months**.

**Extension requests** will be approved for 12 months if the member has a continued benefit to therapy
**Extension requests** where certolizumab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

C. **Rheumatoid arthritis**

Certolizumab may be considered for coverage for Rheumatoid Arthritis when the above criteria is met **AND**:

- Member has a diagnosis of moderate to severe active adult RA as defined by persistent or recurrent symptoms with documented synovitis and morning stiffness of significant duration to inhibit activities of daily living.

- Chart notes are provided documenting a failure to respond to a three-month trial of methotrexate at a maximally tolerated dose.
    - Failure is demonstrated by documentation of provider assessment without improvement in joint counts and/or physical symptoms and inflammatory markers while on therapy.
    - If the member has a contraindication or significant intolerance to methotrexate
        - Chart notes documenting a failure to respond to at least one other nonbiologic DMARDs at a maximally tolerated dose for at least 3 months **AND** documentation confirming why methotrexate cannot be used is required. If a trial of methotrexate is not appropriate due to alcohol use, chart notes must be provided indicating that the patient has been counseled on the need to abstain from alcohol use while taking methotrexate and is unwilling to abstain from alcohol use.

**Initial approval** for **6 months**.

**Extension requests** will be approved for 12 months if the member has a continued benefit to therapy
**Extension requests** where certolizumab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

D. **Psoriasis**
Certolizumab may be considered for coverage for psoriasis when the above criteria is met **AND**:

- The medication is ordered by or in consultation with a dermatologist
- A diagnosis of moderate to severe chronic plaque psoriasis and one of the following:
    - Crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected **OR**
    - At least 10% of the body surface area (BSA) is affected **OR**
    - At least 3% of the body surface area (BSA) is affected AND the member meets any of the following criteria:
        - Member has had an inadequate response or intolerance to either phototherapy (e.g., UVB, PUVA) **OR**
        - Member has had an inadequate response or intolerance to pharmacologic treatment with methotrexate, cyclosporine, or acitretin

**Initial approval** for **6 months**.

**Extension requests** will be approved for 12 months if the member has a continued benefit to therapy
**Extension requests** where certolizumab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

E. **Psoriatic arthritis**
Certolizumab may be considered for coverage for Psoriatic Arthritis when the above criteria is met **AND**:

- Member has a diagnosis of moderate to severe PsA as defined by three or more tender joints AND three or more swollen joints on two separate occasions at least one month apart
- Chart notes documenting failure of at least one NSAID at maximum tolerated dose unless the member has contraindications to NSAID therapy such as cardiovascular disease, peptic ulcer disease or renal disease **AND**
- Chart notes documenting failure to an adequate trial of at least one of the following nonbiologic disease modifying anti-rheumatic drugs (DMARDs): leflunomide, sulfasalazine, or methotrexate.
    - **Members with pure axial manifestations** do not have to have a trial of nonbiologic disease modifying anti-rheumatic drugs (DMARDs)
    - If a trial of methotrexate is not appropriate due to alcohol use, chart notes must be provided indicating that the patient has been counseled on the need to abstain from alcohol use while taking methotrexate and is unwilling to abstain from alcohol use.
- Members with a documented diagnosis of severe PsA do not require failure of NSAID or DMARD

**Initial approval** for **6 months**.

**Extension requests** will be approved for 12 months if the member has a continued benefit to therapy
**Extension requests** where certolizumab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

F. **Ankylosing Spondylitis**
Certolizumab may be considered for coverage for Ankylosing Spondylitis when the above criteria is met **AND**:

- Member has a diagnosis of moderate to severe AS
- Chart notes documenting failure of at least one NSAID at maximum tolerated dose AND documented significant clinical symptoms such as fatigue, spinal pain, arthralgia, inflammation of joints and tendons, morning stiffness duration and therapy AND insufficient response to at least one local corticosteroid injection in patients with symptomatic peripheral arthritis
    - **For members with pure axial manifestations** do not have to have a trial of nonbiologic disease modifying anti-rheumatic drugs (DMARDs)

**Initial approval** for **6 months**.

**Extension requests** will be approved for 12 months if the member has a continued benefit to therapy
**Extension requests** where certolizumab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

G. **Non-radiographic axial spondylarthritis**
Certolizumab may be considered for coverage for non-radiographic axial spondylarthritis when the above criteria is met **AND** member meets all the criteria for Ankylosing Spondylitis.

**Initial approval** for **6 months**.

**Extension requests** will be approved for 12 months if the member has a continued benefit to therapy
**Extension requests** where certolizumab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

H. Juvenile idiopathic arthritis
Requests for certolizumab treat Juvenile idiopathic arthritis will be reviewed on a case-by-case basis using the American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis.

**Initial approval** will be for 6 months

**Extensions requests** will be approved **up to 12 months** if the member has a continued benefit to therapy. Extension requests where the certolizumab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

## Exclusions

The use of certolizumab will not be covered for the following situations:

- Diagnosis of multiple sclerosis
- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling
- Combination therapy that is not supported by current clinical guidelines

## References


1. Clinical Pharmacology. Certolizumab. Revised 10/26/2021. Accessed 01/05/2023.
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7. Singh JA, Guyatt G, Ogdie A, et al. Special Article: 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis Rheumatol. 2019;71(1):5-32.
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**MVP Health Care Medical Policy**

# Medicare Part B: Calcitonin Gene-Related Peptide (CGRP) Antagonists

**Type of Policy:** Drug Therapy
**Prior Approval Date:** 11/01/2023
**Approval Date:** 08/01/2024
**Effective Date:** 10/01/2024
**Related Policies:** **N/A**

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies for drugs that may be covered under the Part D benefit.

## Codes Requiring Prior Authorization (covered under the medical benefit)

J3032 Vyepti (injection, eptinezumab-jjmr, 1mg)

## Overview/Summary of Evidence

Migraine is a common disabling primary headache disorder. In the Global Burden of Disease Study 2010 (GBD2010), it was ranked as the third most prevalent disorder in the world. In GBD2015, it was ranked the third-highest cause of disability worldwide in both males and females under the age of 50 years.

Cluster headaches is a debilitating primary headache disorder defined as a severe attack that can last weeks or months (also known as "cluster periods"). Cluster headaches are categorized as episodic (having pain free remission periods) and chronic (do not have pain free remission periods). Currently, Emgality is the only CGRP Antagonist indicated for the treatment of episodic cluster headache.



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Medication overuse headache is not an approved indication for calcitonin gene-related peptide antagonists and providers should assess their patients and rule out prior to initiating therapy.

Calcitonin Gene-Related Peptides (CGRP) receptor antagonists are a group of medications indicated in either the prophylaxis or acute treatment of migraine headaches. Aimovig, Emgality, Vyepti, Nurtec and Ajovy are FDA approved for migraine prophylaxis while Nurtec and Ubrelvy are FDA approved for acute migraine treatment.

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**Indications/Criteria for prophylaxis for Vyepti**

Requests will be considered for coverage when all the following are met:

- Confirmed diagnosis of chronic or episodic migraine

For chronic migraine:

- Inadequate response (defined as less than a 2 day decrease per month in headache frequency) to at least a 1 (one)trial to at least **1** (one) prophylactic medication (i.e., topiramate, divalproex, propranolol, metoprolol, timolol, amitriptyline, verapamil, venlafaxine) at maximally tolerated doses.

For episodic migraine:

- Inadequate response (defined as less than a 2 day decrease in headache frequency) to at least a 1 (one)-month trial to at least 1 (one) prophylactic medication (i.e., topiramate, divalproex, propranolol, metoprolol, timolol, amitriptyline, verapamil, venlafaxine) at maximally tolerated doses.

For Vyepti:

- All applicable criteria listed above **AND**
- Documentation identifying medical necessity why the member is unable to use a self-administered product (such as a failure, intolerance, or contraindication to self-administered products).
    - If applicable, documentation should also include why the member or caregiver is unable to administer a self-administered product.
    - Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies for drugs that may be covered under the Part D benefit.

**Initial approval** will be for **3 months.**



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**Extension requests** will be approved for **up to 12 months** if the member has a continued benefit to therapy.

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**Exclusions**

- Off-label diagnosis
- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling
- History of hemiplegic ophthalmoplegic, migraine with brainstem aura, or persistent daily headaches
- Use of devices (i.e., nerve blocks and transcranial magnetic stimulation)

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3. https://americanmigrationfoundation.org/understanding-migraine/medication-overuse-headache-2/
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9. Local Coverage Determination L33646; Botulinum Toxins; effective 10/31/2019
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12. Aimovig. Study Details | Study to Evaluate the Efficacy and Safety of Erenumab (AMG 334) in Migraine Prevention | ClinicalTrials.gov. A Controlled Trial of Erenumab for Episodic Migraine | New England Journal of Medicine (nejm.org)

13. Ajovy: Efficacy and Safety of 2 Dose Regimens of TEV-48125 Versus Placebo for the Preventive Treatment of Episodic Migraine - Full Text View - ClinicalTrials.gov. Comparing Efficacy and Safety of 2 Dose Regimens of Subcutaneous Administration of TEV-48125 Versus Placebo for the Preventive Treatment of Chronic Migraine - Full Text View - ClinicalTrials.gov

14. Emgality. Evaluation of Galcanezumab in the Prevention of Episodic Migraine- the EVOLVE-1 Study - Full Text View - ClinicalTrials.gov



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**MVP Health Care Medical Policy**

**Cialis for BPH**

| | |
|---|---|
| **Type of Policy:** | Drug Therapy |
| **Prior Approval Date:** | 08/01/2023 |
| **Approval Date:** | 08/01/2024 |
| **Effective Date:** | 10/01/2024 |
| **Related Policies:** | Quantity Limit for Prescription Drugs<br>Pharmacy Programs Administration<br>Pharmacy Management Programs |

## Drug Requiring Prior Authorization under the pharmacy benefit

Refer to the MVP website for the Medicare Part D formulary for drugs that may covered under the Part D benefit.

Cialis® (tadalafil) 2.5mg, 5 mg

Tadalafil 2.5mg, 5mg

## Overview

Benign prostatic hyperplasia (BPH) refers to enlargement of the prostate gland, which can contribute to lower urinary tract symptoms (LUTS). BPH cannot be reversed and therefore therapy is aimed at reducing symptoms of LUTS; including irritative (frequency, urgency, nocturia) and obstructive (incomplete emptying, stopping and starting, weak stream, and pushing and straining) symptoms. Standard of care includes treatment with alpha-blockers, 5-alpha-reductase-inhibitors (5-ARIs), and/or a combination.

Erectile dysfunction (ED) is the inability to achieve or maintain an erection for sexual intercourse. ED can be caused by disease, injury, psychological dysfunction, or medications. ED is a common side effect of some of the medications used to treat the symptoms of BPH.

A common treatment of ED is phosphodiesterase type 5 (PDE5) inhibitors, which enhances erectile function by increasing the amount of cGMP. In turn, cGMP causes smooth muscle relaxation and increased blood flow to the penis. The mechanism for which PDE5 inhibitors are efficacious in symptom management of BPH is unknown. PDE-5 inhibitors were not included in the 2010 AUA Guidelines as of the date of this policy.

| Class | Drugs | Clinical Use |
|---|---|---|
| alpha-adrenergic blockers | alfuzosin (Uroxatral). | Bladder outlet obstruction (BOO) |
| | doxazosin (Cardura). | |
| | tamsulosin (Flomax). | |
| | terazosin (Hytrin) | |
| | silodosin (Rapaflo). | |
| 5-ARIs | finasteride (Proscar) | Prevent progression, reduce urinary retention |
| | dutasteride (Avodart) | |
| combination therapy (alpha-adrenergic blocker & 5-ARI) | dutasteride & tamsulosin | |

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**Indications/Criteria**

Cialis® (tadalafil) 2.5 mg or 5 mg daily may be considered medically necessary for BPH when the following criteria are met:

- Documentation indicating that the patient has symptomatic BPH
- A failure or intolerance to a trial of an alpha-blocker **AND** a 5-alpha-reductase inhibitor **OR** the member has a contraindication to both an alpha-blocker and a 5-alpha-reductase inhibitor

Initial authorization for BPH, if approved, will be for a period of one year.

For continued therapy:

- Documentation of a reduction in BPH symptoms

**Exclusions**

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling

- Creatinine clearance (CrCl) less than 30 mL/minute (for CrCl 30-50 mL/min start at 2.5 mg)
- Age <18 years old
- Not covered solely for erectile dysfunction symptoms (refer to Quantity Limits for Prescription Drugs policy for enhanced plans)
- Status post radical prostatectomy
- Additional doses for ED when Cialis is approved for BPH
- Use in combination therapy with other PDE-5 inhibitors
- Solely to reduce PSA levels
- More than one tablet daily
- Greater than a 30-day supply per fill

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**References**


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| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Medicare Gold Giveback | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D |
| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

**Colony Stimulating Factors (CSF)**

**Type of Policy:** **Drug Therapy**
**Prior Approval Date:** **10/01/2023**
**Approval Date:** **10/01/2024**
**Effective Date:** **01/01/2025**
**Related Policies:**

**Codes Subject to Retrospective Review**

- J2506 – Injection, pegfilgrastim, 6 mg (Neulasta)
- Q5130- Injection, pegfilgrastim, 6 mg (Fylnetra)
- Q5108 – Injection, pegfilgrastim-jmdb, biosimilar, 0.5mg (Fulphila)
- Q5111 – Injection, Pegfilgrastim-cbqv, biosimilar, 0.5mg (Udenyca)
- Q5110 – Injection, filgrastim-aafi, biosimilar, 1 mcg (Nivestym)
- J1442 – Injection, filgrastim (g-csf), 1mcg (Neupogen)
- Q5101- Injections, filgrastim (g-csf), 1mcg (Zarxio)
- J1447- Injections, tbo-filgrastim, 1mcg (Granix)
- Q5120-Injection, pegfilgrastim-bmez, 6mg (Ziextenzo)
- Q5122 - Injection, pegfilgrastim-apgf, biosimilar,0.5 mg (Nyvepria)
- J1449 – injection, elfapegrastim-xnst, 0.1mg (Rolvedon)
- Q5127 Injection, pegfilgrastim-fpgk (stimufend), biosimilar, 0.5 mg (Stimufend)
- Q5125 Injection, filgrastim-ayow, biosimilar, (releuko), 1 microgram

Refer to the MVP website for the prescription drug formulary for drugs that may be covered under the pharmacy benefit.

Refer to the MVP website for the Medicare Part D formulary for drugs that may be covered under the Part D benefit.

**Overview**
Colony stimulating factors support the survival, clonal expansion, and differentiation of hematopoietic progenitor cells by binding to specific receptors expressed on the cell surface of target cells.

## A. Dosing Limits

**Max Units (per dose and over time) [Medical Benefit]:**

- **Udenyca and Fulphila:**
  - 12 billable units weekly x 2 doses for Acute Radiation Exposure
  - 12 billable units per 14 days for all other indications
- **Neulasta:**
  - 1 billable unit weekly x 2 doses for Acute Radiation Exposure
  - 1 billable unit per 14 days for all other indications
- **Neupogen, Nivestym, Zarxio, Ziextenzo, Stimufend**, **Rolvedon, Nyvepria and Granix:**
  - Severe Chronic Neutropenia: 1380 billable units per day
  - BMT or PBPC or Radiation: 1200 billable units per day
  - All other indications: 600 billable units per day

## B. Initial Approval Criteria

**1. For all indications, the following criteria must be met in addition to the specific diagnosis criteria below.**

Neulasta, and Udenyca are the preferred long-acting granulocyte colony stimulating factor (G-CSF) products.

- Members must have failed, or have a contraindication, or intolerance to Neulasta OR Udenyca prior to consideration of any other long-acting G-CSF product.

Nivestym and Releuko are the preferred short-acting granulocyte colony stimulating factor (G-CSF) products.

- Members must have failed, or have a contraindication, or intolerance to Nivestym OR Releuko prior to consideration of any other short-acting G-CSF product.

**2. Coverage for Neupogen, Nivestym, Zarxio, Ziextenzo, Nyvepria, Stimufend, Rolvedon and Granix is provided in the following conditions unless otherwise notated below:**

- Bone marrow transplant (BMT) -Neupogen and Nivestym only
- Peripheral Blood Progenitor Cell (PBPC) mobilization and transplant -Neupogen and Nivestym only
- Prophylactic use in Members with non-myeloid malignancy
- Member is undergoing myelosuppressive chemotherapy with an expected incidence of febrile neutropenia of 20% or greater; **OR**
- Member is undergoing myelosuppressive chemotherapy with an expected incidence of febrile neutropenia of 10% or greater AND one or more of the following co-morbidities:
  - Elderly Members (age 65 or older) receiving full dose intensity chemotherapy
  - History of recurrent febrile neutropenia from chemotherapy
  - Extensive prior exposure to chemotherapy
  - Previous exposure of pelvis, or other areas of large amounts of bone marrow, to radiation
  - Pre-existing neutropenia (ANC ≤ 1000/$mm^3$) or bone marrow involvement with tumor
  - Member has a condition that can potentially increase the risk of serious infection (i.e. HIV/AIDS)
  - Infection/open wounds
  - Recent surgery
  - Poor performance status
  - Poor renal function (creatinine clearance <50)
  - Liver dysfunction (elevated bilirubin >2.0)
  - Chronic immunosuppression in the post-transplant setting including organ transplant

**3. Treatment of chemotherapy-induced febrile neutropenia -Neupogen, Nivestym, Stimufend, Rolvedon and Zarxio**

- Used for the treatment of chemotherapy induced febrile neutropenia; **AND**

- Member has been on prophylactic therapy with filgrastim; **OR**
- Member has not received prophylactic therapy with a granulocyte colony stimulating factor; **AND**
  - Member has one or more of the following risk factors for developing infection-related complications:
    - Sepsis Syndrome
    - Age >65
    - Absolute neutrophil count [ANC] <100/mcL
    - Duration of neutropenia expected to be greater than 10 days
    - Pneumonia or other clinically documented infections
    - Invasive fungal infection
    - Hospitalization at the time of fever
    - Prior episode of febrile neutropenia

4. **Member who experienced a neutropenic complication from a prior cycle of the same chemotherapy**
5. **Acute Myeloid Leukemia (AML) member following induction or consolidation chemotherapy**
6. **Bone Marrow Transplantation (BMT) failure or Engraftment Delay**
7. **Severe chronic neutropenia**
   - Member must have an absolute neutrophil count (ANC) < 500/$mm^3$; **AND**
   - Member must have a diagnosis of one of the following:
     - Congenital neutropenia; **OR**
     - Cyclic neutropenia; **OR**
     - Idiopathic neutropenia
8. **Myelodysplastic Syndrome**
   - Endogenous serum erythropoietin level of ≤500 mUnits/mL; **AND**
   - Member is receiving concurrent therapy with Erythropoiesis Stimulating Agents (ESAs)
9. **Members acutely exposed to myelosuppressive doses of radiation (Hematopoietic Subsyndrome of Acute Radiation Syndrome**

**10. Prophylactic use in Members with non-myeloid malignancy**

Coverage for Neulasta, Udenyca, and Fulphila is provided in the following conditions:

- Member is undergoing myelosuppressive chemotherapy with an expected incidence of febrile neutropenia of 20% or greater; **OR**
- Member is undergoing myelosuppressive chemotherapy with an expected incidence of febrile neutropenia of 10% or greater **AND** one or more of the following co-morbidities:
  - Elderly Members (age 65 or older)
  - History of recurrent febrile neutropenia from chemotherapy
  - Extensive prior exposure to chemotherapy
  - Previous exposure of pelvis, or other areas of large amounts of bone marrow, to radiation
  - Pre-existing neutropenia (ANC ≤ 1000/$mm^3$) or bone marrow involvement with tumor
  - Member has a condition that can potentially increase the risk of serious infection (i.e. HIV/AIDS)
  - Infection/open wounds
  - Recent surgery
  - Poor performance status
  - Poor renal function (creatinine clearance <50)
  - Liver dysfunction (elevated bilirubin >2.0)
  - Chronic immunosuppression in the post-transplant setting including organ transplant

**11. Member who experienced a neutropenic complication from a prior cycle of the same chemotherapy**

**12. Members acutely exposed to myelosuppressive doses of radiation (Hematopoietic Subsyndrome of Acute Radiation Syndrome)**

**13. Bone marrow transplantation (BMT) failure or engraftment delay**

**14. Peripheral blood progenitor cell (PBPC) mobilization and transplant**

## Renewal Criteria

Coverage can be renewed if member continues to meet above criteria

## Appendix A

### Dosage/Administration

| Indication | Dose |
|---|---|
| Neupogen, Zarxio, Granix, and Nivestym | • 5mcg/kg daily for up to 14 days for non-BMT/PBPC indications<br>• 10mcg/kg daily for up to 14 days for BMT/PBPC/Radiation indications<br>• 6mcg/kg twice daily for Severe Congenital Neutropenia |
| Neulasta, Udenyca and Fulphila, Ziextenzo, Nyvepria All other indications* | <10 kg = 0.1 mg/kg<br>10-20 kg = 1.5 mg<br>21-30 kg = 2.5 mg<br>31-44 kg = 4 mg<br>45 kg and up = 6 mg<br>Dosed no more frequently than every 14 days. |
| Neulasta, Udenyca Fulphila, Ziextenzo, Nyvepria Acute Radiation Exposure | 6 mg subcutaneously weekly x 2 doses (Use weight based dosing for pediatrics weighing <45 kg) |

*Do not administer within 14 days before and 24 hours after administration of cytotoxic chemotherapy
*Onpro On-body Injector may be administered on the same day as chemotherapy as long as the Neulasta is administered no less than 24 hours after administration of chemotherapy. Not recommended for use in Members with acute radiation exposure

---

## References

1. Nivestym [package insert]. Lake Forest, IL; Hospira Inc; July 2018. Accessed July 2018.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) filgrastim-aafi. National Comprehensive Cancer Network, 2018. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL

COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc." To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed July 2018.

3. Smith TJ, Bohlke K, Lyman GH, Carson KR, Crawford J, Cross SJ, Goldberg JM, Khatcheressian JL, Leighl NB, Perkins CL, Somlo G, Wade JL, Wozniak AJ, Armitage JO. Recommendations for the use of WBC growth factors: American Society of Clinical Oncology Clinical Practice Guideline Update. J Clin Oncol. 2015 Jul 13. pii: JCO.2015.62.3488. [Epub ahead of print]
4. Udenyca [package insert]. Redwood City, California; Coherus Biosciences; November 2018. Accessed November 2018.
5. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) pegfilgrastim. National Comprehensive Cancer Network, 2018. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc." To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed November 2018.
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10. Staber, P. B., et al. "Fixed-dose single administration of Pegfilgrastim vs daily Filgrastim in patients with haematological malignancies undergoing autologous peripheral blood stem cell transplantation." Bone marrow transplantation 35.9 (2005): 889-893.

11. Vanstraelen, Gaëtan, et al. "Pegfilgrastim compared with Filgrastim after autologous hematopoietic peripheral blood stem cell transplantation." Experimental hematology 34.3 (2006): 382-388.
12. Neupogen [package insert]. Thousand Oaks, CA; Amgen Inc; June 2016. Accessed March 2018.
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14. Neulasta [package insert]. Thousand Oaks, CA; Amgen Inc; June 2018. Accessed October 2018.
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16. Granix [package insert]. North Wales, PA; Teva Pharmaceuticals; July 2018. Accessed March 2019.
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20. Nyvepria [package insert]. Lake Forest, Il; Hospira. April 2021.

| Member 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 | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Potential for Retrospective Review |
| MVP Child Health Plus | Potential for Retrospective Review |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Potential for Retrospective Review |
| MVP Medicare Gold Giveback | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |

| | |
|---|---|
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP VT HMO | Potential for Retrospective Review |
| MVP VT Plus HMO | Potential for Retrospective Review |
| MVP VT HDHP 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

**Compounded (Extemporaneous) Medications**

**Type of Policy:** **Drug Therapy/Medical Therapy**
**Prior Approval Date:** **12/01/2023**
**Approval Date:** **12/01/2024**
**Effective Date:** **02/01/2025**
**Related Policies:** **Experimental or Investigational**

## All Compounds Require Prior Authorization when the cost is greater than $100 per claim

Refer to the MVP website for the Medicare Part D formulary for drugs that may be covered under the Part D benefit.

Refer to the MVP website for the Medicare Part B policies for coverage criteria of drugs covered under the medical benefit.

## Overview

The FDA regards traditional compounding as the extemporaneous combining, mixing, or altering of ingredients by a pharmacist in response to a physician's prescription to create a medication tailored to the specialized needs of an individual member. Traditional compounding typically is used to prepare medications that are not available commercially, such as a drug for a member who is allergic to an ingredient in a mass-produced drug, or diluted dosages for children.[1]

## Indications/Criteria

Coverage for compounded medications which contain at least 2 ingredients may be considered when **ALL** of the following criteria are met:

- Contains at least one active ingredient that is an FDA Approved Federal Legend Drug
- Contains no bulk powder drugs
- Active ingredient is being used for an FDA approved indication or the off-label use meets the Experimental or Investigation Policy criteria

- For topical compounds, the compound ingredients are FDA or compendia supported for topical use
- Documentation supporting clinical necessity of a compounded medication that has the same active ingredient as a commercially available product except for the dose, inactive ingredients, and/or dosage form (e.g., weight or age of member requires dose that is not available, specific allergy to inactive ingredient, unable to swallow tablets, etc.)
- There is no similar commercially available prescription product that would meet the needs of the individual member
- All self-administered prescription compounded medications must be processed through the pharmacy benefit manager
- Medications administered by intrathecal pump must be FDA approved for use with implanted pumps for intrathecal infusion

Compounded prescriptions are non-formulary, tier 3

Compounded prescriptions using a specialty drug will be required to be filled through a contracted specialty pharmacy

**Initial authorization** will be for up to 12 months

**Continuation of coverage** may be considered for up to 12 months if an appropriate response to therapy is documented

**Medical Therapy**

In addition to meeting the above criteria, medications compounded by a pharmacy and administered in an office setting, will require prior authorization when the cost exceeds $100

**Medicaid Variation**

In addition to meeting the criteria above, the compounded prescription must meet one of the following conditions:

- It must be a combination of any TWO or more legend drugs found on the List of Medicaid Reimbursable Drugs, **OR**
- It must be a combination of any legend drug(s) included on the List of Medicaid Reimbursable Drugs and any other item(s) not commercially available as an ethical or proprietary product, **OR**
- It must be a combination of two or more products which are labeled as "Caution: For Manufacturing Purpose Only"

The compounded prescription must meet all the following conditions below:

- Compounds may not be made to add coloring, flavoring, perfumes or other non-active ingredient additives to a commercially available product
- Compounds may not contain drugs or be made for NYS Medicaid excluded indications as per the Social Security Act §1927(d)(2) including but not limited to drugs to treat weight loss or sexual dysfunction or for cosmetic purposes
- Compounds may not be made in therapeutic amounts or combinations not FDA approved, or compendia supported.
- Foot baths, other soaks, or irrigations are excluded
- Prepared compounds that mimic a commercial product must include on the prescription and in the members medical chart documentation of the reason for compounding (i.e., sensitivity or contraindication to dyes, preservatives, or fillers or lack of availability of a commercial product)
- Compounds may not be made to bypass the criteria within the *NYRx, the Medicaid Pharmacy Program Preferred Drug List*. Compounds may not be made with or to replace drug products removed from the marketplace due to safety reasons.
- Compounding kits packaged for convenience with premeasured ingredients are not covered as an outpatient drug per Social Security Act §1927(k)(2)(A)(i) and Social Security Act §1902(a)(54).

For example:

- The combination of Aquaphor and Hydrocortisone Cream 2.5% is NOT considered a compound since it does not meet any of the above requirements. The reconstitution of a commercially available product is NOT considered compounding. All ingredients of a compound must be submitted on a claim regardless of reimbursement.

A Medicaid list of reimbursable drugs can be found at: https://www.emedny.org/info/formfile.aspx Medications that are a pharmacy benefit are covered and billed to New York State Fee-For-Service (FFS) program. They are defined as medications that go through a retail or specialty pharmacy, including self-administered injectable products. Pharmacy medications are subject to FFS's clinical criteria including (but not limited to) coverage, quantity limit, step therapy, and prior

authorization. Pharmacy benefit information can be found here: https://www.emedny.org/info/fullform.pdf

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**Exclusions**

1. Compounded drugs that the commercial product was withdrawn or removed from the market due to safety reasons
2. Compounded drug products that are commercially available in the marketplace or that are essentially copies of commercially available FDA-approved drug products
3. Prescription history contradicts documentation of clinical necessity
4. Compounded prescriptions (prescriptions that require the mixing of two or more ingredients) that do not contain at least one FDA-Approved Drug
5. Drug formulations compounded solely for the convenience or ease of administration
6. Compounded drugs used for cosmetic purposes (i.e., topical vitamin A and topical vitamin D preparations)
7. Compounded drugs intended for off-label use that do not meet the Experimental or Investigation Policy criteria. The following are examples of experimental or investigational preparations that MVP Health Care considers to be excluded due to inadequate or inconclusive long-term scientific evidence relative to outcomes:
    - Compounded bioidentical hormones[2] (i.e., estrone, estradiol, progesterone, testosterone, DHEA)
    - Estriol
    - Implantable estradiol pellets
    - Nebulized anti-infectives for nasal administration[3] (i.e., tobramycin, gentamicin, ciprofloxacin, levofloxacin)
    - Any compound containing ketamine
    - Megavitamin therapy (orthomolecular medicine)
8. Self-administered compounded medications processed through the medical claims system
9. Pre-packaged compound kits
10. OTC ingredients (including diluents) in the compound will not be covered
11. Intrathecal medications
    - Medicines not FDA approved for intrathecal administration or intrathecal implanted pump use (for example, bupivacaine, fentanyl, clonidine) will not be covered
    - Any mixture of two or more different kinds of medicines to be used in a pump will not be covered
    - Any compounded medicine (for example, to achieve higher concentration or different formulation of an FDA approved medicine) will not be covered

12. Indication, age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling.

---

**References**


1. US Food and Drug Administration (FDA). Inspections, Compliance, Enforcement, and Criminal Investigations. Pharmacy Compounding http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm155168.htm. (Accessed January 2014).
2. Compounded bioidentical menopausal hormone therapy. Committee Opinion No. 532. American College of Obstetricians and Gynecologists. Obstet Gynecol 2012; 120:411-5. (Accessed January 2014)
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4. New York State Medicaid Update. February 2014. Volume 30, Number 2. Page 13. Available at: https://www.health.ny.gov/health_care/medicaid/program/update/2014/feb14_mu.pdf
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8. Center for Drug Evaluation, Research. Regulatory policy information. U.S. Food and Drug Administration. Published October 10, 2023. Accessed November 15, 2023. https://www.fda.gov/drugs/human-drug-compounding/regulatory-policy-information

9. Compounded Bioidentical Hormone Therapy. Endocrine.org. Published October 2, 2019. Accessed November 15, 2023. https://www.endocrine.org/advocacy/position-statements/compounded-bioidentical-hormone-therapy

10. Reminder: Compound Policy. New York Medicaid Update. April 2024 Volume 40 Number 4. Accessed New York State Medicaid Update - April 2024 Volume 40 - Number 4 (ny.gov)

| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Complete Wellness | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| USA Care PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

# Copayment Adjustment for Medical Necessity

| | |
|---|---|
| **Type of Policy:** | Drug Therapy |
| **Prior Approval Date:** | 06/01/2024 |
| **Approval Date:** | 04/01/2025 |
| **Effective Date:** | 06/01/2025 |
| **Related Policies:** | N/A |

## Codes Requiring Prior Authorization

NA

## Overview

Copayment reductions for medical necessity will be considered on a case-by-case basis for brand multi-source drug differential copayments only. This policy applies to members with prescription drug coverage that specifically requires brand-generic differential copayments. A member should review therapeutically appropriate alternatives with their physician and, when all options have been eliminated, may pursue copayment exception based on medical necessity. Review is based on medical considerations which demonstrate the potential for adverse medical outcome(s) to the member.

## Indications/Criteria

The prescriber must submit a Prior Authorization request with supporting documentation. The request must clearly indicate "Copayment Reduction".

Documentation must include a complete medication history detailing at least one of the following with respect to each therapeutically appropriate covered alternative available at the lower co-payment:

- Specific member contraindication
- Allergy or significant adverse reaction
- Physical symptoms resulting from administration (i.e. rash with topical patch)
- Lack of efficacy following adequate trial (including dose and duration)
- Changes in therapy with high potential for adverse medical outcome

**Variation for contraceptive coverage under the Affordable Care Act:**

- Documentation for copay reduction of multi-source brand contraceptives must include a supporting statement of medical necessity from the prescribing physician with at least one of the following:
    - Generic alternative of the requested contraceptive was not as effective as the brand name medication or resulted in a significant adverse reaction or side effect
    - Change to the generic alternative of the requested contraceptive would result in significant adverse medical outcome
    - Alternative covered contraceptives would be less effective or result in adverse effects including but not limited to differences in permanence and reversibility of contraceptives
    - Ability to adhere to the appropriate use of the item or service

MVP will defer to prescriber determinations of medical necessity that are documented properly.

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## Exclusions

- Except for contraceptives covered under Women's Preventive Services of the Affordable Care Act,
    - No reduction will be considered if member contract does not have differential copayments for multi-source brand drugs.
    - No co-payment reduction will be considered if a covered therapeutic alternative at a lesser co-payment to the higher co-payment product is available.
    - No co-payment reduction will be considered when member preference or increases in member adherence are the reason for the request.
- Requests for any portion of copayment for the requested product with dates of services prior to approval of copayment reduction
- No copayment reductions will be considered for drugs coded as single-source or generics by the Pharmacy Benefit Manager (PBM).
-
-
- Off label use of medications that do not meet the Experimental policy are not eligible for copay adjustments
- Medicare Part D prescription benefits are excluded from this policy

---

## References

1. FAQS about Affordable Care Act Implementation (part XXVI), published May 11.2015.

| 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 Medicaid Managed Care | Not Covered |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Not Covered |
| MVP Complete Wellness | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
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| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
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| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| USA Care PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
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| MVP VT Plus HMO | Prior Auth |
| MVP VT HDHP HMO | Prior Auth |
| MVP VT Plus HDHP HMO | Prior Auth |
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| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

**Cosmetic Drug Agents**

| | |
|---|---|
| **Type of Policy:** | Drug Therapy |
| **Prior Approval Date:** | 04/01/2024 |
| **Approval Date:** | 04/01/2025 |
| **Effective Date:** | 06/01/2025 |
| **Related Policies:** | Cosmetic and Reconstructive Surgery<br><br>Vitiligo Treatment<br>Alopecia Treatment |

## Drugs Generally Not Covered

Refer to the MVP website for the Medicare Part D formulary for drugs that may covered under the Part D benefit.

Any drug used for a cosmetic purpose is generally not a covered pharmacy benefit. Examples are:

| Chemical Name | Brand Name Drug Examples |
|---|---|
| bimatoprost | Latisse |
| deoxycholic acid | Kybella |
| dihydroxyacetone | Chromelin, Vitadye, Dy-o-derm solution |
| eflornithine | Vaniqa |
| Finasteride 1mg | Propecia |
| hyaluronic acid, sodium hyaluronate | Perlane, Restylane, Volbella XC, Prevelle Silk, Juvederm |
| hydroquinone | Melquin, Esoterica, Aclaro, Epiquin Micro, Kaxm, Keido, Kuxm, Kutea, Remergent, Blanche cream, Esoterica, Ambi-fade, Skin Success cream, Keya |

| | |
|---|---|
| Hydroquinone-hydrocortisone-tretinoin | Kataryaxn, Ketarya, Kuvarya, Katarya, Yaxatarxyn, Yokatar, Kutaryaxmpa, Kutaryaxm |
| hydroquinone-fluocinolone-tretinoin | Tri-Luma |
| Hydroquinone-tretinoin-triamcinolone | Kuvarye, Kotaraxap, Kevaraxap |
| kinetin | Kinerase |
| minoxidil | Rogaine, Daylogic, Gainextra |
| onabotulinumtoxin A | Botox Cosmetic.<br>Botox when used for non-cosmetic purposes is eligible for coverage but is subject to prior authorization. |
| prabotuliniumtoxinA | Jeuveau |
| tazarotene | Avage.<br>Tazarotene when used for psoriasis or acne (Tazorac) does not require prior authorization |
| tesamorelin acetate | Egrifta is excluded for MVP Medicaid.<br>Egrifta does not require PA for other lines of business but is not covered when used solely for cosmetic purposes. |
| various tretinoin products labeled for facial wrinkles | Renova, Refissa |

**Overview**

Oral retinoids are indicated in the treatment of acne. Topical agents are indicated for the treatment of fine wrinkles, keratinization, photoaging, hyperpigmentation, acne, and psoriasis.

Oral and topical pigmenting and depigmenting agents are indicated for reversing depigmented areas (e.g., vitiligo). Other topical agents are indicated for reversible bleaching of hyperpigmented skin (i.e., freckles, senile lentigines, chloasma and melasma, and other forms of melanin hyperpigmentation).

Other agents, i.e., minoxidil, are indicated for hair loss.

## Indications/Criteria

- The pharmacy benefit manager's (PBM) list of agents which are commonly used for cosmetic purposes will be used to reject claims for non-covered cosmetic agents or require prior authorization which will be subject to the member's benefit and a medical necessity determination.
- Retinoid Agents: Tretinoin-type products such as Retin-A, Retin-A Micro, and Accutane are medications used in the treatment of acne vulgaris.
- Psoralen products (i.e.: Oxsoralen®) do not require prior authorization for the following conditions but formulary rules may apply:
    - Psoriasis
    - Atopic dermatitis
    - Actinic dermatitis
    - Lichen planus
    - Mycosis fungoidis
    - Other non-cosmetic indications

## Exclusions

- Retinoids, similar products (i.e., Renova, Vaniqa) and pigmenting/depigmenting agents are not covered for cosmetic or non-medically necessary reasons. This includes prevention of wrinkling of the skin and for affecting the color, tone, pigmentation, or texture of the skin
- Agents on the pharmacy benefits manager (PBM) list of agents commonly used for cosmetic purposes will be excluded or require prior authorization as defined by member benefit
- Renova and Refissa are topical medications used as adjunctive treatment of fine wrinkles, mottled hyperpigmentation, and tactile roughness of facial skin. Renova and Refissa are deemed cosmetic and therefore are not covered when excluded or requires prior authorization as defined by member benefit
- Retinoid Agents are not considered medically necessary for unlabeled uses such as actinic keratosis, flat warts in children up to age 18, various skin cancers, and various dermatologic conditions including lamellar ichthyosis, mollusca contagiosa, verrucae plantaris, verrucae planae juvenilis, hyperpigmented lesions, ichthyosis vulgaris, bullous congenital ichthyosiform, and pityroasis rubra pilaris.

- Pigmenting and Depigmenting Agents: These agents are deemed cosmetic and are not covered when excluded or require prior authorization to determine medically necessity as defined by member benefit.

| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Complete Wellness | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| USA Care PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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).** | |
| *© 2025 MVP Health Plan, Inc. All rights reserved. Descriptions contained within MVP's Medical Policies are not a guarantee of coverage. Each MVP Group or Subscriber Contract contains specific limitations, exclusions and requirements that may affect a Policy. If there is any discrepancy between your Group or Subscriber Contract and a Policy, your Group or Subscriber Contract shall in all cases govern.* | |

***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 |

**MVP Health Care Medical Policy**

**Cystic Fibrosis (select agents for inhalation)**

| | |
|---|---|
| **Type of Policy:** | Drug Therapy |
| **Prior Approval Date:** | 07/01/2023 |
| **Approval Date:** | 07/01/2024 |
| **Effective Date:** | 09/01/2024 |
| **Related Policies:** | Medicare Part B vs. Part D Determination |

**Drugs Requiring Prior Authorization (covered under the pharmacy benefit – see grid for variation)**

Bethkis (tobramycin inhalation solution –J7682)
Cayston® (aztreonam inhalation solution – J7699)
Pulmozyme® (dornase alfa inhalation solution – J7639)
TOBI®, Kitabis Pak (tobramycin inhalation solution – J7682)
TOBI Podhaler ® (tobramycin inhalation powder)
Tobramycin nebulizer solution

Refer to the Medicare Part D formulary for drugs that may be covered under the Part D benefit.

**Overview**

In cystic fibrosis (CF) patients, retention of viscous purulent secretions in the airways contributes both to reduced pulmonary function and to exacerbations of infection. Purulent pulmonary secretions contain very high concentrations of extracellular DNA released by degenerating leukocytes that accumulate in response to infection.

Dornase alfa is a solution of recombinant human deoxyribonuclease I (rhDNase), an enzyme which selectively cleaves DNA. Dornase alfa hydrolyzes the DNA in sputum of CF patients and reduces sputum viscoelasticity. Daily administration of dornase alpha in conjunction with standard therapies is indicated in the management of cystic fibrosis patients to improve pulmonary function. In patients with an FVC ≥40% of predicted, daily administration of Pulmozyme has also been shown to reduce the risk of respiratory tract infections requiring parenteral antibiotics.

Tobramycin is an aminoglycoside antibiotic produced by *Streptomyces tenebrarius*. It acts primarily by disrupting protein synthesis, leading to altered cell membrane permeability, progressive disruption of the cell envelope, and eventual cell death. Tobramycin inhalation solution is indicated for the management of cystic fibrosis patients with *P. aeruginosa*. An inhalation powder formulation is also available for tobramycin and is dispensed through the Podhaler® device.

Aztreonam is a monobactam antibacterial agent which exhibits activity *in vitro* against Gram-negative aerobic pathogens including *P. aeruginosa*. Aztreonam binds to penicillin binding proteins of susceptible bacteria, which leads to inhibition of bacterial cell wall synthesis and death of the cell[5].

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**Indications/Criteria**

ALL the following criteria must be met for coverage:

- Ordered by a pulmonologist
- For Dornase alfa inhalation solution:
    - Coverage will be considered medically necessary when the member has a diagnosis of cystic fibrosis
- For Tobramycin inhalation solution/powder and aztreonam inhalation solution:
    - Coverage will be considered medically necessary when:
    - the member has a diagnosis of cystic fibrosis
      **AND**
    - sputum culture is positive for *Pseudomonas. Aeruginosa* as confirmed by culture results

**Initial** approval will be for up to a maximum of 1 year.
**Extensions** of therapy will be considered for up to a maximum of 3 years if the member has evidence of disease stability or improvement such as:

- continued benefit from therapy (e.g., decrease in lung infections, improvement in symptoms, decrease in intravenous medications for lung infections),
- improved FEV1 (from baseline)
- decrease in sputum density of *P. Aeruginosa* for tobramycin and aztreonam inhalation solution.

**Medicare Variation**

Medicare requires B vs. D determination for all Medicare beneficiaries. If the medication is determined to fall under the Part B/DME benefit, a prescription rider is not required

but medication must be adjudicated on-line to the pharmacy benefit manager. Please refer to the Local Coverage Determination article **L33370 AND** the National Coverage Determination policy article **A52466** for the appropriate coverage of nebulized products.

**Exclusions:**

- Age, dose, frequency, outside of the FDA package label.
- TOBI, Kitabis Pak and aztreonam inhalation solution are not covered in patients with FEV1 <25% or >75% predicted.
- TOBI Podhaler will not be covered in patients with FEV1 <25% or >80% predicted
- Bethkis is not covered in patients with FEV1 <40% or >80% predicated
- Tobramycin and aztreonam inhalation solution in patients colonized with Burkholderia cepacia.

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2. TOBI® (tobramycin inhalation solution). Prescribing Information. East Hanover, NJ: Novartis Pharmaceutical Corporation; October 2018.
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7. National Coalition for Health Professional Education in Genetics. Cystic Fibrosis-Gene Mutations and CFTR Protein [Internet]. Available from: http://www.nchpeg.org/nutrition/index.php?option=com_content&view=article&id=462&Itemid=564&limitstart=4.
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15. NHIC, Inc. Article for Nebulizers (A52466). Original Article Effective Date 10/1/2015. Revised Effective Date 01/01/2024. Available from: Article - Nebulizers - Policy Article (A52466) (cms.gov)

| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Medicare Gold Giveback | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D |
| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

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| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Complete Wellness | Refer |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D |
| USA Care 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 |

**MVP Health Care Medical Policy**

**Cystic Fibrosis (select oral agents)**

| | |
|---|---|
| **Type of Policy:** | Drug Therapy |
| **Prior Approval Date:** | 07/01/2023 |
| **Approval Date:** | 04/01/2024 |
| **Effective Date:** | 04/01/2024 |
| **Related Policies:** | Cystic Fibrosis (select agents for inhalation) |

## Drugs Requiring Prior Authorization (covered under the pharmacy benefit )

Kalydeco® (ivacaftor) tablets, oral granules
Orkambi™ (lumacaftor/ivacaftor) tablets
Symdeko™ (tezacaftor/ivacaftor) tablets
Trikafta® (elexacaftor/ tezacaftor/ ivacaftor)

Refer to the Medicare Part D formulary for drugs that may be covered under the Part D benefit.

## Overview

In cystic fibrosis (CF) patients, retention of viscous purulent secretions in the airways contributes both to reduced pulmonary function and to exacerbations of infection. Purulent pulmonary secretions contain very high concentrations of extracellular DNA released by degenerating leukocytes that accumulate in response to infection.

Ivacaftor potentiates the action of the transmembrane conductance regulator (CFTR) protein in patients in whom these channels are not properly regulated but still maintain some degree of function. It is indicated for patients with one mutation in the CFTR gene that is responsive to ivacaftor based on clinical and/or in vitro assay data. Specific responsive genes can be found in the package insert for Kalydeco, see link below.

Combination lumacaftor and ivacaftor (Orkambi) is a CFTR potentiator, indicated for patients who are homozygous for the *F508del* mutation in the CFTR gene.

Combination tezacaftor and ivacaftor work together to increase chloride transport and the function of the cystic fibrosis CFTR protein. It is indicated for patients who are

homozygous for the F508del mutation or have at least one mutation in the CFTR gene that is responsive to tezacaftor and ivacaftor.

Combination elexacaftor, tezacaftor and ivacaftor work together to increase chloride transport and the function of the cystic fibrosis CFTR protein. It is indicated for patients with at least 1 F508del mutation in the CTFR gene.

---

**Indications/Criteria**

**A. For all medications listed in this policy, all of the following criteria must be met in addition to the specific medication criteria below.**

- Ordered by a pulmonologist **AND**
- Baseline BMI and percent predictive $FEV_1$ ($ppFEV_1$) must be provided **AND**
    - For pediatric members less than 5 years old spirometry should be attempted as early as age 3 depending on the developmental stage of the individual child. Requests for pediatric cases without spirometry will be reviewed on a case-by-case basis.

- Member has a confirmed diagnosis of cystic fibrosis

**B. Kalydeco**

In addition to section A, all the following criteria must be met for coverage for Kalydeco:

- Member has a diagnosis of cystic fibrosis **AND** documentation of an FDA cleared CF mutation test detecting the presence of mutation of a CFTR gene indicated in the Kalydeco package insert as responsive to Kalydeco based on clinical and/or in vitro assay data.
    - Please reference the Kalydeco package insert here: https://pi.vrtx.com/files/uspi_ivacaftor.pdf
    - If the patient's genotype is unknown, documentation should be provided of an FDA cleared CF mutation test detecting the presence of a CFTR mutation followed by verification with bi-directional sequencing when recommended by the mutation test instructions for use

**B. Orkambi**

In addition to section A , all the following must be met for coverage of Orkambi:

- $ppFEV_1$ must be greater than or equal to 40% at the start of therapy

- Member has a diagnosis of cystic fibrosis **AND** documentation of a homozygous F508del mutation in the CFTR gene.
  - If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of F508del mutation on both alleles of the CFTR gene

**C. Symdeko**

In addition to section A, all the following must be met for coverage of Symdeko:

- Must have documentation that the member is homozygous for the F508del mutation **OR** have at least 1 mutation in the CFTR gene that is responsive to tezacaftor; ivacaftor.
  - If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of a CFTR mutation followed by verification with bi-directional sequencing when recommended by the mutation test instructions for use.

**D. Trikafta**

In addition to section A, all the following must be met for Trikafta:

- Documentation of at least one F508del mutation in the CFTR gene OR a mutation in the CFTR gene that is responsive based on in vitro data.
  - If genotype is unknown, an FDA-cleared Cystic Fibrosis mutation test must be used to confirm the presence of at least one F508del mutation or a mutation that is responsive based on *in vitro* data

**For Kalydeco, Orkambi, Symdeko and Trikafta:**

**Initial** approval will be for 6 months

**Extensions** will be for 12 months if the member meets **<u>two</u>** of the following:

1. Stabilization or improvement in ppFEV$_1$ from baseline
2. Increase in BMI from baseline
3. Decrease in the number of pulmonary exacerbations from baseline

---

**Exclusions**

- Age, dose, frequency, outside of the FDA package label.
- Kalydeco in patients homozygous for the F508del mutation in the CFTR gene

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**References**

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| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Medicare Gold Giveback | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |

| | |
|---|---|
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D |
| 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).** | |
| *© 2024 MVP Health Plan, Inc. All rights reserved. Descriptions contained within MVP's Medical Policies are not a guarantee of coverage. Each MVP Group or Subscriber Contract contains specific limitations, exclusions and requirements that may affect a Policy. If there is any discrepancy between your Group or Subscriber Contract and a Policy, your Group or Subscriber Contract shall in all cases govern.* | |

***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 |

**MVP Health Care Medical Policy**

**Daybue™ (trofinetide)**

**Type of Policy:** **Drug Therapy**
**Prior Approval Date:** **11/01/2023**
**Approval Date:** **11/01/2024**
**Effective Date:** **01/01/2025**

**Related Policies:** **Genetic and Molecular Diagnostic Testing**

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies.

## Drugs Requiring Prior Authorization under the pharmacy benefit

Daybue (trofinetide) Oral Solution

## Overview

Daybue™ (trofinetide) is an is a synthetic analog of a naturally occurring molecule known as the tripeptide glycine-proline-glutamate (GPE), a cleavage product of insulin-like growth factor-1 (IGF-1) indicated for the treatment of Rett Syndrome (RTT) in patients ages 2 and older.

RTT is a rare genetic neurodevelopmental disorder affecting mostly females. In most patients, RTT is caused by mutations in the Methyl-CpG-binding protein 2 (MECP2) gene, which is found on the X chromosome. MECP2 is an essential gene for normal brain development and function. A blood test can confirm the presence of the MECP2 mutation; however, since this mutation is seen in other disorders, the presence of the mutation itself is not sufficient to diagnosis RTT. Therefore, diagnosis of RTT also requires a clinical diagnosis based on observed signs and symptoms. Patients with RTT experience a progressive loss of motor skills and language. Between 6 and 18 months of age babies lose their ability to walk and communicate and may experience breathing

difficulties, cardiac issues, swallowing and digestion abnormalities, scoliosis, and epileptic seizures.

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**Indications/Criteria**

Daybue may be considered for coverage when the following criteria is met:

- Member has a confirmed Rett Syndrome (RTT) diagnosis
    - Diagnosis of typical (or classic) and atypical (or variant) RTT requires observed postnatal deceleration of head growth and a period of regression followed by recovery or stabilization period.
- For members with Typical RTT, the followingclinical criteria must be met:
    - ALL **Main Criteria** and ALL **Exclusion Criteria** listed below.
- For members with Atypical RTT, the following following clinical criteria must be met:
    - At least 2 of 4 **Main Criteria AND**
    - At least 5 of 11 **Supportive Criteria** listed below.
- **Main Criteria**
    - Partial or complete loss of acquired purposeful hand skills
    - Partial or complete loss of acquired spoken language
    - Gait abnormalities (impaired (dyspraxic) or absence of ability)
    - Stereotypic hand movements (hand wringing/squeezing, clapping/tapping, mouthing, washing/rubbing automatisms)
- **Exclusion Criteria**
    - Brain injury secondary to trauma (peri- or post-natally), neurometabolic disease, or severe infection that causes neurological problems. Neurological or ophthalmological examination and MRI/CT documenting insult.
    - Grossly abnormal psychomotor development in first 6 months of life.
- **Supportive Criteria**
    - Breathing disturbances when awake
    - Bruxism when awake
    - Impaired sleep pattern
    - Abnormal muscle tone
    - Peripheral vasomotor disturbances
    - Scoliosis/kyphosis
    - Growth retardation

- Small, cold hands and feet
- Inappropriate laughing or screaming spells
- Diminished response to pain
- "Eye pointing"/intense eye communication

**Initial approval** will be for 6 months.

**Extension requests** will be approved for up to 12 months based on documentation of continued benefit to therapy and improvement in Rett syndrome symptomatology.

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**Exclusions**

The use of Daybue™ (trofinetide) will not be covered for the following situations:

Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling **References**


1. DAYBUE™ (trofinetide) oral solution. Prescribing Information. San Diego, CA. Acadia Pharmaceuticals, Inc.; March 2023.

2. Clinical Pharmacology. Trofinetide. Revised 04/14/2023. Accessed 06/02/2023.

3. Neul JL, Kaufmann WE, Glaze DG, et al for the RettSearch Consortium. Rett syndrome: revised diagnostic criteria and nomenclature. *Ann Neurol*. 2010;68(6):944-950.

4. Vidal S, Xiol C, Pascual-Alonso A, O'Callaghan M, Pineda M, Armstrong J. Genetic Landscape of Rett Syndrome Spectrum: Improvements and Challenges. Int J Mol Sci. 2019;20(16):3925. Published 12 Aug 2019.

5. Amir RE, Van den Veyver IB, Wan M, et al. Rett syndrome is caused by mutations in X-linked MECP2, encoding methyl-CpG-binding protein 2. *Nat Genet*. 1999;23(2):185-188.

6. Percy AK, Neul JL, Glaze DG, et al. Rett syndrome diagnostic criteria: Lessons from the Natural History Study. *Ann Neurol*. 2010;68(6):951-955.

7. Tillotson R, Bird A. The molecular basis of MeCP2 function in the brain. *J Mol Biol*. 2019;S0022-2836(19)30595-3059.

8. Neul JL, Glaze DG, Percy AK, et al. Improving treatment trial outcomes for Rett syndrome: the development of Rett-specific anchors for the Clinical Global Impression Scale. *J Child Neurol*. 2015;30(13):1743-1748.

9. *Acadia Pharmaceuticals*. (September 2024). Daybue (trofinetide). https://daybuehcp.com

10. Fu C, Armstrong D, Marsh E, Lieberman D, Motil K, Witt R, Standridge S, Nues P, Lane J, Dinkel T, Coenraads M, von Hehn J, Jones M, Hale K, Suter B, Glaze D, Neul J, Percy A, Benke T. Consensus guidelines on managing Rett syndrome across the lifespan. BMJ Paediatr Open. 2020 Sep 13;4(1):e000717. doi: 10.1136/bmjpo-2020-000717. PMID: 32984552; PMCID: PMC7488790.

| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Complete Wellness | Refer |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D |
| USA Care 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 | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

**Dojolvi**

**Type of Policy:** **Drug Therapy**
**Prior Approval Date:** **10/01/2023**
**Approval Date:** **10/01/2024**
**Effective Date:** **01/01/2025**
**Related Policies:** **Enteral Therapy Vermont, Enteral Therapy New York**

Refer to the Medicare Part D formulary for drugs that may be covered under the Part D benefit.

**Drugs Requiring Prior Authorization (covered under the pharmacy benefit)**
Dojolvi (triheptanoin) oral liquid

## Overview

Dojolvi is an oral liquid source of calories and fatty acids consisting of three odd-chain 7-carbon length fatty acids (heptanoate) that bypass the long-chain FAOD enzyme deficiencies for energy production and replacement for pediatric and adult patients with molecularly confirmed long-chain fatty acid oxidation disorders (LC-FAODs). LC-FAODs are a group of rare, inborn errors of metabolism in which the body is unable to convert long-chain fatty acids into energy.

## Indications/Criteria

Coverage is considered medically necessary when the following criteria is met:

1. Documented diagnosis of LC-FAOD confirmed by at least TWO of the following:
    a. Disease specific elevation of acylcarnitines on a newborn blood spot or in plasma
    b. Low enzyme activity in cultured fibroblasts (very long-chain acyl-CoA dehydrogenase (VLCAD) deficiency, carnitine palmitoyltransferease I (CPT I) or II (CPT II) deficiency, carnitine-acylcarnitine translocase (CACT) deficiency, trifunctional protein (TFP) deficiency, long-chain 3-hydroxyacyl-CoA dehydrogenase deficiency (LCHAD))

   c. One or more known pathogenic mutations in CPT2, ACADVL, HADHA, or HADHB
2. Currently managed on a stable treatment regimen including diet (such as a low fat, high carbohydrate diet, fasting avoidance, carnitine and /or MCT oil)
3. Documentation indicating symptomatic clinical manifestations of LC-FAOD despite current management such as:
   - Episodes of hypoglycemia, rhabdomyolysis, or exacerbation of cardiomyopathy requiring emergency room visits, acute care visits or hospitalizations
   - Evidence of functional cardiomyopathy documenting poor ejection fraction requiring ongoing medical management

**Initial authorization** will be granted for 12 months

**Subsequent authorizations** up to 12 months will be granted with documentation of continued clinical benefit and continued compliance with dietary management

**Exclusions**

- Indication, age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling
- Use in combination with:
  - Pancreatic lipase inhibitors
  - Another medium-chain triglyceride (MCT) product
- Pancreatic insufficiency
- Doses exceeding 35% of members total prescribed daily caloric intake

**References**

1. Dojolvi (triheptanoin) oral liquid. Prescribing Information. September 2020. Ultragenyx Pharmaceutical Inc. Novato, CA.
2. Dojolvi. Ultragenyx Pharmaceutical Inc. Available at: https://www.dojolvi.com/?utm_source=google&utm_medium=cpc&utm_campaign=22_Dojolvi_DTC_Branded_Brand&utm_content=General%20%7C%20Exact&utm_term=dojolvi%20prescribing%20information&gclid=Cj0KCQjw852XBhC6ARIsAJsFPN0PRfhRnarEwd5EuirF8NK2gtDfqtHF8RcQMNnGvL8P371BI4KWjJEaAk1vEALw_wcB&gclsrc=aw.ds
3. Dojolvi (triheptanoin) oral liquid. Prescribing Information. September 2020. Revised 11/2021. Ultragenyx Pharmaceutical Inc. Novato, CA.
4. Dojolvi (triheptanoin) oral liquid. Prescribing Information. Revised 10/2023. Ultragenyx Pharmaceutical Inc. Novato, CA.

Erru Yang, Eliza Kruger, Major clinical events and healthcare resource use among patients with long-chain fatty acid oxidation disorders in the United States: Results from LC-FAOD Odyssey program, Molecular Genetics and Metabolism,Volume 142, Issue 1, 2024, 108350,ISSN 1096-7192, https://doi.org/10.1016/j.ymgme.2024.108350.

| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Medicare Gold Giveback | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D |
| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

# Donislecel

**Type of Policy:** Drug Therapy
**Prior Approval Date:** 02/01/2024
**Approval Date:** 02/01/2025
**Effective Date:** 04/01/2025
**Related Policies:** Teplizumab

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies.

## Drugs Requiring Prior Authorization under the medical benefit

J3590 donislecel-JUJN, IV suspension (Lantidra)

## Overview

Donislecel is the first allogeneic (donor) pancreatic islet cellular therapy made from deceased donor pancreatic cells. It is indicated for the treatment of adults with type 1 diabetes mellitus (T1DM) who are unable to approach target hemoglobin A1C because of current repeated episodes of severe hypoglycemia despite intensive T1DM management and education.

The primary mechanism of action of donislecel is believed to be secretion of insulin by infused (transplanted) pancreatic beta cells. Pancreatic islets regulate blood glucose levels through secretion of multiple hormones in response to increases and decreases in blood glucose. Endocrine cells within pancreatic islets release insulin, glucagon, somatostatin, pancreatic peptide, and ghrelin. Insulin stimulates glucose uptake by peripheral tissues; glucagon mobilizes glucose from the liver into circulation; somatostatin inhibits both alpha and beta cell secretions; pancreatic peptide inhibits pancreatic exocrine secretion; and ghrelin inhibits insulin secretion.

## Indications/Criteria

### Type 1 Diabetes

Lantidra (donislecel) may be considered for coverage when:

- Prescribed by or in consultation with an endocrinologist
- Member is between18 years and <65 years of age
    - Safety and effectiveness has not been established in patients greater than 65 years of age
- Member has a confirmed diagnosis of Type 1 diabetes for more than 5 years AND one of the following complications:
    - Documentation of at least one episode of severe hypoglycemia in the past 3 years. Defined as:
        - Member required assistance from another person **AND**
        - Member had a blood glucose level <50mg/dL **OR**
        - Member recovered after oral carbohydrate, intravenous glucose or glucagon administration.
    - Reduced awareness of hypoglycemia
        - Defined as the absence of autonomic symptoms at capillary glucose levels of <54mg/dL.
- Documentation that member is unable to approach target HbA1c due to current repeated episodes of severe hypoglycemia.
- Documentation of intensive diabetes management and education.
- Documentation of PCP and CMV prophylaxis or Provider attestation that they will be provided.
- Documentation that member is up to date with all vaccinations prior to initiating therapy.
- Provider attestation that immunosuppression will continue permanently to prevent islet graft rejection.
- Documentation of negative T-cell and B-cell crossmatch assay.
    - Members with a positive T-cell and B-cell crossmatch between recipient serum and donor lymphocytes may reject the islet cells.
- If applicable, documentation of previous donislecel infusion including the date of infusion(s).

**Initial approval for the first infusion** will be for one infusion within 12 months.

Donislecel is eligible for 3 infusions total. **Extension requests** for a second or third infusion may be considered medically necessary when the following criteria are met in addition to updated clinical chart notes addressing all criteria above:

- A second infusion may be administered if the member does not achieve independence from exogenous insulin within one year of infusion or within one year after losing independence from exogenous insulin after a previous infusion. Approval will be for one infusion within 12 months.
    - Claims history is subject to review.
    - Not covered for members who experienced prior portal thrombosis, unless the thrombosis was limited to second- or third-order portal vein branches

- A third infusion may be administered using the same criteria as the second infusion. Approval will be for one infusion within 12 months.
    - Claims history is subject to review.
    - Not covered for members who experienced prior portal thrombosis, unless the thrombosis was limited to second- or third-order portal vein branches

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**Exclusions**

The use of donislecel will not be covered for the following situations:

- Members whom immunosuppression is contraindicated.
- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling.
- More than 3 infusions per lifetime.
- Member is pregnant
- Renal failure
- Hepatic disease
    - Liver Function Tests (LFTs) outside normal range
- Not covered for members who experienced prior portal thrombosis, unless the thrombosis was limited to second- or third-order portal vein branches

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**References**

1. Clinical Pharmacology. Donislecel. Revision date July 21, 2023. Accessed December 5, 2023.

2. Lantidra. Package Insert. Cell Trans. Chicago IL. June 2023. Package Insert - LANTIDRA (fda.gov)

3. Results Posted | Islet Transplantation in Type 1 Diabetic Patients Using the Edmonton Protocol of Steroid Free Immunosuppression | ClinicalTrials.gov

4. Islet Transplantation for Brittle Type 1 Diabetes: The UIC Protocol - American Journal of Transplantation (amjtransplant.org)

5. Study Details | Islet Transplantation in Type 1 Diabetic Patients Using the University of Illinois at Chicago (UIC) Protocol | ClinicalTrials.gov

| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Complete Wellness | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| USA Care PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

# Medicare Part B: Donislecel

**Type of Policy:** Drug Therapy
**Prior Approval Date:** 02/01/2024
**Approval Date:** 02/01/2025
**Effective Date:** 04/01/2025
**Related Policies:** Teplizumab

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies.

## Drugs Requiring Prior Authorization under the medical benefit

J3590 donislecel-JUJN, IV suspension

## Overview/Summary of Evidence

Donislecel is the first allogeneic (donor) pancreatic islet cellular therapy made from deceased donor pancreatic cells. It is indicated for the treatment of adults with type 1 diabetes mellitus (T1DM) who are unable to approach target hemoglobin A1C because of current repeated episodes of severe hypoglycemia despite intensive T1DM management and education.

The primary mechanism of action of donislecel is believed to be secretion of insulin by infused (transplanted) pancreatic beta cells. Pancreatic islets regulate blood glucose levels through secretion of multiple hormones in response to increases and decreases in blood glucose. Endocrine cells within pancreatic islets release insulin, glucagon, somatostatin, pancreatic peptide, and ghrelin. Insulin stimulates glucose uptake by peripheral tissues; glucagon mobilizes glucose from the liver into circulation; somatostatin inhibits both alpha and beta cell secretions; pancreatic peptide inhibits pancreatic exocrine secretion; and ghrelin inhibits insulin secretion.

## Indications/Criteria

### Type 1 Diabetes

Lantidra (donislecel) may be considered for coverage when:

- Prescribed by or in consultation with an endocrinologist
- Member is between18 years and <65 years of age
    - Safety and effectiveness has not been established in patients greater than 65 years of age
- Member has a confirmed diagnosis of Type 1 diabetes for more than 5 years AND one of the following complications:
    - Documentation of at least one episode of severe hypoglycemia in the past 3 years. Defined as:
        - Member required assistance from another person **AND**
        - Member had a blood glucose level <50mg/dL **OR**
        - Member recovered after oral carbohydrate, intravenous glucose or glucagon administration.
    - Reduced awareness of hypoglycemia
        - Defined as the absence of autonomic symptoms at capillary glucose levels of <54mg/dL.
- Documentation that member is unable to approach target HbA1c due to current repeated episodes of severe hypoglycemia.
- Documentation of intensive diabetes management and education.
- Documentation of PCP and CMV prophylaxis or Provider attestation that they will be provided.
- Documentation that member is up to date with all vaccinations prior to initiating therapy.
- Provider attestation that immunosuppression will continue permanently to prevent islet graft rejection.
- Documentation of negative T-cell and B-cell crossmatch assay.
    - Members with a positive T-cell and B-cell crossmatch between recipient serum and donor lymphocytes may reject the islet cells.
- If applicable, documentation of previous donislecel infusion including the date of infusion(s).

**Initial approval for the first infusion** will be for one infusion within 12 months.

Donislecel is eligible for 3 infusions total. **Extension requests** for a second or third infusion may be considered medically necessary when the following criteria are met in addition to updated clinical chart notes addressing all criteria above:

- A second infusion may be administered if the member does not achieve independence from exogenous insulin within one year of infusion or within one year after losing independence from exogenous insulin after a previous infusion. Approval will be for one infusion within 12 months.
    - Claims history is subject to review.
    - Not covered for members who experienced prior portal thrombosis, unless the thrombosis was limited to second- or third-order portal vein branches

- A third infusion may be administered using the same criteria as the second infusion. Approval will be for one infusion within 12 months.
    - Claims history is subject to review.
    - Not covered for members who experienced prior portal thrombosis, unless the thrombosis was limited to second- or third-order portal vein branches

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**Exclusions**

The use of donislecel will not be covered for the following situations:

- Members whom immunosuppression is contraindicated.
- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling.
- More than 3 infusions per lifetime.
- Member is pregnant
- Renal failure
- Hepatic disease
    - Liver Function Tests (LFTs) outside normal range
- Not covered for members who experienced prior portal thrombosis, unless the thrombosis was limited to second- or third-order portal vein branches

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**References**

1. Clinical Pharmacology. Donislecel. Revision date July 21, 2023. Accessed December 5, 2023.

2. Lantidra. Package Insert. Cell Trans. Chicago IL. June 2023. Package Insert - LANTIDRA (fda.gov)

3. Results Posted | Islet Transplantation in Type 1 Diabetic Patients Using the Edmonton Protocol of Steroid Free Immunosuppression | ClinicalTrials.gov

4. Islet Transplantation for Brittle Type 1 Diabetes: The UIC Protocol - American Journal of Transplantation (amjtransplant.org)

5. Study Details | Islet Transplantation in Type 1 Diabetic Patients Using the University of Illinois at Chicago (UIC) Protocol | ClinicalTrials.gov

**MVP Health Care Medical Policy**

# Dose Rounding for Systemic Therapy

| | |
|---|---|
| **Type of Policy:** | **Drug/Medical Therapy** |
| **Prior Approval Date:** | **11/01/2023** |
| **Approval Date:** | **12/01/2024** |
| **Effective Date:** | **02/01/2025** |

**Related Policies:**

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies.

## Overview

As part of an effort to work with our providers to reduce waste, minimize healthcare worker exposure, ensure treatment accuracy, and reduce the total cost of cancer care, Optum's Cancer Guidance Program is implementing dose rounding on select cancer drugs (see Definitions for full list of drugs).

The Hematology/Oncology Pharmacy Association (HOPA) position statement supports rounding of biologic and cytotoxic agents within 10% of the ordered dose as routine clinical care. The HOPA position statement has been reviewed and endorsed by the National Comprehensive Cancer Network (NCCN) and published by the American Society of Clinical Oncology (ASCO).

In line with this guidance, Optum's Cancer Guidance Program will round a select set of cancer drugs down to the nearest vial size in cases where rounding would result in fewer vials used per treatment without reducing treatment efficacy (i.e., rounding down less than 10%).

## Considerations

Optum's Cancer Guidance Program (CGP) is implementing dose rounding on select cancer drugs (see table for full list of drugs). Working with providers to reduce waste,

ensure treatment accuracy, ensure treatment efficacy, and reduce the total cost of cancer care.

**Recommendation**

When a provider, or operations user, submits a prior authorization request through MBMNow, Optum's Cancer Guidance Program automatically determines cases where dose rounding would apply and calculate the per treatment dosage based on the member's height and/or weight, and the NCCN-recommended dosage for that regimen.

A rounded dose is recommended in cases where rounding down (less than 10%) the NCCN recommendation per treatment results in the use of fewer vial(s) and less waste. If rounding down will not result in the use of fewer vial(s) per treatment, dose rounding is not applied.

- If the rounded dose is accepted by the provider (when offered in MBMNow), the request may be able to be automatically approved. The authorization will include the total approved billable units for the course of the treatment based on the rounded dose and the approved cycles.
    - If the member's weight changes significantly (>=10%) during the course of therapy, a new authorization will need to be submitted to ensure the total authorized dose is not exceeded.
- If the rounded dose is not accepted, the request will require custom review and a Cancer Guidance Program Nurse may reach out for more information.

Acceptance of rounded dose is voluntary and is not required to receive a prior authorization for cancer treatment. Clinicians must use independent medical judgment in the context of individual clinical circumstances to determine any member's care or treatment. Care decisions are between the provider and member.

---

**Drug table for Dose Rounding**

| HCPCS Code | Drug |
|---|---|
| J0893 | Decitabine(sun pharma) |
| J0894 | Decitabine (Dacogen®) |
| J9025 | Azacitidine (Vidaza®) |
| J9033 | Bendamustine (Treanda®) |
| J9034 | Bendamustine (Bendeka®) |
| J9035 | Bevacizumab (Avastin®) |
| J9036 | Bendamustine HCl (Belrapzo®) |
| J9041 | Bortezomib (Velcade®) |

| | |
|---|---|
| J9042 | Brentuximab (Adcetris®) |
| J9043 | Cabazitaxel (Jevtana®) |
| J9046 | Bortezomib(dr. reddy's) |
| J9047 | Carfilzomib (Kyprolis®) |
| J9048 | Bortezomib(Fresenius kabi) |
| J9049 | Bortezomib(Hospira) |
| J9055 | Cetuximab (Erbitux®) |
| J9056 | Bendamustine(Vivimusta) |
| J9058 | Bendamustine(Apotex) |
| J9059 | Bendamustine(Baxter) |
| J9145 | Daratumumab (Darzalex®) |
| J9176 | Elotuzumab (Empliciti®) |
| J9179 | Eribulin Mesylate (Halaven®) |
| J9207 | Ixabepoline (Ixempra®) |
| J9228 | Ipilimumab (Yervoy®) |
| J9271 | Pembrolizumab (Keytruda®) |
| J9294 | Pemetrexed(Hospira) |
| J9296 | Pemetrexed(Accord) |
| J9297 | Pemetrexed(Sandoz) |
| J9299 | Nivolumab (Opdivo®) |
| J9303 | Panitumumab (Vectibix®) |
| J9304 | Pemetrexed (Pemfexy®) |
| J9305 | Pemetrexed (Alimta®) |
| J9312 | Rituximab (Rituxan®) |
| J9314 | Pemetrexed(teva) |
| J9322 | Pemetrexed(Bluepoint) |
| J9323 | Pemetrexed ditromethamine |
| J9324 | Pemetrexed (Pemrydi RTU®) |
| J9352 | Trabectedin (Yondelis®) |
| J9354 | Ado-trastuzumab emtansine (Kadcyla®) |
| Q2050 | Doxorubicin, Liposomal (Doxil®) |
| Q5107 | Bevacizumab-awwb, biosimilar (Mvasi™) |
| Q5115 | Rituximab-abbs, biosimilar (Truxima®) |
| Q5118 | Bevacizumab-bvzr, biosimilar (Zirabev®) |
| Q5119 | Rituximab-pvvr, biosimilar (Ruxience®) |
| Q5123 | Rituximab-arrx, biosimilar (Riabni®) |
| Q5126 | Bevacizumab-maly, biosimilar (Alymsys®) |
| Q5129 | Bevacizumab-adcd, biosimilar (Vegzelma®) |

## References

1. Dose Rounding of Biologic and Cytotoxic Anticancer Agents. A Position State of the Hematology/Oncology Pharmacy Association. Available at www.hopa.org. Accessed March 30, 2023.

| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Complete Wellness | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| USA Care PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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).** | |
| *© 2025 MVP Health Plan, Inc. All rights reserved. Descriptions contained within MVP's Medical Policies are not a guarantee of coverage. Each MVP Group or Subscriber Contract contains specific limitations, exclusions and requirements that may affect a Policy. If there is any discrepancy between your Group or Subscriber Contract and a Policy, your Group or Subscriber Contract shall in all cases govern.* | |

***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 |

**MVP Health Care Medical Policy**

# Medicare Part B: Dose Rounding for Systemic Therapy

| | |
|---|---|
| **Type of Policy:** | **Drug/Medical Therapy** |
| **Prior Approval Date:** | **NA** |
| **Approval Date:** | **12/01/2024** |
| **Effective Date:** | **02/01/2025** |
| **Related Policies:** | **NA** |

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies.

## Overview

As part of an effort to work with our providers to reduce waste, minimize healthcare worker exposure, ensure treatment accuracy, and reduce the total cost of cancer care, Optum's Cancer Guidance Program is implementing dose rounding on select cancer drugs (see Definitions for full list of drugs).

The Hematology/Oncology Pharmacy Association (HOPA) position statement supports rounding of biologic and cytotoxic agents within 10% of the ordered dose as routine clinical care. The HOPA position statement has been reviewed and endorsed by the National Comprehensive Cancer Network (NCCN) and published by the American Society of Clinical Oncology (ASCO).

In line with this guidance, Optum's Cancer Guidance Program will round a select set of cancer drugs down to the nearest vial size in cases where rounding would result in fewer vials used per treatment without reducing treatment efficacy (i.e., rounding down less than 10%).

## Considerations

Optum's Cancer Guidance Program (CGP) is implementing dose rounding on select cancer drugs (see table for full list of drugs). Working with providers to reduce waste,

ensure treatment accuracy, ensure treatment efficacy, and reduce the total cost of cancer care.

**Recommendation**

When a provider, or operations user, submits a prior authorization request through MBMNow, Optum's Cancer Guidance Program automatically determines cases where dose rounding would apply and calculate the per treatment dosage based on the member's height and/or weight, and the NCCN-recommended dosage for that regimen.

A rounded dose is recommended in cases where rounding down (less than 10%) the NCCN recommendation per treatment results in the use of fewer vial(s) and less waste. If rounding down will not result in the use of fewer vial(s) per treatment, dose rounding is not applied.

- If the rounded dose is accepted by the provider (when offered in MBMNow), the request may be able to be automatically approved. The authorization will include the total approved billable units for the course of the treatment based on the rounded dose and the approved cycles.
    - If the member's weight changes significantly (>=10%) during the course of therapy, a new authorization will need to be submitted to ensure the total authorized dose is not exceeded.
- If the rounded dose is not accepted, the request will require custom review and a Cancer Guidance Program Nurse may reach out for more information.

Acceptance of rounded dose is voluntary and is not required to receive a prior authorization for cancer treatment. Clinicians must use independent medical judgment in the context of individual clinical circumstances to determine any member's care or treatment. Care decisions are between the provider and member.

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**Drug table for Dose Rounding**

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| J9033 | Bendamustine (Treanda®) |
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| | |
|---|---|
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| J9047 | Carfilzomib (Kyprolis®) |
| J9048 | Bortezomib(Fresenius kabi) |
| J9049 | Bortezomib(Hospira) |
| J9055 | Cetuximab (Erbitux®) |
| J9056 | Bendamustine(Vivimusta) |
| J9058 | Bendamustine(Apotex) |
| J9059 | Bendamustine(Baxter) |
| J9145 | Daratumumab (Darzalex®) |
| J9176 | Elotuzumab (Empliciti®) |
| J9179 | Eribulin Mesylate (Halaven®) |
| J9207 | Ixabepoline (Ixempra®) |
| J9228 | Ipilimumab (Yervoy®) |
| J9271 | Pembrolizumab (Keytruda®) |
| J9294 | Pemetrexed(Hospira) |
| J9296 | Pemetrexed(Accord) |
| J9297 | Pemetrexed(Sandoz) |
| J9299 | Nivolumab (Opdivo®) |
| J9303 | Panitumumab (Vectibix®) |
| J9304 | Pemetrexed (Pemfexy®) |
| J9305 | Pemetrexed (Alimta®) |
| J9312 | Rituximab (Rituxan®) |
| J9314 | Pemetrexed(teva) |
| J9322 | Pemetrexed(Bluepoint) |
| J9323 | Pemetrexed ditromethamine |
| J9324 | Pemetrexed (Pemrydi RTU®) |
| J9352 | Trabectedin (Yondelis®) |
| J9354 | Ado-trastuzumab emtansine (Kadcyla®) |
| Q2050 | Doxorubicin, Liposomal (Doxil®) |
| Q5107 | Bevacizumab-awwb, biosimilar (Mvasi™) |
| Q5115 | Rituximab-abbs, biosimilar (Truxima®) |
| Q5118 | Bevacizumab-bvzr, biosimilar (Zirabev®) |
| Q5119 | Rituximab-pvvr, biosimilar (Ruxience®) |
| Q5123 | Rituximab-arrx, biosimilar (Riabni®) |
| Q5126 | Bevacizumab-maly, biosimilar (Alymsys®) |
| Q5129 | Bevacizumab-adcd, biosimilar (Vegzelma®) |

## References

1. Dose Rounding of Biologic and Cytotoxic Anticancer Agents. A Position State of the Hematology/Oncology Pharmacy Association. Available at www.hopa.org. Accessed March 30, 2023.

**MVP Health Care Medical Policy**

# D-SNP Over-the-Counter (OTC) and Prescription Drug Coverage (For D-SNP Members Only)

**Type of Policy:** **Administrative**
**Prior Approval Date:** **12/01/2023**
**Approval Date:** **12/01/2024**
**Effective Date:** **02/01/2025**

**Related Policies:** **Government Programs Over-the-Counter (OTC) Drug Coverage (for Child Health Plus and select Essential Plan Members Only)**

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies.

## Overview

MVP Dual Special Needs (D-SNP) plans are Medicare Advantage plans available to those who qualify for both Medicare and Medicaid. D-SNP plans combine benefits from both Medicare and Medicaid.

Medicare is a federal health insurance program for people aged 65 or older, people under age 65 with certain disabilities, and people of all ages with End-Stage Renal Disease or Amyotrophic Lateral Sclerosis. People who are eligible for Medicare have their prescription benefits covered under Medicare Part D, however New York State (NYS) Medicaid will still cover select prescription and non-prescription drugs that are not covered by Medicare.

Effective April 1, 2023, NYRx, The NYS Medicaid Pharmacy Program, covers prescription drugs, over-the-counter (OTC) products, and medical supplies.

## Criteria

**Prescription Drugs**
The NYRx program provides prescription drug coverage only for the drugs listed below for members who are also enrolled in a Medicare Part D drug plan and Medicare Advantage Drug Contracting (MAPD) plans. All other prescription medications should be reimbursed through the Part D plan. For drugs covered under the Medicare Part D benefit, refer to the MVP website for the Medicare Part D formulary and Part D policies.

For the most up to date coverage information for the products below, refer to the https://www.emedny.org/info/formfile.aspx (the NYRx List of Reimbursable Drugs)..

Prescription Drugs covered for dual eligible beneficiaries:

- **Vitamins**
  - Folic acid – oral
  - Hydroxocobalamin – injection
  - Vitamin B12 - injection/nasal
  - Vitamin D2 – oral
  - Vitamin K - oral
- **Cough and Cold**
  - Benzonatate
- **Agents to promote fertility**
  - Bromocriptine
  - Clomiphene – Prior authorization required
  - Letrozole
  - Tamoxifen

**Over-the-Counter (OTC) Drugs**
NYRx covers certain OTC drugs for dual eligible members, if coverage is not available under Medicare. Only NYRx reimbursable drugs excluded by Medicare law are covered for dual eligible members. Therefore, NYRx does not cover OTC insulin and some OTC products which have legend drug substitutes that are covered by Medicare Part D and MAPD plans.

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**Exclusions**

- NYRx does not provide dual eligible members with coverage of compounded prescriptions.

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## References


1. Drugs Covered by NYRx for Dual Eligible Members Effective 10/220/2020. New York State Department of Health. Available at: Prescription Drugs Covered by NYRx for Dual Eligible Members Effective 10/22/2020.

2. New York State Department of Health Medicaid NYRx Drug Search Tool. Available at: Search for OTC and Prescription Drugs (emedny.org)

3. NYRx List of Reimbursable Drugs. Available at: https://www.emedny.org/info/formfile.aspx

4. Medicare Prescription Drug Benefit Manual, Chapter 6. Available at https://cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter 6.pdf.


| Member Product | Medical Management Requirements* |
|---|---|
| **New York Products** | |
| HMO | N/A |
| PPO in Plan | N/A |
| PPO OOP | N/A |
| POS in Plan | N/A |
| POS OOP | N/A |
| Essential Plan | N/A |
| MVP Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | N/A |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Complete Wellness | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D |
| USA Care PPO | Refer to the MVP website for the Medicare Part B and Part D |
| Healthy NY | N/A |

| | |
|---|---|
| MVP Premier | N/A |
| MVP Premier Plus | N/A |
| MVP Premier Plus HDHP | N/A |
| MVP Secure | N/A |
| MVP EPO | N/A |
| MVP EPO HDHP | N/A |
| MVP PPO | N/A |
| MVP PPO HDHP | N/A |
| Student Health Plans | N/A |
| ASO | N/A |
| **Vermont Products** | |
| POS in Plan | N/A |
| POS OOP | N/A |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| MVP VT HMO | N/A |
| MVP VT Plus HMO | N/A |
| MVP VT HDHP HMO | N/A |
| MVP VT Plus HDHP HMO | N/A |
| MVP Secure | N/A |
| ASO | N/A |
| **♦ 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).** | |
| *© 2025 MVP Health Plan, Inc. All rights reserved. Descriptions contained within MVP's Medical Policies are not a guarantee of coverage. Each MVP Group or Subscriber Contract contains specific limitations, exclusions and requirements that may affect a Policy. If there is any discrepancy between your Group or Subscriber Contract and a Policy, your Group or Subscriber Contract shall in all cases govern.* | |

***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 |

**MVP Health Care Medical Policy**

**Drug Utilization Review and Monitoring Program**

| | |
|---|---|
| **Type of Policy:** | **N/A** |
| **Prior Approval Date:** | **12/01/2024** |
| **Approval Date:** | **04/01/2025** |
| **Effective Date:** | **06/01/2025** |
| **Related Policies:** | **NA** |

## Overview

The Drug Utilization Review and Monitoring Program is a multifaceted program to ensure that medications; especially behavioral health drugs, are appropriately utilized to optimize therapeutic outcomes and reduce the risk of adverse events through improved medication use.

The program uses a combination of point-of-sale safety review edits and retrospective claims evaluation which may result in member and/or prescriber interventions. Through the pharmacy benefit manager, MVP has implemented a series of edits to verify prescription history for drug conflicts and potential safety issues. Retrospective Safety Reviews are also performed on a regular basis. MVP Health Care also performs monitoring and reporting on select classes of medications in compliance with H.R. 6, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act. This program is provided by the MVP Health Care Pharmacy Management department and the pharmacy benefit manager.

The Drug Utilization Review and Monitoring Program has been developed and approved by licensed and practicing pharmacists and physicians who are members of the MVP Pharmacy & Therapeutics and Quality Improvement Committees.

## Policy

Documentation, Process, and Quality Standards Requirements.

I. Eligibility of members will be determined by the Integrated Health Drug Monitoring Program data analysis. The edits and/or reviews of this program will apply to all eligible New York State Medicaid, HARP, Commercial/Exchange, and Medicare D-SNP (Dual Special Needs Plan) integrated plans including Integrated Benefit Plan (IBP) and Medicaid Advantage Plus (MAP) members. Interventions will



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be communicated to all targeted providers including Behavioral Health, Primary Care Physicians, and Specialists.

II. At the point of adjudication, alerts and rejects are applied to the claim for all pharmacy benefit members managed by the plan. The dispensing pharmacist will evaluate and override the intervention to receive a paid claim, or the safety concern will be addressed on retro review. High-risk drug classes, including controlled substances, polypharmacy, and provider shopping are monitored, evaluated for intervention, and followed up on a quarterly basis. These edits and reviews will not limit access to care and apply to Commercial/Exchange plans.

Potential Point of Sale intervention types:

- Apparent Drug Misuse
- Cumulative acetaminophen check
- Cumulative morphine milligram equivalent
- Drug-Age precaution
- Drug-Disease precaution
- Drug-Drug interaction
- Drug-Gender Alert
- Drug-Pregnancy Alert
- Excessive Duration Alert
- High Dose Alert
- Ingredient Duplication
- Low Dose Alert
- Refill too soon
- Therapeutic Duplication
- Underuse precaution

The safety activity report is a retrospective review that is performed daily by the pharmacy benefit manager. The prescriber is notified with an actionable, member-specific communication within 72 hours of the claim processing.

Potential Retrospective Safety Reviews:

- Drug-Drug Interaction Management

The Safety and Monitoring Program focuses on inappropriate use. On a quarterly basis a clinical evaluation is performed by the pharmacy benefit manager on controlled substance claims to identify potential medication misuse and inappropriate claims. Intervention letters may be sent to the provider with quarterly monitoring and follow-ups as necessary.



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Safety and monitoring therapeutic class targets:

- Narcotics
- Anti-anxiety and sedative hypnotics
- Non-benzodiazepine sedatives and hypnotics
- Muscle relaxants
- Central Nervous System stimulants

III. Integrated Health Drug Monitoring

A clinician from the MVP Health Care pharmacy department will review all reports listed below and identify any medication related issues. If a medication-related problem or an opportunity to optimize therapy is identified upon clinical review an intervention will be made as listed below:

| **New York State Medicaid, HARP, IBP, and MAP Members** | | | | |
|---|---|---|---|---|
| **Monitoring Target** | **Criteria** | **Frequency** | **Intervention** | **Follow up** |
| Atypical antipsychotic use in pediatric patients | Identify any member under the age of 6 taking atypical antipsychotics. | Monthly | The prescribing physician or other appropriate member of the healthcare team will be contacted by phone and/or mail | Re-assessed within 6 months |
| Metabolic and Cardiovascular side effects | Identify currently enrolled members on an atypical antipsychotic medication for at least 28 days in the past month and no prior utilization in the past 6 months. Use of data to identify opportunities for intervention will be stratified by the following age groups: a. 0-5 years; b. 6-12 years; c. 13-17 years; and d. 18-20 years. | Monthly | The prescribing physician or other appropriate member of the healthcare team will be contacted by mail; and the member may receive a letter to discuss the issue with their provider. | Re-assessed within 12 months |
| Naloxone | Identify currently enrolled members at | Monthly | The prescribing physician or other | Re-assessed |



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| | risk for opioid overdose. A 6-month lookback to identify members with an opioid poisoning diagnosis and greater than 28 cumulative day supply of a prescription opioid without a prescription claim for naloxone. | | appropriate member of the healthcare team will be contacted by mail. | within 3 months |

| **Commercial/Exchange Members** | | | | |
|---|---|---|---|---|
| **Monitoring Target** | **Criteria** | **Frequency** | **Intervention** | **Follow up** |
| Atypical antipsychotic use in pediatric patients | Identify any member under the age of 6 taking atypical antipsychotics. | Monthly | The prescribing physician or other appropriate member of the healthcare team will be contacted by phone and/or mail | Re-assessed within 6 months |
| Same class polypharmacy | Identify currently eligible members with a psychotic disorder diagnosis in the past 12 months and 2 or more concurrent prescriptions from the same therapeutic class (GPI 4) for greater than 45 days concurrence in the past 6 months. Use of data to identify opportunities for intervention will be stratified by the following age groups: a. 0-5 years; b. 6-12 years; c. 13-17 years; and d. 18-20 years. | Monthly | The prescribing physician or other appropriate member of the healthcare team will be contacted by phone and/or mail | Re-assessed within 6 months |



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| Multiple class polypharmacy | Identify currently eligible members with a psychotic disorder diagnosis in the past 12 months and 2 or more prescriptions from multiple behavioral health classes from multiple prescribers for greater than 60 days concurrence in the past 6 months. Use of data to identify opportunities for intervention will be stratified by the following age groups: a. 0-5 years; b. 6-12 years; 13-17 years; and d. 18-20 years. | Monthly | The prescribing physician or other appropriate member of the healthcare team will be contacted by phone and/or mail | Re-assessed within 6 months |
| Non-adherence | Identify currently eligible members continuously enrolled for past 6 months with at least a 90 day supply of any Second generation antipsychotic (SGA) or First generation antipsychotic (FGA) and less than 75% of days covered. | Monthly | The prescribing physician or other appropriate member of the healthcare team will be contacted by phone and/or mail; and the member may be contacted to discuss issue; and/or the member may receive a letter to discuss the issue with their provider. | Re-assessed within 6 months |
| Overdosing | A 6-month lookback to identify currently eligible members with consistent (>=90 days) prescription doses of medication in the above classes above | Monthly | The prescribing physician or other appropriate member of the healthcare team will be contacted by phone and/or mail; and the member may be contacted to | Re-assessed within 3 months |



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| | the FDA approved max dose. | | discuss issue; and/or the member may receive a letter to discuss the issue with their provider. | |
| Metabolic and Cardiovascular side effects | Identify currently enrolled members on an atypical antipsychotic medication for at least 28 days in the past month and no prior utilization in the past 6 months. Use of data to identify opportunities for intervention will be stratified by the following age groups: a. 0-5 years; b. 6-12 years; c. 13-17 years; and d. 18-20 years. | Monthly | The prescribing physician or other appropriate member of the healthcare team will be contacted by mail; and the member may receive a letter to discuss the issue with their provider. | Re-assessed within 12 months |
| Naloxone | Identify currently enrolled members at risk for opioid overdose. A 6-month lookback to identify members with an opioid poisoning diagnosis and greater than 28 cumulative day supply of a prescription opioid without a prescription claim for naloxone. | Monthly | The prescribing physician or other appropriate member of the healthcare team will be contacted by mail. | Re-assessed within 3 months |
| Substance use disorder and concurrent opioid use | This is a hard edit at point of sale, every occurrence would require a clinical review. This edit will not prevent access to medication assisted treatment in any way. | In real time as occurring | A clinical review will occur with provider and member communications by phone and mail. | |



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| Opioid and concurrent benzodiazepine use. | Identify currently enrolled members on an benzodiazepine and a concurrent opiate for at least 7 days in the past month. Retrospective review performed by the Pharmacy Benefits Manager and reported in Safety and Monitoring DUR reports. | Every three months | The prescribing physician or other appropriate member of the healthcare team will be contacted by phone and/or mail | Re-assessed within 3 months |

**Procedure**

Interventions made under the Integrated Health Drug Monitoring will be recorded and communicated with MVP Health Care departments to enhance coordination of care. Use of electronic alerts within the care management tool will ensure all targeted members (including Foster Care and medically fragile children) are identified across departments. The MVP Health Care pharmacist may escalate high risk interventions to an MVP Health Care Behavioral Health Medical Director for consultation or peer-to-peer discussion with the prescriber(s). Members identified with multiple interventions may be referred to an MVP Care Manager. Members may also be presented to the Patient Safety Committee for additional multi-disciplinary review.
The pharmacy benefit manager will provide reporting on all Point of Sale Drug Utilization Review Activity, Retrospective Safety Review, and Safety Monitoring Program on a quarterly basis to the plan.

The MVP Health Care Pharmacy Department will present results of all reporting to the MVP Pharmacy and Therapeutics and the Quality Improvement committee for review on a quarterly basis.



Classified as Confidential

**MVP Health Care Medical Policy**

**Duchenne Muscular Dystrophy**

**Type of Policy:** **Drug Therapy**
**Prior Approval Date:** **04/01/2024**
**Approval Date:** **11/01/2024**
**Effective Date:** **01/01/2025**

**Drug Requiring Prior Authorization (covered under the pharmacy benefit)**

Emflaza
Deflazacort
Agamree

**Drugs Requiring Prior Authorization (covered under the medical benefit)**

J1428 Exondys 51(eteplirsen)

J1429 Vyondys 53 (golodirsen)

J1427 Viltepso (viltolarsen)

J1426 Amondys 45 (casimersen)

J1413 Elevidys (delandistrogene moxeparvovec-rokl)

Refer to the MVP website for the Medicare Part D formulary for drugs that may be covered under the Part D benefit.

**Overview**

Duchenne muscular dystrophy is caused by a defective gene located on the X chromosome that is responsible for the production of dystrophin. The clinical onset usually occurs between two and three years of age and may include muscle weakness, cardiomyopathy and conduction abnormalities, bone fractures, and scoliosis. Treatment with glucocorticoids such as prednisone and deflazacort is beneficial in the treatment motor function, strength, pulmonary function and reducing the risk of scoliosis.

EXONDYS 51 is indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 51 skipping. A clinical benefit of EXONDYS 51 has not been established. Continued FDA

approval for this indication may be contingent upon verification of a clinical benefit in confirmatory trials. If clinical trials fail to verify clinical benefit, the FDA may initiate proceedings to withdraw approval of the drug.

Vyondys 53 is indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping. Approximately 8% of the DMD population have this mutation. Continued FDA approval for this indication may be contingent upon verification of a clinical benefit in confirmatory trials.

Viltepso is indicated for the treatment of Duchenne Muscular Dystrophy (DMD) in patients with a confirmed mutation in the DMD gene amenable to exon 53 skipping. Continued FDA approval for this indication may be contingent upon verification of a clinical benefit in confirmatory trials.

Amondys 45 is indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 45 skipping. This indication is approved under accelerated approval based on an increase in dystrophin production in skeletal muscle observed in trials. Continued FDA approval for this indication may be contingent upon verification of a clinical benefit in confirmatory trials.

Elevidys is indicated for the treatment of Duchenne muscular dystrophy (DMD) in ambulatory patients with a confirmed mutation of the DMD gene. This indication is approved under accelerated approval based on an increase in dystrophin production in skeletal muscle observed in trials. Continued FDA approval for this indication may be contingent upon verification of a clinical benefit in confirmatory trials.

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## Indications/Criteria

**A. ALL the following criteria must be met for coverage for Emflaza and Agamree:**

- Diagnosis of Duchenne muscular dystrophy (DMD) confirmed by genetic testing
- Member is 2 years of age or older
- Prescribed by or in consultation with a provider who specialized in the treatment of DMD or neuromuscular disorders

- After a minimum of a 6-month trial of prednisone the member has had at least one of the following intolerable adverse effects (chart notes supporting one of the below must be submitted):
    - Weight gain defined as at least a 10% increase in weight from baseline after 6 months of prednisone therapy
    - Cushingoid appearance
    - Severe psychiatric adverse effects such as aggression, abnormal behavior or mood swings that would necessitate a prednisone dose reduction

**Initial approval** will be for 6 months.

**Extension requests** up to 12 months will be apprved if the member shows a continued benefit to therapy such as:

- increase in muscle strength, pulmonary function tests or timed function tests
- Decrease in adverse effects experienced while receiving prednisone.

**B. Medicaid Variation**

- Medications that are a pharmacy benefit are covered and billed to New York State Fee-For-Service (FFS) program. They are defined as medications that go through a retail or specialty pharmacy, including self administered injectable products. Pharmacy medications are subject to FFS's clinical criteria including (but not limited to) coverage, quantity limit, step therapy, and prior authorization. Pharmacy benefit information can be found here: https://www.emedny.org/info/fullform.pdf
- Requests for Exondys 51, Vyondys 53, Amondys 45 and Viltepso will be reviewed when **ALL** the following criteria are met (based on New York State Department of Health Fee-For-Service criteria):
    - Member must have a diagnosis of Duchenne Muscular Disease (DMD) **AND**
    - Documentation of genetic testing must confirm the DMD gene mutation of the member is amenable to exon 45, 51, or 53 skipping **AND**
    - Documentation must confirm a stable dose of corticosteroids prior to starting therapy or a documented reason not to be on corticosteroids **AND**
    - Documentation indicates kidney function testing prior to starting therapy (except eteplirsen) **AND**
    - Member is not concurrently being treated with another exon skipping therapy for DMD
- Requests for Elevidys will be reviewed

- Member must have a diagnosis of Duchenne Muscular Disease (DMD) **AND**
- Documentation of genetic testing must confirm the DMD gene mutation **AND**
- Confirmation that member is ambulatory **AND**
- Member is at least 4 years old **AND**
- Documentation that member does not have a deletion in exon 8 and/or exon 9 in the DMD gene **AND**
- Member has anti-AAVrh74 total binding antibody titers <1:400 **AND**
- Documentation of liver function, platelet counts and troponin-I assessment prior to starting therapy **AND**
- Member is not concurrently being treated with another exon skipping therapy for DMD

C. Elevidys

- Elevidys may be considered for coverage when all the following criteria are met:
  - Member is at least 4 years old
  - Member has a confirmed diagnosis of Duchenne Muscular Disease (DMD) **AND**
  - Chart notes documenting genetic testing must confirm the DMD gene mutation
  - Confirmation that the member is ambulatory
  - Documentation that the member does not have a deletion in exon 8 and/or exon 9 in the DMD gene **AND**
  - Member has anti-AAVrh74 total binding antibody titers <1:400 **AND**
  - Documentation of liver function, platelet counts and troponin-I assessment prior to starting therapy **AND**
  - Member is not concurrently being treated with another exon skipping therapy for DMD

## Exclusions

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling Combination therapy with other corticosteroids

- EXONDYS 51 to treat all diagnoses including Duchenne muscular dystrophy, as the clinical benefit, including improved motor function, has not been demonstrated.
- Vyondys 53 to treat all diagnoses including Duchenne muscular dystrophy, as the clinical benefit has not been confirmed.
- Viltepso to treat all diagnoses including Duchenne muscular dystrophy, as the clinical benefit has not been confirmed.
- Amondys 45 to treat all diagnoses including Duchenne muscular dystrophy, as the clinical benefit has not been confirmed.
- Elevidys to treatnon-ambulatory members with Duchenne Muscular Dystrophy, as the clinical benefit has not been confirmed.

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2. Gloss DG, Moxley RT, Ashwal S, Oskoui M. Practice guideline update summary: Corticosteroid treatment of Duchenne muscular dystrophy. Neurology 2016; 86:465-472
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4. Exondys 51 (eteplirsen) injection. Prescribing Information. Cambridge, MA: Sarepta Therapeutics, Inc. September 2016.
5. Viltepso (viltolarsen) injection, for intravenous use. Prescribing Information. Paramus, NJ: NS Pharma. August 2020.
6. Amondys 45 (casimersen) injection. Prescribing Information. Cambridge, MA: Sarepta Therapeutics, Inc. February 2021.
7. New York State Medicaid Update. January 2022. Volume 38: Number 1. Medicaid Fee-For-Service Guidance for Duchenne Muscular Dystrophy Drugs. New York State Medicaid Update - January 2022 Volume 38 - Number 1 (ny.gov)
8. Elevidys. Package Insert - ELEVIDYS (fda.gov). Revised August 2024.
9. Agamree. Package Insert. Santhera Pharmaceuticals. March 2024.


| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Complete Wellness | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D |
| USA Care 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 | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

**Dupixent**

**Type of Policy:** **Drug Therapy**
**Prior Approval Date:** **04/01/2024**
**Approval Date:** **12/01/2024**
**Effective Date:** **02/01/2025**
**Related Policies:** Xolair, Select Injectables for Asthma

## Drugs Requiring Prior Authorization (covered under the pharmacy benefit)

Dupixent (dupilumab)

Refer to the MVP website for the Medicare Part D formulary for drugs that may covered under the Part D benefit.

## Overview

Dupixent is an interleukin-4 receptor alpha antagonist, which inhibits IL-4 and IL-13 cytokine-induced inflammatory response, including the release of proinflammatory cytokines, chemokines, nitric oxide, and IgE, which plays a role in the development of asthma. Dupixent has several FDA approved indications including nasal polyps, atopic dermatitis, asthma, puruigo nodularis and eosinophilic esophagitis.

## Indication/Criteria

The use of Dupixent may be considered medically necessary if all the following criteria are met:

1. Chronic Rhinosinusitis with Nasal Polyps

   Dupixent may be considered for coverage for chronic rhinosinusitis with nasal polyps when the following criteria is met:

a. Confirmed diagnosis of nasal polyps. Chart notes must document diagnosis confirmation by examination, endoscopy or sinus computed tomography (CT) scan.
b. Prescribed by or in consultation with an allergist, otolaryngologist or immunologist
c. Documented trial and failure of three (3) months to at least one intranasal corticosteroid indicated to treat nasal polyps
d. Documented failure, contraindication, intolerance, or allergy to other therapy used in the management of nasal polyps such as nasal saline irrigations, or antileukotriene agents (montelukast, zafirlukast, zileuton)
e. Documentation of prior oral corticosteroid therapy and/or sinus surgery

Dupixent will be add on maintenance in combination with an intranasal corticosteroid. **Initial coverage** will be for 12 months.

**Continued authorization** up to 3 yearsmust be accompanied by current chart notes identifying continued benefit and compliance with combination therapy. Claims history must show compliance with combination therapy.

2. Asthma

Dupixent may be considered for coverage for moderate to severe asthma characterized by eosinophilic phenotype OR with oral corticosteroid dependent asthma when the following criteria is met:

a. Member has one of the following diagnoses:
    i. Documented diagnosis of asthma with eosinophilic phenotype with eosinophil count between ≥150 cells/mcL to ≤ 1500 cells/mcL in the past 12 months **OR** FeNO ≥ 25ppb **OR**
    ii. Documented diagnosis of oral corticosteroid dependent asthma with at least 1 month of daily oral corticosteroid use within the last 3 months **AND**

b. Member must be followed by an allergist, immunologist or pulmonologist **AND**
c. Documentation and claim history must identify that the member is compliant with the use of a high-dose inhaled corticosteroid (ICS) and a long-acting beta2-agonist (LABA) **AND**

d. Member still experiencing poor asthma control and has had at least two asthma exacerbations in the previous year

**Initial approval** will be for 12 months.

**Continued authorization** for up to 3 years will be considered if there is a documented decrease in asthma symptoms and exacerbations

3. Atopic Dermatitis
   Dupixent may be considered for coverage for atopic dermatitis when the following criteria is met:
   a. Chart notes documenting a confirmed diagnosis of moderate-to-severe atopic dermatitis (widespread areas of dry skin, severe limitation of everyday activities, nightly loss of sleep).
   b. Must have at least 10% BSA involvement at baseline documented in chart notes
   c. Chart notes documenting that symptom control has not been achieved with one of the following after an adequate trial:
      i. Medium or high potency topical corticosteroids **OR**
      ii. Topical calcineurin inhibitors (i.e. tacrolimus ointment, pimecrolimus cream)
   d. Must be prescribed by or in consultation with a dermatologist, allergist or immunologist

   **Initial approval** will be for 12 months.
   **Continued authorization** up to 3 years months must be accompanied by current chart notes identifying continued benefit and improvement in symptoms from baseline.

4. Eosinophilic Esophagitis
   Dupixent may be considered for coverage for eosinophilic esophagitis when the following criteria is met:
   a. Prescribed by or in consult with a gastroenterologist AND
   b. Member has a diagnosis of eosinophilic esophagitis confirmed by esophageal biopsy with the presence of ≥ 15 intraepithelial eosinophils per high-power field (eos/hpf) AND
   c. Secondary causes of eosinophilic esophagitis have been ruled out (such as food allergy and hypereosinophilic syndrome) AND

d. Chart notes documenting symptoms (such as dysphagia, reflux, vomiting, food getting stuck in esophagus, trouble feeding).
e. Documentation of a previous trial with a proton pump inhibitor, corticosteroids and dietary modifications OR
    i. Documentation that a trial of a proton pump inhibitor, corticosteroids, and dietary modifications are not medically appropriate for the member.

**Initial approval** will be for 12 months.
**Continued authorization** up to 3 years must be accompanied by current chart notes identifying continued benefit and improvement in symptoms from baseline.

5. Pruruigo Nodularis
Dupixent may be considered for coverage for Pruruigo Nodularis when the following criteria is met:

    a. Confirmed diagnosis of pruruigo nodularis with pruritus lasting at least 6 weeks AND
    b. Prescribed by or in consult with a dermatologist, allergist or immunologist AND
    c. Documentation of an inadequate response to one of the following OR documentation indicating why the following therapies are not medically appropriate for the member:
        i. A medium to high potency topical corticosteroid
        ii. A topical calcineurin inhibitor
        iii. Phototherapy
        iv. Methotrexate or cyclosporine

    **Initial approval** will be for 12 months.
    **Continued authorization** up to 3 years must be accompanied by current chart notes identifying continued benefit and improvement in symptoms from baseline.

6. Chronic Obstructive Pulmonary Disease (COPD)
Dupixent may be considered for coverage for COPD when the following criteria is met:
    a. Confirmed diagnosis of COPD

b. Member is followed by an allergist, immunologist or pulmonologist
c. Documentation of inadequate control with combination therapy (either double or triple therapy) consisting of an inhaled corticosteroid (ICS), long-acting beta agonist (LABA), or long-acting muscarinic antagonist (LAMA)
d. Member has eosinophilic phenotype with eosinophil count ≥300 cells/microliter
e. Provider attestation that Dupixent will be add on maintenance treatment

**Initial approval** will be for 12 months.

**Continued authorization** up to 3 years must be accompanied by current chart notes identifying continued benefit and improvement in symptoms from baseline.

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**Exclusions**

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling Dupixent is a self-administered product. Office or outpatient administration is not a covered benefit
- Treatment of acute bronchospasm or status asthmaticus
- Dual therapy with another monoclonal antibody is not a covered benefit

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**References**


1. Dupixent (Dupilumab) injection package insert. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.;January 2024.
2. Eichenfield L, Tom W, Berger T, et al. Guidelines of care for the management of atopic dermatitis. Section 2. Management and treatment of atopic dermatitis with topical therapies. J Am Acad Dermatol 2014;71(1):116-32
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| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Complete Wellness | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| USA Care PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

**Enteral Therapy New York**
(enteral, modified solid foods and medical foods)

| | |
|---|---|
| **Type of Policy:** | **Drug Therapy** |
| **Prior Approval Date:** | **08/01/2023** |
| **Approval Date:** | **10/01/2024** |
| **Effective Date:** | **01/01/2025** |
| **Related Policies:** | **Enteral Therapy Vermont** |

**Codes May Require Prior Authorization (covered under the pharmacy benefit)**

**Enteral formula:** B4100, B4102, B4103, B4104, B4149, B4150, B4152, B4153, B4154, B4155, B4157, B4158, B4159, B4160, B4161, B4162, Various NDC/UPC numbers

**Medical foods (modified solid foods) for inborn errors of metabolism:** S9435

**Overview**

**Enteral** nutrition is a form of nutrition that is delivered into the digestive system as a liquid. Enteral nutrition may be provided orally or through a feeding tube. Enteral products may be liquids or powders that are reconstituted to a liquid form.

Specific diseases for which enteral formulas have been proven effective include, but are not limited to:

- Inherited diseases of amino acid or organic acid metabolism, e.g. phenylketonuria (PKU), homocystinuria, maple syrup urine disease (MSUD), methylmalonic aciduria.
- Crohn's Disease
- Gastroesophageal reflux
- Disorders of the gastrointestinal motility such as chronic intestinal pseudo-obstruction; or
- Multiple, severe food allergies including but not limited to:
    - Immunoglobulin E and non-immunoglobulin E-mediated allergies,
    - Severe food protein induced enterocolitis syndrome
    - Eosinophilic disorders
    - Impaired absorption of nutrients caused by disorders affecting the absorptive surface, function, length, and motility of the gastrointestinal tract.

- Significant enteritis as diagnosed by a pediatric specialist.

**Modified Solid Foods** are products (flours, breads, pasta etc.) that may be low in protein or contain modified protein and are required for certain inherited diseases of amino acid and organic acid metabolism. Medically necessary nutritional bars (PhenylAde, etc.), for the purpose of coverage under this benefit, will be considered modified solid foods.

**Medical Foods,** defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee (b) (3)) are "a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation.". In general, to be considered a medical food, a product must, at a minimum, meet the following criteria: the product must be a food for oral or tube feeding; the product must be labeled for the dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements; and the product must be intended to be used under medical supervision.

**Indications/Criteria**

- Medical necessity must be documented in the medical record and available upon request

- Must be a written order by a participating provider legally authorized to prescribe under Title VIII of the Education Law of the State of New York

- The disease or condition must require distinctive nutritional requirements, based on recognized scientific principles which are published in national guidelines or other nationally recognized standards of care

- Enteral nutrition coverage is limited to enteral formulas formulated specifically to treat an underlying metabolic disease documented as requiring enteral therapy in this policy

- Specialized infant formulas, formulas that are used solely to increase caloric intake and products that are not specifically listed in this policy require prior authorization

- GERD requires that appropriate drug therapy be ongoing

- Infants poorly tolerant to standard formula must have GERD or evidence of blood in the stool (which would represent significant enteritis) as observed by member's physician with supporting clinical evidence

- Infants with respiratory manifestations of multiple food allergies may qualify for coverage.

- Nutritional products that are calorically incomplete (e.g. Duocal) will only be considered for coverage when used in combination with a covered enteral formula when no alternatives are available to increase caloric intake

- Provider attestation indicating a nutritional consult prior to coverage **AND** that adequate nutrition is not possible by dietary adjustment and/or oral supplements

- Prescription drug coverage is required

- Enteral products must adjudicate through the pharmacy benefits manager at the point-of-service for all vendors (including but not limited to pharmacies, durable medical equipment and home care/home infusion providers). Please see ASO Variation as some groups adjudicate through the medical benefit.

- Enteral therapy is subject to the applicable pharmacy copayments and days' supply per dispensing

- Coverage for modified solid foods shall not exceed $2500 for any calendar year when billed through the medical benefit as DME.

**Initial AND continuation** approval duration is for up to 12 months

The following formulas do not require prior authorization and will automatically adjudicate through the pharmacy benefits management system. **All other products require prior authorization to determine medical necessity for all vendors.** This list is subject to change at any time.

| | | | |
|---|---|---|---|
| ACERFLEX POW | MSUD 2 POW | PHENYL-FREE POW 1 | UCD TRIO POW |
| BCAD 1 POW | MSUD AID POW | PHENYL-FREE POW 2 | WND POW |
| BCAD 2 POW | MSUD ANALOG POW | PHENYL-FREE POW 2HP | WND 1 POW |
| CAMINO PRO POW BETTRMLK | MSUD COOLER LIQ | PHLEXY-10 | WND 2 POW |
| CAMINO PRO15 LIQ | MSUD COOLER LIQ 20 | PHLEXY-VITS | XLEU ANALOG POW |
| COMPLEX MSD POW JUNIOR | MSUD EXP20 PAK | PKU 2 POW | XLEU MAXAMAD POW |

| | | | |
|---|---|---|---|
| COMPLEX MSD POW VANILLA | MSUD EXPRESS PAK | PKU 3 POW | XLEU MAXAMUM POW |
| COMPLEX MSUD BAR AMINO AC | MSUD GEL PAK | PKU COOLER LIQ 15 | XLYS XTRP POW ANALOG |
| COMPLEX MSUD POW | MSUD LOPHLEX LIQ LQ | PKU COOLR 10 LIQ | XLYS-XTRP POW MAXAMAID |
| CYCLINEX-1 POW | MSUD MAXAMAD POW | PKU COOLR 15 LIQ | XLYS-XTRP POW MAXAMUM |
| CYCLINEX-2 POW | MSUD MAXAMUM POW | PKU COOLR 20 LIQ | XMET ANALOG POW |
| GA POW | OA 1 POW | PKU EXP20 PAK | XMET MAXAMAD POW |
| GA DIET POW | OA 1 DIET POW | PKU EXPRESS POW | XMET MAXAMUM POW |
| GLUTAREX-1 POW | OA 2 POW | PKU GEL PAK | XMTVI ANALOG POW |
| GLUTAREX-2 POW | OA 2 DIET POW | PKU LOPHLEX LIQ LQ 20 | XMTVI MAXAMD POW |
| GLYTACTIN | OS 2 POW | PKU TRIO POW | XMTVI MAXAMU POW |
| HCY 1 POW | PEPTAMEN JR LIQ | PORTAGEN POW | XPHE MAXAMAD POW |
| HCY 1 DIET POW | PERIFLEX POW ADVANCE | PROPIMEX-1 POW | XPHE MAXAMUM POW |
| HCY 2 POW | PERIFLEX POW INFANT | PROPIMEX-2 POW | XPHE-XTYR POW ANALOG |
| HOM 2 POW | PERIFLEX POW JUNIOR | TYR COOLER LIQ | XPHE-XTYR POW MAXAMAID |
| HOMINEX-1 POW | PERIFLEX LQ LIQ PKU | TYR COOLER LIQ 20 | XPTM ANALOG POW |
| HOMINEX-2 POW | PERIFLEX LQ LIQ PKU | TYR EXP20 PAK | |
| I-VALEX-1 POW | PFD 1 POW | TYR EXPRESS PAK | |
| I-VALEX-2 POW | PFD 2 POW | TYR GEL PAK | |
| KETONEX-1 POW | PHENEX-1 POW | TYR LOPHLEX LIQ LQ | |
| KETONEX-2 POW | PHENEX-2 POW | TYREX-1 POW | |
| LANAFLEX PAK | PHENYLADE | TYREX-2 POW | |
| LMD POW | PHENYLADE POW ESSNTL | TYROS 1 POW | |
| LMD DIET POW | PHENYLADE POW MTE | TYROS 2 POW | |
| LOPHLEX POW | PHENYLADE40 POW | UCD 2 POW | |
| LOPHLEX LQ LIQ 20 | PHENYLADE60 POW | UCD ANAMIX POW JUNIOR | |
| METHIONAID POW | PROMACTIN AA PLUS | | |

## Exclusions/Limitations

- Enteral administration kits when the member does not have a disposable medical supply rider
- Enteral supplies (including but not limited to enteral feeding kits, pumps and poles) and/or nursing and home services when the formula is determined to be not medically necessary.
    - MVP shall review all claims retrospectively for services and supplies, including but not limited to nursing services, per diem charges, pumps, poles and feeding bags, associated with enteral formulas

- Any enteral, modified solid, or medical foods is not considered medically necessary for any of the following:
    - Use is not based on recognized scientific principles, including but not limited to, accepted standards of care, will be considered not medically necessary

  - Taken electively (i.e. to replace a missed meal in persons who have normal GI functioning)
  - Not disease specific, this includes nutritional supplements and herbal or natural compounds, whether or not a prescription is required (Examples (not limited to) : UltraClear®, Estrium®, Protrypsin®, glucosamine, glucosamine/chondroitin, etc.)
  - Medical foods that replace or supplement standard drug treatment (i.e. Limbrel, Fosteum, Nicazel and Perative) for a specific disease or condition

- Patients with a functioning gastrointestinal tract **unless medical necessity criteria are met**
- Gluten-free solid foods used for the treatment of celiac disease
- Components of medically prescribed diets (i.e. low residue or diverticular diets)
- Formulas recommended as an alternative food source due to intolerance of standard formulas, but not as a specific treatment for an underlying disease process
- Infants with colic without evidence of medical complications
- Thickening agents that do not meet medical necessity criteria
- Enzyme packed cartridges (e.g., Relizorb (Alcresta Pharmaceuticals)) for enzyme replacement in patients receiving enteral tube feedings are considered experimental/investigational

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**Medicare Variation**

**Enteral nutrition is covered under the Prosthetic Device benefit as per the Medicare Local Coverage Determination (LCD) for Enteral Nutrition (L38955) and the LCD-related Policy Article (A58833). Please refer to this guidance for appropriate coverage.**

Coverage of In-line digestive enzyme cartridges (ie. RELiZORB) is considered reasonable and necessary for the management of Medicare beneficiaries with a diagnosis of Exocrine Pancreatic Insufficiency (EPI) to maintain weight and strength corresponding with their overall health status. Please refer to LCD L38955.

Supplemental nutritional therapy including modified solid foods, medical foods, nutritional supplements, and enteral products administered orally or products that do not meet the Medicare definition of enteral therapy are not covered under Medicare Part B or Medicare Part D.

**DSNP Variation (for MAP plans ONLY)**

Enteral nutrition for DSNP members is covered if it meets criteria outlined in the above Medicare Variation OR for the following conditions:

- Tube-fed individuals who cannot chew or swallow food and must obtain nutrition through formula via tube
- Individuals with rare inborn metabolic disorders requiring specific medical formulas to provide essential nutrients not available through any other means. Coverage of certain inherited disease of amino acid and organic acid metabolism shall include modified solid food products that are low-protein, or which contain modified protein

**Managed Medicaid Variation**

Medications that are a pharmacy benefit are covered and billed to New York State Fee-For-Service (FFS) program. They are defined as medications that go through a retail or specialty pharmacy, including self administered injectable products. Pharmacy medications are subject to FFS's clinical criteria including (but not limited to) coverage, quantity limit, step therapy, and prior authorization. Pharmacy benefit information can be found here: https://www.emedny.org/info/fullform.pdf

**ASO Variation**

Enteral nutritional formulas will be limited to members who meet the criteria in this policy and:

1. Must be proven to be an effective treatment for individuals who, without this nutrition, would suffer from malnourishment, chronic disability, mental retardation, or death.

2. Treatment of GERD will require co-existing failure to thrive.

*Failure to thrive refers to infants who fail to grow at normal standards for growth velocity/rate. Thus, it does not include infants and young children with genetic short stature, constitutional growth delay, prematurity, or intrauterine growth restriction who have appropriate weight-for-length and normal growth velocity. Failure to thrive is diagnosed when a child's weight for age is below the fifth percentile or crosses two major percentile lines. It is recommended that the WHO growth charts be used for infants and toddlers who are less than 2 years old. The CDC growth charts can still be used for older children. Coverage of enteral nutrition varies by ASO group. For ASO groups that cover enteral nutrition, coverage may be through the pharmacy benefit or the medical benefit. Group-specific coverage can be determined by using the MVP Benefit Check List reference documents.

**References**

1. Durable Medical Equipment Regional Carrier (DMERC A), HCFA, (2000) Coverage Issues Manual 65-10 Prosthetic Device, *Enteral Nutrition*.

2. United States Food and Drug Administration (FDA) The Orphan Drug Act (Relevant Excerpts). Last updated 8/2023.
3. American Society for Parenteral and Enteral Nutrition (1992). Standards for home nutrition support. Nutrition in Clinical Practice, 7,65-69. (On-line).
4. National Cancer Institute (Updated May 16, 2024). Nutrition. PDQâ -Supportive Care-Patients. -Health Professional Version
5. New York State Insurance Law (Last Amended 6/28/2024). Article 32: Group or blanket accident and health insurance policies; standard provisions. Section 3221, Subsection (K).
6. Pediatr Rev. 1992 Dec;13(12):453-60. Failure to thrive/growth deficiency**.** Bithoney WG, Dubowitz H, Egan H. Harvard Medical School, Boston, MA.
7. New York Law, Title 18 (Social Services) Paragraph (3) of Subdivision (g) of Section 505.5
8. Local Coverage Determination for Enteral Nutrition (L38955). Original Effective Date: 09/05/2021. Revision Effective Date: 01/01/2024.
9. Enteral Nutrition – Policy Article (A58833). Original Effective Date: 09/05/2021. Revision Effective Date: 10/01/2023.
10. NEW YORK STATE MEDICAID PROGRAM DURABLE MEDICAL EQUIPMENT, PROSTHETICS, ORTHOTICS, AND SUPPLIES PROCEDURE CODES AND COVERAGE GUIDELINES. (n.d.).
11. State, N. (n.d.). Medicaid Advantage Plus Contract MEDICAID ADVANTAGE PLUS (MAP) MODEL CONTRACT MISCELLANEOUS/CONSULTANT SERVICES. Valid 01/01/2022-12/31/2026.
12. Mirtallo, J., Canada, T., Johnson, D., Kumpf, V., Petersen, C., Sacks, G., Seres, D., & Guenter, P. (2004). Safe Practices for Parenteral Nutrition. Journal of Parenteral and Enteral Nutrition, 28(6), S39–S70.
13. Boullata, J. I., Carrera, A. L., Harvey, L., Escuro, A. A., Hudson, L., Mays, A., McGinnis, C., Wessel, J. J., Bajpai, S., Beebe, M. L., Kinn, T. J., Klang, M. G., Lord, L., Martin, K., Pompeii-Wolfe, C., Sullivan, J., Wood, A., Malone, A., & Guenter, P. (2016). ASPEN Safe Practices for Enteral Nutrition Therapy. Journal of Parenteral and Enteral Nutrition, 41(1), 15–103.
14. Clinical Guidelines for the Use of Parenteral and Enteral Nutrition in Adult and Pediatric Patients, 2009. (2009). Journal of Parenteral and Enteral Nutrition, 33(3), 255–259.
15. Jaffe, A. C. (2011). Failure to Thrive: Current Clinical Concepts. Pediatrics in Review, 32(3), 100–108.
16. Guidelines for the Diagnosis and Management of Food Allergy in the United States. National Institute of Allergy and Infectious Disease. May 2011

| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Medicare Gold Giveback | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | N/A |
| POS OOP | N/A |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP VT HMO | N/A |
| MVP VT Plus HMO | N/A |
| MVP VT HDHP HMO | N/A |
| MVP VT Plus HDHP HMO | N/A |
| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

**Medicare Part B: Enteral Therapy**
(enteral, modified solid foods and medical foods)

| | |
|---|---|
| **Type of Policy:** | **Drug Therapy** |
| **Prior Approval Date:** | **11/01/2023** |
| **Approval Date:** | **10/01/2024** |
| **Effective Date:** | **12/01/2024** |
| **Related Policies:** | **Medicare Part B Drug Therapy** |
| | **Medicare Part B vs. Part D Determination** |

## Overview/Summary of Evidence

**Enteral** nutrition is a form of nutrition that is delivered into the digestive system as a liquid. Enteral nutrition may be provided orally or through a feeding tube. Enteral products may be liquids or powders that are reconstituted to a liquid form.

## Indications/Criteria

- Enteral nutrition is covered under the Prosthetic Device benefit as per the Medicare Local Coverage Determination (LCD) for Enteral Nutrition (L38955) and the LCD-related Policy Article (A58833). Please refer to this guidance for appropriate coverage.
- Coverage of **In-line digestive enzyme cartridges** (ie. RELiZORB) is considered reasonable and necessary for the management of Medicare beneficiaries with a diagnosis of Exocrine Pancreatic Insufficiency (EPI) to maintain weight and strength corresponding with their overall health status. Please refer to LCD L38955.
- **Supplemental nutritional therapy** including modified solid foods, medical foods, nutritional supplements, and enteral products administered orally or products that do not meet the Medicare definition of enteral therapy are not covered under Medicare Part B or Medicare Part D.

## DSNP Variation (for MAP plans ONLY):

Enteral nutrition for DSNP members is covered if it meets criteria outlined in the above Medicare Variation OR for the following conditions:

- Tube-fed individuals who cannot chew or swallow food and must obtain nutrition through formula via tube
- Individuals with rare inborn metabolic disorders requiring specific medical formulas to provide essential nutrients not available through any other means. Coverage of certain inherited disease of amino acid and organic acid metabolism shall include modified solid food products that are low-protein, or which contain modified protein

**References**


1. Durable Medical Equipment Regional Carrier (DMERC A), HCFA, (2000) Coverage Issues Manual 65-10 Prosthetic Device, Enteral Nutrition.
2. American Society for Parenteral and Enteral Nutrition (1992). Standards for home nutrition support. Nutrition in Clinical Practice, 7,65-69. (On-line).
3. National Cancer Institute (Updated May 16, 2024). Nutrition. PDQâ -Supportive Care-Health Professional Version.
4. New York State Insurance Law (Last Amended 6/28/2024). Article 32: Group or blanket accident and health insurance policies; standard provisions. Section 3221, Subsection (K).
5. Local Coverage Determination for Enteral Nutrition (L38955). Original Effective Date: 09/05/2021. Revision Effective Date: 01/01/2024.
6. Enteral Nutrition – Policy Article (A58833). Original Effective Date: 09/05/2021. Revision Effective Date: 10/01/2023.
7. NEW YORK STATE MEDICAID PROGRAM DURABLE MEDICAL EQUIPMENT, PROSTHETICS, ORTHOTICS, AND SUPPLIES PROCEDURE CODES AND COVERAGE GUIDELINES. (n.d.).
8. State, N. (n.d.). Medicaid Advantage Plus Contract MEDICAID ADVANTAGE PLUS (MAP) MODEL CONTRACT MISCELLANEOUS/CONSULTANT SERVICES. Valid 01/01/2022-12/31/2026.
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10. Boullata, J. I., Carrera, A. L., Harvey, L., Escuro, A. A., Hudson, L., Mays, A., McGinnis, C., Wessel, J. J., Bajpai, S., Beebe, M. L., Kinn, T. J., Klang, M. G., Lord, L., Martin, K., Pompeii-Wolfe, C., Sullivan, J., Wood, A., Malone, A., & Guenter, P. (2016). ASPEN Safe Practices for Enteral Nutrition Therapy. Journal of Parenteral and Enteral Nutrition, 41(1), 15–103.
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12. Jaffe, A. C. (2011). Failure to Thrive: Current Clinical Concepts. Pediatrics in Review, 32(3), 100–108.

- Any enteral, modified solid or medical foods whose use is not based on recognized scientific principles, including but not limited to, accepted standards of care, will be considered not medically necessary.
- Any enteral, modified solid or medical foods taken electively (i.e. to replace a missed meal in persons who have normal GI functioning) will be considered not medically necessary.
- Enteral nutrition is not covered for patients with a functioning gastrointestinal tract except when medical necessity criteria is met.
- Adequate nutrition must not be possible by dietary adjustment.
- Gluten-free solid foods used for the treatment of celiac disease do not meet coverage criteria.
- Components of medically prescribed diets (i.e. low residue or diverticular diets) do not meet coverage criteria.
- Formulas recommended as an alternative food source due to intolerance of standard formulas, but not as a specific treatment for an underlying disease process.
- Medical foods that replace or supplement standard drug treatment (i.e. Limbrel, Fosteum, Nicazel and Perative) for a specific disease or condition are not covered.
- Enteral supplies (including but not limited to enteral feeding kits, pumps and poles) and/or nursing and home services when the formula is determined to be not medically necessary. MVP shall review all claims retrospectively for services and supplies, including but not limited to nursing services, per diem charges, pumps, poles and feeding bags, associated with enteral formulas.
- Thickening agents that do not meet medical necessity criteria described above.

**Medicare Variation**

**Enteral nutrition is covered under the prosthetic device benefit as per the Medicare Local Coverage Determination (LCD) for Enteral Nutrition (L38955) and the LCD-related Policy Article A58833. Please refer to this guidance for appropriate coverage.**

**MVP Health Care Medical Policy**

**Enteral Therapy Vermont**
(enteral, modified solid foods and medical foods)

| | |
|---|---|
| **Type of Policy:** | **Medical Therapy** |
| **Prior Approval Date:** | **10/01/2023** |
| **Approval Date:** | **10/01/2024** |
| **Effective Date:** | **01/01/2025** |
| **Related Policies:** | **Enteral Therapy New York** |

***Codes May Require Prior Authorization (covered under the medical benefit)***

**Enteral formula:** B4100, B4102, B4103, B4104, B4149, B4150, B4152, B4153, B4154, B4155, B4157, B4158, B4159, B4160, B4161, B4162, Various NDC/UPC numbers

**Medical foods (modified solid foods) for inborn errors of metabolism:** S9435

## Overview

The Vermont statute covering the treatment of inherited metabolic disease mandates that infants born in the state are tested for certain diseases and conditions for which early identification and treatment will prevent severe disability or death, and, for those affected, to assure timely initiation of treatment services.

The Vermont state mandate defines medical foods and low protein modified food products as follows:

- **Medical Food** - an amino acid modified preparation that is intended to be under the direction of a physician for the dietary treatment of inherited metabolic diseases, this includes enteral formulas; and
- **Low Protein Modified Solid Food product** - a food product specially formulated to have less than one gram of protein per serving and is intended to be used under the direction of a physician for the dietary treatment of a metabolic disease, e.g. low protein modified pasta

**Indications/Criteria**

- Medical diagnosis to support the request of an enteral formula or low protein food
- Indication of impaired absorption of nutrients or to replace or supplement a regular diet in the management of inherited metabolic diseases/ inborn errors of metabolism
- Medical necessity must be documented in the medical record and available upon request
- Provider attestation indicating a nutritional consult prior to coverage **AND** that adequate nutrition is not possible by dietary adjustment and/or oral supplements
- Nutritional products that are calorically incomplete (e.g. Duocal) will only be considered for coverage when used in combination with a covered enteral formula when no alternatives are available to increase caloric intake
- Enteral products must adjudicate through the pharmacy benefits manager at the point-of-service including but not limited to pharmacies, durable medical equipment and home care/home infusion providers
- Medical foods and low protein modified solid food products for home use are covered for Vermont groups for diseases caused by an inherited abnormality of body chemistry for which the state of Vermont screens newborn infants
- Coverage is dependent on the specific member benefit

**Initial AND continuation** approval duration is for up to12 months

**Diseases screened for by the State of Vermont:**

- 3-Methylcrotonyl-CoA carboxylase deficiency (3MCC)
- 3-OH 3-CH3 glutaric aciduria (HMG)
- Argininosuccinic acidemia (ASA)
- Beta-ketothiolase deficiency (BKT)
- Biotinidase deficiency (BIOT)
- Carnitine uptake defect (CUD)
- Citrullinemia (CIT)
- Congenital adrenal hyperplasia (CAH)
- Congenital hypothyroidism (CH)
- Critical congenital heart disease (CCHD)
- Cystic fibrosis (CF)

- Galactosemia (Classical) (GALT)
- Glutaric acidemia type I (GA I)
- Hb S/Beta-thalassemia (Hb S/BTh)
- Hb S/C disease (Hb S/C)
- Hearing
- Holocarboxylase synthetase deficiency (MCD or multiple carboxylase deficiency)
- Homocystinuria (HCY)
- Isovaleric acidemia (IVA)
- Long-chain L-3-OH acyl-CoA dehydrogenase deficiency (LCHAD)
- Maple syrup urine disease (MSUD)
- Medium-chain acyl-CoA dehydrogenase deficiency (MCAD)
- Methylmalonic acidemia (Cbl A, B)
- Methylmalonic acidemia (mutase deficiency) (MUT)
- Mucopolysaccharidosis Type I (MPS I)
- Phenylketonuria (PKU)
- Pompe Disease
- Propionic acidemia (PROP)
- Severe combined immunodeficiency (SCID)
- Sickle cell anemia (Hb SS disease) (SS)
- Spinal Muscular Atrophy (SMA)
- Trifunctional protein deficiency (TFP)
- Tyrosinemia type I (TYR I)
- Very long-chain acyl-CoA dehydrogenase deficiency (VLCAD).
- X-linked adrenoleukodystrophy (X-ALD)

The following formulas do not require prior authorization and will automatically adjudicate through the pharmacy benefits management system. **All other products require prior authorization to determine medical necessity for all vendors.** This list is subject to change at any time.

| | | | |
|---|---|---|---|
| ACERFLEX POW | MSUD 2 POW | PHENYL-FREE POW 1 | UCD TRIO POW |
| BCAD 1 POW | MSUD AID POW | PHENYL-FREE POW 2 | WND POW |
| BCAD 2 POW | MSUD ANALOG POW | PHENYL-FREE POW 2HP | WND 1 POW |
| CAMINO PRO POW BETTRMLK | MSUD COOLER LIQ | PHLEXY-10 | WND 2 POW |
| CAMINO PRO15 LIQ | MSUD COOLER LIQ 20 | PHLEXY-VITS | XLEU ANALOG POW |
| COMPLEX MSD POW JUNIOR | MSUD EXP20 PAK | PKU 2 POW | XLEU MAXAMAD POW |
| COMPLEX MSD POW VANILLA | MSUD EXPRESS PAK | PKU 3 POW | XLEU MAXAMUM POW |
| COMPLEX MSUD BAR AMINO AC | MSUD GEL PAK | PKU COOLER LIQ 15 | XLYS XTRP POW ANALOG |
| COMPLEX MSUD POW | MSUD LOPHLEX LIQ LQ | PKU COOLR 10 LIQ | XLYS-XTRP POW MAXAMAID |
| CYCLINEX-1 POW | MSUD MAXAMAD POW | PKU COOLR 15 LIQ | XLYS-XTRP POW MAXAMUM |
| CYCLINEX-2 POW | MSUD MAXAMUM POW | PKU COOLR 20 LIQ | XMET ANALOG POW |

| | | | |
|---|---|---|---|
| GA POW | OA 1 POW | PKU EXP20 PAK | XMET MAXAMAD POW |
| GA DIET POW | OA 1 DIET POW | PKU EXPRESS POW | XMET MAXAMUM POW |
| GLUTAREX-1 POW | OA 2 POW | PKU GEL PAK | XMTVI ANALOG POW |
| GLUTAREX-2 POW | OA 2 DIET POW | PKU LOPHLEX LIQ LQ 20 | XMTVI MAXAMD POW |
| GLYTACTIN | OS 2 POW | PKU TRIO POW | XMTVI MAXAMU POW |
| HCY 1 POW | PEPTAMEN JR LIQ | PORTAGEN POW | XPHE MAXAMAD POW |
| HCY 1 DIET POW | PERIFLEX POW ADVANCE | PROPIMEX-1 POW | XPHE MAXAMUM POW |
| HCY 2 POW | PERIFLEX POW INFANT | PROPIMEX-2 POW | XPHE-XTYR POW ANALOG |
| HOM 2 POW | PERIFLEX POW JUNIOR | TYR COOLER LIQ | XPHE-XTYR POW MAXAMAID |
| HOMINEX-1 POW | PERIFLEX LQ LIQ PKU | TYR COOLER LIQ 20 | XPTM ANALOG POW |
| HOMINEX-2 POW | PERIFLEX LQ LIQ PKU | TYR EXP20 PAK | |
| I-VALEX-1 POW | PFD 1 POW | TYR EXPRESS PAK | |
| I-VALEX-2 POW | PFD 2 POW | TYR GEL PAK | |
| KETONEX-1 POW | PHENEX-1 POW | TYR LOPHLEX LIQ LQ | |
| KETONEX-2 POW | PHENEX-2 POW | TYREX-1 POW | |
| LANAFLEX PAK | PHENYLADE | TYREX-2 POW | |
| LMD POW | PHENYLADE POW ESSNTL | TYROS 1 POW | |
| LMD DIET POW | PHENYLADE POW MTE | TYROS 2 POW | |
| LOPHLEX POW | PHENYLADE40 POW | UCD 2 POW | |
| LOPHLEX LQ LIQ 20 | PHENYLADE60 POW | UCD ANAMIX POW JUNIOR | |
| METHIONAID POW | PROMACTIN AA PLUS | | |

## Exclusions/Limitations

- A prescription drug rider is **not** required for Vermont plans for enteral formula, modified solid foods, or medical foods that meet the medical criteria
- For Vermont Large Group plans, disposable supply kits are **not covered unless** the member has a disposable medical supply rider
- Enteral supplies (including but not limited to enteral feeding kits, pumps and poles) and/or nursing and home services when the formula is determined to be not medically necessary
    - MVP shall review all claims retrospectively for services and supplies, including but not limited to nursing services, per diem charges, pumps, poles and feeding bags, associated with enteral formulas

- Any enteral, modified solid, or medical foods is not considered medically necessary for any of the following:
    - Use is not based on recognized scientific principles, including but not limited to, accepted standards of care, will be considered not medically necessary
    - Taken electively (i.e. to replace a missed meal in persons who have normal GI functioning)

    - Not disease specific, this includes nutritional supplements and herbal or natural compounds, whether or not a prescription is required (Examples (not limited to) : UltraClear®, Estrium®, Protrypsin®, glucosamine, glucosamine/chondroitin, etc.)
    - Medical foods that replace or supplement standard drug treatment (i.e. Limbrel, Fosteum, Nicazel and Perative) for a specific disease or condition

- Patients with a functioning gastrointestinal tract **unless medical necessity criteria are met**
- Gluten-free solid foods used for the treatment of celiac disease
- Components of medically prescribed diets (i.e. low residue or diverticular diets)
- Formulas recommended as an alternative food source due to intolerance of standard formulas, but not as a specific treatment for an underlying disease process
- Infants with colic without evidence of medical complications
- Thickening agents that do not meet medical necessity criteria
- Enzyme packed cartridges (e.g., Relizorb (Alcresta Pharmaceuticals)) for enzyme replacement in patients receiving enteral tube feedings are considered experimental/investigational

**Initial AND continuation** approval duration is for up to 12 months

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**Medicare Variation**

**Enteral nutrition is covered under the Prosthetic Device benefit as per the Medicare Local Coverage Determination (LCD) for Enteral Nutrition (L38955) and the LCD-related Policy Article (A58833). Please refer to this guidance for appropriate coverage.**

Coverage of In-line digestive enzyme cartridges (ie. RELiZORB) is considered reasonable and necessary for the management of Medicare beneficiaries with a diagnosis of Exocrine Pancreatic Insufficiency (EPI) to maintain weight and strength corresponding with their overall health status. Please refer to LCD L38955.

Supplemental nutritional therapy including modified solid foods, medical foods, nutritional supplements, and enteral products administered orally or products that do not meet the Medicare definition of enteral therapy are not covered under Medicare Part B or Medicare Part D.

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## References


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10. Jaffe, A. C. (2011). Failure to Thrive: Current Clinical Concepts. Pediatrics in Review, 32(3), 100–108.
11. Guidelines for the Diagnosis and Management of Food Allergy in the United States. National Institute of Allergy and Infectious Disease. May 2011


| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |

| | |
|---|---|
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Medicare Gold Giveback | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | N/A |
| POS OOP | N/A |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP VT HMO | N/A |
| MVP VT Plus HMO | N/A |
| MVP VT HDHP HMO | N/A |
| MVP VT Plus HDHP HMO | N/A |
| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

**ENTYVIO (vedolizumab)**

**Type of Policy:** **Drug/Medical Therapy**
**Prior Approval Date:** **07/01/2024**
**Approval Date:** **11/01/2024**
**Effective Date:** **01/01/2025**
**Related Policies:**

Experimental or Investigational Procedures
Infliximab,
Certolizumab
Risankizumab
Upadacitinib
Ustekinumab

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Refer to the MVP website for the Medicare Part D formulary for drugs that may covered under the Part D benefit.

Refer to the MVP website for the Medicare Part B policies for coverage criteria of drugs covered under the medical benefit.

**Drugs Requiring Prior Authorization (covered under the medical benefit)**
J3380 Entyvio (vedolizumab, injection 1mg)

**Drugs Requiring Prior Authorization (covered under the pharmacy benefit)**
Entyvio subcutaneous prefilled pen

## Overview

ENTYVIO is an integrin receptor antagonist indicated for adult ulcerative colitis and adult Crohn's disease. Prior to initiating treatment with ENTYVIO, all patients should be brought up to date with all immunizations according to current immunization guidelines. ENTYVIO is not recommended in patients with active, severe infections until the infections are controlled. Providers should consider withholding treatment in patients who develop a severe infection while on treatment with ENTYVIO. Providers should perform screening for tuberculosis (TB) according to the local practice.

**Medicaid Variation:** Medications that are a pharmacy benefit are covered and billed to New York State Fee-For-Service (FFS) program. They are defined as medications that go through a retail or specialty pharmacy, including self-administered injectable products. Pharmacy medications are subject to FFS's clinical criteria including (but not limited to) coverage, quantity limit, step therapy, and prior authorization. Pharmacy benefit information can be found here: https://www.emedny.org/info/fullform.pdf

## Indications/Criteria

A. Entyvio subcutaneous pen may be considered for coverage for **Crohn's Disease** when the following criteria are met:

- Diagnosis of moderate to severe active Crohn's disease confirmed by endoscopy (or capsule endoscopy when appropriate)
- Documentation including the assessment of growth, nutrition, extraintestinal complications, therapy-induced complications and functional ability and any clinical signs and symptoms outlined in Crohn's Disease Activity Index (CDAI) such as frequent liquid stools >4/day, severity grade and frequency of abdominal pain, presence of an abdominal mass, general well-being, extra-intestinal symptoms (arthralgia, uveitis, erythema, stomatitis, abscess, fever >37.5 in the last week), taking opiates or diphenoxylate/atropine for diarrhea, anemia, and weight loss >10%.

**Initial approval** for 6 months

**Extension requests** will be approved for 12 months if the member has a continued benefit to therapy. Extension requests where Entyvio SQ that did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing

B. Entyvio subcutaneous pen may be considered for coverage for **ulcerative colitis** when the following criteria are met:
    - A diagnosis of moderate to severe Ulcerative Colitis
    - Chart notes are provided identifying inadequate response, intolerance, or contraindication to conventional therapy for maintenance of remission (i.e., anti-inflammatory aminosalicylates [e.g., mesalamine (5-ASA), sulfasalazine], 6-mercaptopurine, and azathioprine)
    - If conventional therapy is not considered medically appropriate, documentation must be provided

**Initial approval** for 6 months

**Extension requests** will be approved for 12 months if the member has a continued benefit to therapy. Extension requests where Entyvio SQ that did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing

C. For all indications, Entyvio IV may be considered for **medical** coverage when the following conditions are met:

    - Member is at least 18 years of age; AND
    - Must be prescribed by, or in consultation with, a specialist in gastroenterology; AND
    - Member is not on concurrent treatment with another TNF-inhibitor, biologic response modifier, natalizumab products, or other non-biologic agent (i.e., apremilast, tofacitinib, baricitinib, upadacitinib, etc.); AND
    - Site of Care
        - Per the MVP Health Care Pharmacy Management Programs policy, Entyvio IV is subject to Site of Care requirements and must be obtained through a preferred home infusion vendor. Prior Authorization and medical justification is required for Entyvio IV obtained and administered in other outpatient settings such as a provider's office or hospital facility.

- MVP will allow 60 days after prior authorization approval for members to transfer to a preferred infusion site.
- This requirement does not apply to MVP Medicare and Medicaid members

D. Entyvio IV may be considered for coverage for the treatment of **Crohn's disease** when the above criteria in Section C is met AND:

- Documented moderate to severe active disease; AND
- Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum (3) month trial of corticosteroids or immunomodulators (e.g., azathioprine, 6-mercaptopurine, or methotrexate); **OR**
- Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum (3) month trial on previous therapy with a TNF modifier such as adalimumab, certolizumab, or infliximab

**Initial approval** for 6 months

**Extension requests** will be approved for 12 months when the following documentation is provided:

- Disease response as indicated by improvement in signs and symptoms compared to baseline such as endoscopic activity, number of liquid stools, presence and severity of abdominal pain, presence of abdominal mass, body weight compared to IBW, hematocrit, presence of extra intestinal complications, use of anti-diarrheal drugs, tapering or discontinuation of corticosteroid therapy, and/or an improvement on a disease activity scoring tool [e.g., an improvement on the Crohn's Disease Activity Index (CDAI) score or the Harvey-Bradshaw Index score].

D. Entyvio IV may be considered for coverage for the treatment of **Ulcerative Colitis** when the above criteria in Section B is met AND:

- Documented moderate to severe active disease; AND
- Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum (3) month trial of corticosteroids or immunomodulators (e.g., azathioprine, 6-mercaptopurine, or methotrexate); **OR**

- Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum (3) month trial on previous therapy with a TNF modifier such as adalimumab, golimumab, or infliximab
- Requests for patients with moderately severe UC, who are naïve to biologic therapies will be reviewed on a case-by-case basis consistent with the AGA guidelines.

**Initial approval** for 6 months

**Extension requests** will be approved for 12 months when the following documentation is provided:

- Disease response as indicated by improvement in signs and symptoms compared to baseline such as stool frequency, rectal bleeding, and/or endoscopic activity, tapering or discontinuation of corticosteroid therapy, and/or an improvement on a disease activity scoring tool [e.g., an improvement on the Ulcerative Colitis Endoscopic Index of Severity (UCEIS) score or the Mayo Score].

E. Entyvio IV may be considered for coverage for the management of **Immune Checkpoint Inhibitor-Related Diarrhea/Colitis** when the above criteria in Section C is met AND:

• Member has been receiving therapy with an immune checkpoint inhibitor (e.g., nivolumab, pembrolizumab, atezolizumab, avelumab, durvalumab, cemiplimab, etc.); AND

• Member has moderate (grade 2) to severe (grade 3-4) diarrhea or colitis related to their immunotherapy

Entyvio IV for Immune Checkpoint Inhibitor Related Diarrhea/Colitis may not be renewed

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**Exclusions**

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling
- Combination therapy that is not supported by current clinical guidelines

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## References


1. Entyvio [package insert]. Lexington, MA 02421; Takeda Pharmaceuticals America, Inc; August 2021. Accessed September 2021.
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12. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG clinical guideline: ulcerative colitis in adults. Am J Gastroenterol. 2019 Mar;114(3):384-413.
13. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) vedolizumab. National Comprehensive Cancer Network, 2021. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL
14. ACG Clinical Guidline: Ulcerative Colitis in Adults. The American Journal of Gastroenterology: March 2019 - Volume 114 - Issue 3 - p 384-413 doi: 10.14309/ajg.0000000000000152. Accessed: ACG Clinical Guideline: Ulcerative Colitis in Adults : Official journal of the American College of Gastroenterology | ACG (lww.com)

| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Complete Wellness | Refer |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| USA Care 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 | Refer to the MVP website for the Medicare Part B and Part D policies. |

| | |
|---|---|
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

**Medicare Part B: ENTYVIO (vedolizumab)**

| | |
|---|---|
| **Type of Policy:** | **Drug/Medical Therapy** |
| **Prior Approval Date:** | **N/A** |
| **Approval Date:** | **1/01/2024** |
| **Effective Date:** | **01/01/2024** |

**Related Policies:**

**Inflammatory Biologic Drug Therapy**

**Experimental or Investigational Procedures**

**Infliximab**

Refer to the MVP website for the Medicare Part D formulary for drugs that may covered under the Part D benefit.

**Drugs Requiring Prior Authorization (covered under the medical benefit)**

J3380 Entyvio (vedolizumab, injection 1mg)

**Overview/Summary of Evidence**ENTYVIO is an integrin receptor antagonist indicated for adult ulcerative colitis and adult Crohn's disease. Prior to initiating treatment with ENTYVIO, all patients should be brought up to date with all immunizations according to current immunization guidelines. ENTYVIO is not recommended in patients with active, severe infections until the infections are controlled. Providers should consider withholding treatment in patients who develop a severe infection while on treatment with ENTYVIO. Providers should perform screening for tuberculosis (TB) according to the local practice.

**Indications/Criteria**

Coverage is provided in the following conditions:

Universal Criteria:

- Patient is at least 18 years of age; AND

- Must be prescribed by, or in consultation with, a specialist in gastroenterology; AND

- Patient is not on concurrent treatment with another TNF-inhibitor, biologic response modifier, natalizumab products or other non-biologic agent (i.e., apremilast, tofacitinib, baricitinib, upadacitinib, etc.);

- Coverage duration (unless otherwise specified for applicable indication)
    - Initial coverage up to 3 months
    - Continuation of coverage 12 months

For the treatment of **Crohn's disease**:

Documented moderate to severe active disease; AND
• Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum (3) month trial on previous therapy with a TNF modifier such as adalimumab, certolizumab, or infliximab

Continuation of therapy will require documentation of:

Disease response as indicated by improvement in signs and symptoms compared to baseline such as endoscopic activity, number of liquid stools, presence and severity of abdominal pain, presence of abdominal mass, body weight compared to IBW, hematocrit, presence of extra intestinal complications, use of anti-diarrheal drugs, tapering or discontinuation of corticosteroid therapy, and/or an improvement on a disease activity scoring tool [e.g., an improvement on the Crohn's Disease Activity Index (CDAI) score or the Harvey-Bradshaw Index score].

For the treatment of **Ulcerative Colitis**:

Documented moderate to severe active disease; AND
• Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum (3) month trial of corticosteroids or immunomodulators (e.g., azathioprine, 6-mercaptopurine, or methotrexate); OR

• Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum (3) month trial on previous therapy with a TNF modifier such as adalimumab, golimumab, or infliximab
- Requests for patients with moderately severe UC, who are naïve to biologic therapies will be reviewed on a case-by-case basis consistent with the AGA guidelines.

Continuation of therapy will require documentation of:

Disease response as indicated by improvement in signs and symptoms compared to baseline such as stool frequency, rectal bleeding, and/or endoscopic activity, tapering or discontinuation of corticosteroid therapy, and/or an improvement on a disease activity scoring tool [e.g., an improvement on the Ulcerative Colitis Endoscopic Index of Severity (UCEIS) score or the Mayo Score].

Management of **Immune Checkpoint Inhibitor-Related Diarrhea/Colitis**:

• Patient has been receiving therapy with an immune checkpoint inhibitor (e.g., nivolumab, pembrolizumab, atezolizumab, avelumab, durvalumab, cemiplimab, etc.); AND

• Patient has moderate (grade 2) to severe (grade 3-4) diarrhea or colitis related to their immunotherapy

Continuation of therapy will require documentation of:

May not be renewed

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**Exclusions**

Age, dose, frequency outside of FDA approved labeling

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**MVP Health Care Medical Policy**

**Erythropoiesis Stimulating Agents (ESAs)**

**Type of Policy:** **Drug Therapy**
**Prior Approval Date:** **10/01/2023**
**Approval Date:** **10/01/2024**
**Effective Date:** **01/01/2025**
**Related Policies: NA**

**Codes Subject to Retrospective Review**
Q5106 – Injection, epoetin alfa, biosimilar,(for non-esrd use), 1000 units Retacrit® (epoetin alfa-epbx)
J0885 – Injection, epoetin alfa, (for non-esrd use), 1000 units Epogen/Procrit® (epoetin alfa)
J0881- Injection, darbepoetin alfa, (for non-esrd use), 1000 units Aranesp

Refer to the MVP website for the prescription drug formulary for drugs that may be covered under the pharmacy benefit.

Refer to the MVP website for the Medicare Part D formulary for drugs that may be covered under the Part D benefit.

**Overview**
Erythropoietin (EPO) is a glycoprotein that regulates the production of red blood cells by stimulating the division and differentiation of committed erythroid progenitor cells in the bone marrow. Epoetin alfa has the same biological activity as native EPO.

## I. Dosing Limits

### A. Retacrit:

Max Units (per dose and over time) [Medical Benefit]:

- MDS and MPN: 120 billable units every 7 days
- Surgery patients: 600 billable units every 15 days

- All other indications: 60 billable units every 7 days

**B. Epogen/Procrit:**

Max Units (per dose and over time) [Medical Benefit]:

- MDS and MPN: 120 billable units every 7 days
- Surgery patients: 600 billable units every 15 days
- All other indications: 60 billable units every 7 days

**C. Aranesp:**

Max Units (per dose and over time) [Medical Benefit]:

- MDS and MPN: 120 billable units every 7 days
- Surgery patients: 600 billable units every 15 days
- All other indications: 60 billable units every 7 days

## II. Indications/Criteria

- Lab values are obtained within 30 days of the date of administration (unless otherwise indicated); **AND**
- Prior to initiation of therapy, patient should have adequate iron stores as demonstrated by serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) ≥ 20%*****; **AND**
- Initiation of therapy Hemoglobin (Hb) < 10 g/dL and/or Hematocrit (Hct) < 30% (unless otherwise specified); **AND**
- Other causes of anemia (e.g. hemolysis, bleeding, vitamin deficiency, etc.) have been ruled out; **AND**
- Covered for the following indications:

**Anemia secondary to myelodysplastic syndrome (MDS)**
Treatment of lower risk disease associated with symptomatic anemia; **AND**
Endogenous serum erythropoietin level of ≤ 500 mUnits/mL
**Anemia secondary to Myeloproliferative Neoplasms (MPN) - Myelofibrosis**
Endogenous serum erythropoietin level of < 500 mUnits/mL
**Anemia secondary to Hepatitis C treatment**

- Patient is receiving interferon AND ribavirin

**Anemia secondary to rheumatoid arthritis**
**Anemia secondary to chemotherapy treatment**
Patient is receiving concurrent myelosuppressive chemotherapy; **AND**
Patient's chemotherapy is not intended to cure their disease (i.e., palliative treatment); **AND**
There are a minimum of two additional months of planned chemotherapy
**Anemia secondary to chronic kidney disease (non-dialysis patients)**
**Anemia secondary to zidovudine treated, HIV-infected patients**
Endogenous serum erythropoietin level of ≤ 500 mUnits/mL; **AND**
Patient is receiving zidovudine administered at ≤ 4200 mg/week
**Reduction of allogeneic blood transfusions in elective, non-cardiac, non-vascular surgery**
Hemoglobin (Hb) between 10 g/dL and 13 g/dL and/or Hematocrit (Hct) between 30% and 39%; **AND**
Surgery must be elective, non-cardiac and non-vascular
**Anemia of Prematurity**
Used in combination with iron supplementation

## III. Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Last dose less than 60 days ago; **AND**
- Disease response; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe cardiovascular events (stroke, myocardial infarction, thromboembolism, uncontrolled hypertension), tumor progression or recurrence in patients with cancer, seizures, pure red cell aplasia, severe cutaneous reactions (erythema multiforme, Stevens-Johnson syndrome/toxic epidermal necrolysis), "gasping syndrome" (central nervous system depression, metabolic acidosis, gasping respirations) due to benzyl alcohol preservative, etc.; **AND**
- Lab values are obtained within 30 days of the date of administration (unless otherwise indicated); **AND**

- Adequate iron stores as demonstrated by serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) ≥ 20% measured within the previous 3 months*****; **AND**
- Other causes of anemia (e.g. hemolysis, bleeding, vitamin deficiency, etc.) have been ruled out; **AND**

**Anemia secondary to myelodysplastic syndrome (MDS):**

- Hemoglobin (Hb) <12 g/dL and/or Hematocrit (Hct) <36%

**Anemia secondary to myeloproliferative neoplasms (MF, post-PV myelofibrosis, post-ET myelofibrosis)**

- Hemoglobin (Hb) <10 g/dL and/or Hematocrit (Hct) <30%

**Reduction of allogeneic blood transfusions in elective, non-cardiac, non-vascular surgery**

- Hemoglobin(Hb) between 10 g/dL and 13 g/dL and/or Hematocrit(Hct) between 30% and 39%

**Anemia secondary to chemotherapy treatment**

- Hemoglobin (Hb) <10 g/dL and/or Hematocrit (Hct) < 30%; **AND**
- Patient is receiving concurrent myelosuppressive chemotherapy; **AND**
- There are a minimum of two additional months of planned chemotherapy

**Anemia secondary to zidovudine treated, HIV-infected patients:**

- Hemoglobin (Hb)< 12 g/dL and/or Hematocrit (Hct) < 36%; **AND**
- Patient is receiving zidovudine administered at ≤ 4200 mg/week

**Anemia secondary to Hepatitis C treatment:**

- Hemoglobin (Hb) < 11 g/dL and/or Hematocrit (Hct) < 33%; **AND**
- Patient must be receiving interferon AND ribavirin

**Anemia secondary to chronic kidney disease:**

- **Pediatric patients:** Hemoglobin (Hb) < 12 g/dL and/or Hematocrit (Hct) < 36%
- **Adults:** Hemoglobin (Hb) < 11 g/dL and/or Hematocrit (Hct) < 33%

**All other indications:**

- Hemoglobin (Hb) < 11 g/dL and/or Hematocrit (Hct) < 33%

***** Intravenous iron supplementation may be taken into account when evaluating iron status

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## IV. Dosage/Administration

| Indication | Dose |
|---|---|
| Anemia due to CKD – non-dialysis | • Adults: 50-100 units/kg intravenously or subcutaneously three times weekly<br>• Pediatric patients (1 month or older): 50 units/kg intravenously or subcutaneously three times weekly |
| Anemia due to HIV on zidovudine | • 100 units/kg three times weekly<br>• May titrate up to 300 units/kg |
| Anemia due to chemotherapy | • Adults: 150 units/kg intravenously or subcutaneously three times weekly or 40,000 units once weekly<br>  ○ May titrate up to 300 units/kg three times weekly or 60,000 units once weekly<br>• Pediatric patients (5-18 years): 600 units/kg intravenously or subcutaneously once weekly<br>  ○ May titrate up to 900 units/kg once weekly |
| Perioperative use | • 300 units/kg/day subcutaneously for 10 days before surgery, on the day of surgery, and for 4 days after surgery (15 days total)<br>• 600 units/kg/dose subcutaneously on days 21, 14, and 7 before surgery plus 1 dose on the day of surgery (4 total doses) |
| Anemia due to HCV | • 40,000 units intravenously or subcutaneously once weekly<br>• May titrate up to 60,000 units weekly |
| Anemia due to MDS/MPN | • 150-300 units/kg intravenously or subcutaneously three times weekly<br>• 40,000 to 60,000 units once to twice weekly |

| | |
|---|---|
| All other indications | Dosing varies; generally up to 150 units/kg intravenously or subcutaneously three times weekly |
| Most commonly initiated dose | 40,000 units weekly |

## References


1. Retacrit [package insert]. Lake Forest, IL; Hospira, Inc; May 2018. Accessed May 2018.
2. Aranesp [package insert]. Thousand Oaks, CA; Amgen; June 2011. Accessed March 2019.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) epoetin alfa. National Comprehensive Cancer Network, 2018. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc." To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed May 2018.
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| Member 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 | Pharmacy benefit carved out to Medicaid FFS, Medical benefit<br>Potential for Retrospective Review |
| MVP Child Health Plus | |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit<br>Potential for Retrospective Review |
| MVP Medicare Gold Giveback | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP VT HMO | Potential for Retrospective Review |
| MVP VT Plus HMO | Potential for Retrospective Review |
| MVP VT HDHP 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

**Etanercept**

| | |
|---|---|
| **Type of Policy:** | **Drug/Medical Therapy** |
| **Prior Approval Date:** | **10/01/2023** |
| **Approval Date:** | **02/01/2024** |
| **Effective Date:** | **04/01/2024** |
| **Related Policies:** | **Apremilast** |
| | **Adalimumab** |
| | **Infliximab** |
| | **Risankizumab** |
| | **Secukinumab** |
| | **Tofacitinib** |
| | **Upadacitinib** |
| | **Ustekinumab** |
| | **Zeposia** |

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies.

## Drugs Requiring Prior Authorization under the pharmacy benefit

Enbrel (J1438, etanercept)

## Overview

Etanercept is a subcutaneously administered tumor necrosis factor (TNF) blocker that is a soluble TNF receptor. Like other TNF blockers, etanercept is useful in a variety of inflammatory disorders such as rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and psoriasis. Etanercept carries a black box warning for infection and

malignancy. Members should be screened for immunologic and infectious disease prior to initiating therapy. **Medicare Variation**

- Refer to the Medicare Part D formulary for drugs that may be covered under the Part D benefit.
- Medicare Part B variation: Step through therapy is NOT required for medical drugs.

**Medicaid Variation:** Medications that are a pharmacy benefit are covered and billed to New York State Fee-For-Service (FFS) program. They are defined as medications that go through a retail or specialty pharmacy, including self-administered injectable products. Pharmacy medications are subject to FFS's clinical criteria including (but not limited to) coverage, quantity limit, step therapy, and prior authorization. Pharmacy benefit information can be found here: https://www.emedny.org/info/fullform.pdf

**Indications/Criteria**

**A. For all indications, the following criteria must be met in addition to the specific diagnosis criteria below.**

- Prescription drugs covered under the pharmacy benefit must be self-administered. If office administration is being requested documentation must be provided identifying why the member or caregiver is unable to administer the medication
- Must be ordered by or with consult from an appropriate specialist: rheumatologist/immunologist/dermatologist
- Must be prescribed for an FDA approved indication

**B. Ankylosing Spondylitis**

Etanercept may be considered for coverage for Ankylosing Spondylitis when:

- Chart notes documenting failure of at least one NSAIDS at maximum tolerated dose unless the member has contraindications to NSAID therapy such as cardiovascular disease, peptic ulcer disease or renal disease **AND**
- Documented significant clinical symptoms such as fatigue, spinal pain, arthralgia, inflammation of joints and tendons, morning stiffness duration and therapy **AND**

- Insufficient response to at least one local corticosteroid injection in patients with symptomatic peripheral arthritis **AND**
- **Members with pure axial manifestations** do not have to have a trial of nonbiologic disease modifying anti-rheumatic drugs (DMARDs)

**Initial approval** will be for 6 months

**Extension requests** will be approved for up to 12 months if the member has a continued benefit to therapy. Extension requests where the Etanercept did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

**C. Psoriasis**

Etanercept may be considered for coverage for Psoriasis when:

- The medication is ordered by or in consultation with a dermatologist
- A diagnosis of moderate to severe chronic plaque psoriasis and one of the following:
    - Crucial body areas (e.g. hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected OR
    - At least 10% of the body surface area (BSA) is affected OR
    - At least 3% of the body surface area (BSA) is affected AND the member meets any of the following criteria:
        - Member has had an inadequate response or intolerance to either phototherapy (e.g. UVB, PUVA) OR
        - Member has had an inadequate response or intolerance to pharmacologic treatment with methotrexate, cyclosporine, or acitretin

**Initial approval** for **6 months**.

**Extension requests** will be approved for 12 months if the member has a continued benefit to therapy. Extension requests where etanercept did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

**D. Psoriatic Arthritis**

Etanercept may be considered for coverage for Psoriatic Arthritis when:

- Member has a diagnosis of moderate to severe psoriatic arthritis as indicated by three or more tender joints AND three or more swollen joints on two separate occasions at least one month apart
- Chart notes documenting a failure of at least one NSAIDS at maximum tolerated dose unless the member has contraindications to NSAID therapy such as cardiovascular disease, peptic ulcer disease or renal disease **AND**
- Chart notes documenting a failure to respond to an adequate trial of at least one of the following nonbiologic disease modifying anti-rheumatic drugs (DMARDs): leflunomide, sulfasalazine, or methotrexate.

    - **Members with pure axial manifestations** do not have to have a trial of nonbiologic disease modifying anti-rheumatic drugs (DMARDs)
    - If a trial of methotrexate is not appropriate due to alcohol use and both leflunomide and sulfasalazine are not clinically appropriate, chart notes must be provided indicating that the patient has been counseled on the need to abstain from alcohol use while taking methotrexate and is unwilling to abstain from alcohol use.

**Initial approval** will be for 6 months

**Extensions requests** will be approved **up to 12 months** if the member has a continued benefit to therapy. Extension requests where the Etanercept did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

## E. Rheumatoid Arthritis

Etanercept may be considered for coverage for Rheumatoid Arthritis when:

- Member has a diagnosis of moderate to severe active adult **rheumatoid arthritis** as defined by persistent or recurrent symptoms with documented synovitis and morning stiffness of significant duration to inhibit activities of daily living **AND**
- Chart notes documenting a failure to respond to one or more nonbiologic disease modifying anti-rheumatic drugs (DMARDs), one of which includes a three-month trial of maximally tolerated dose of methotrexate.

- Failure is demonstrated by documentation of provider assessment without improvement in joint counts and/or physical symptoms and inflammatory markers while on therapy.
- If the member has a contraindication or significant intolerance to methotrexate
  - Chart notes documenting a failure to respond to at least one other nonbiologic DMARDs at a maximally tolerated dose for at least 3 months **AND**
  - Documentation confirming why methotrexate cannot be used is required. If a trial of methotrexate is not appropriate due to alcohol use, chart notes must be provided indicating that the patient has been counseled on the need to abstain from alcohol use while taking methotrexate and is unwilling to abstain from alcohol use.

- Etanercept may be used without prior methotrexate trial if the member has an acute, aggressive, very rapidly progressive intense inflammatory symmetrical arthritis disease as defined by their rheumatologist

**Initial approval** will be for 6 months

**Extensions requests** will be approved **up to 12 months** if the member has a continued benefit to therapy. Extension requests where the Etanercept did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

**F. Juvenile Idiopathic Arthritis**

Requests for etanercept treat Juvenile idiopathic arthritis will be reviewed on a case-by-case basis using the American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis.

**Initial approval** will be for 6 months

**Extensions requests** will be approved **up to 12 months** if the member has a continued benefit to therapy. Extension requests where the Etanercept did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

## Exclusions

The use of etanercept will not be covered for the following situations:

- Dosing/age and/or frequency outside of the FDA approved package labeling.
- Etanercept in combination with other biologics is excluded from coverage
- Combination therapy that is not supported by guidelines
- History of Multiple Sclerosis

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## References


1. Enbrel® (etanercept) injection. Prescribing Information. Thousand Oaks, CA: Immunex Corporation; June 2022.
2. Etanercept. Clinical Pharmacology powered by ClinicalKey. Philadelphia (PA): Elsevier. C2021 - [cited 2023 Aug 21]. Available from: http://www.clinicalkey.com.


| 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 | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Authorization |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Medicare Gold Giveback | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |

| | |
|---|---|
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D |
| 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).** | |
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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 |

**MVP Health Care Medical Policy**

**Etrasimod**

**Type of Policy:** Drug/Medical therapy (administered by the pharmacy department)

**Prior Approval Date: NA**

**Approval Date:** 10/01/2024

**Effective Date:** 01/01/2025

**Related Policies:** Ozanimod

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies.

## Drugs Requiring Prior Authorization under the pharmacy benefit

Velsipity (etrasimod)

## Overview

Etrasimod is an oral sphingosine 1-phosphate receptor modulator. It is indicated for moderately to severely active ulcerative colitis (UC) in adult patients. Etrasimod binds with high affinity to S1P receptors 1, 4, and 5 (S1P1,4,5). Etrasimod has minimal activity on S1P3 and no activity on S1P2. Etrasimod partially and reversibly blocks the capacity of lymphocytes to egress from lymphoid organs, reducing the number of lymphocytes in peripheral blood. The mechanism by which etrasimod exerts therapeutic effects in UC is unknown but may involve the reduction of lymphocyte migration into the intestines.

## Indications/Criteria

**A. Ulcerative Colitis**

Etrasimod may be considered for coverage for ulcerative colitis when all the following criteria is met:

- A diagnosis of moderate to severe Ulcerative Colitis
- Ordered by a participating gastroenterologist or colorectal surgeon
- Documentation identifying inadequate response, intolerance, or contraindication to conventional therapy for maintenance of remission (i.e., anti-inflammatory aminosalicylates [e.g., mesalamine (5-ASA), sulfasalazine], 6-mercaptopurine, and azathioprine)
    - If conventional therapy is not considered medically appropriate, documentation must be provided
- Provider attestation that the member has not experienced the following in the last 6 months: myocardial infarction, unstable angina pectoris, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III or IV heart failure
- Provider attestation that the member does not have a history or presence of Mobitz type II second-degree or third-degree atrioventricular (AV) block, sick sinus syndrome, or sino-atrial block, unless the patient has a functioning pacemaker

**Initial approval** will be for 6 months

**Extension requests** will be approved for up to 12 months if the member has a continued benefit to therapy. Extension requests where the etrasimod did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

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**Exclusions**

The use of Etrasimod will not be covered for the following situations:

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling
- Combination therapy that is not supported by current clinical guidelines

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## References


1. Etrasimod. In: Clinical Pharmacology [database on the Internet]. Tampa (FL): Elsevier. 2024 [cited September 9, 2024]. Available from: www.clinicalpharmacology.com. Subscription required to view.

2. Velsipity [package insert]. New York, NY: Pfizer; June 2024.


| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Medicare Gold Giveback | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP VT HMO | Prior Auth |

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

**MVP Health Care Medical Policy**

**Formulary Exception for Non-Covered Drugs**

**Type of Policy:** **Drug Therapy**
**Prior Approval Date:** **03/01/2023**
**Approval Date:** **12/01/2024**
**Effective Date:** **02/01/2025**
**Related Policies:** **N/A**

**Drugs Requiring Prior Authorization** N/A

## Overview

The Pharmacy and Therapeutics (P&T) Committee excludes coverage for all newly released drugs for a period of at least six months so committee members and specialists can become familiar with the drug's use in clinical practice. The P&T Committee may approve early review at any time after FDA approval. Generic equivalents of existing drugs will become reimbursable when they are added to the pharmacy benefit management (PBM) prescription processing system.

The P&T Committee recommends drugs to be excluded from coverage if they do not have significant clinical and/or therapeutic advantages over drugs currently covered by the Plan. The Committee uses utilization, pharmaco-economic and clinical data to develop the exclusions. However, not every member may be able to tolerate formulary drugs due to clinical ineffectiveness or adverse/allergic reactions. Therefore, a formulary exception (prior authorization) process for these exceptions will allow members to receive otherwise non-covered medications.

This policy serves two purposes:

1. To provide physicians a means by which they can select the most appropriate and cost-effective drugs for their patients.
2. To develop a procedure by which a physician may request a non-covered drug for member use under MVP's policies.

**Indications/Criteria**

Formulary exceptions are reviewed on a case-by-case basis for non-formulary and excluded drugs, subject to the determination of medical necessity based on the criteria below.

A pharmacist and/or the Medical Director will review all requests for formulary exceptions.

1. The prescriber will submit the completed request for coverage form to the Plan for review prior to the prescription being filled. To avoid transcription problems and to ensure that current clinical information is reviewed, requests from third parties, including but not limited to pharmacy service providers and manufacturers, will not be honored.
2. This policy cannot cover all situations likely to be encountered. The clinical reviewer must exercise discretion and document rationale for approvals. Review is based on medical considerations which clearly demonstrate the potential for adverse medical outcome to the member. Examples include but are not limited to:
    a. Documented allergic/adverse reaction to formulary agents.
    b. Documented failure on formulary agents.
    c. Documented member therapy stability issues in patients where a formulary agent is contraindicated or a change in therapy is not advisable.
    d. Policy and/or benefit interpretation
    e. Member contract and/or prescription drug rider
3. If documentation submitted substantiates an approval, the pharmacist will make the determination. A Plan medical director reviews all requests that are recommended by a pharmacist for medical necessity denial.
4. A reply (approval or denial) will be provided to both the member and physician in a timely fashion.

When approved, the member is responsible for the usual pharmacy co-payment per contract/rider.

Brand or generic status is determined by the PBM pricing source for all drugs.

Initial approval for a formulary exception will be up to 6 months

Extension requests will be approved for up to 12 months and must include the following:

- Provider attestation that the member has a continued benefit to therapy **and**

- Provider attestation that formulary alternatives, including new therapies added to the formulary, are not medically appropriate for the member.

**VT Commercial and VT Exchange turnaround time**

a. All requests are considered urgent. We will make a formulary exception determination within 24 hours of provider receipt and documentation.

**NY Commercial and NY Exchange turnaround time**

Standard Review. We will make a formulary exception determination within 72 hours of provider receipt and documentation.

a. Expedited (Urgent) Review. If the requesting health care professional asserts that the member has a medical condition that places the member's health in serious jeopardy without the prescription drug prescribed by the requesting health care professional the formulary exception will be made within 24 hours of provider receipt and documentation.

## Formulary Exception (Medicaid)

Medications that are a pharmacy benefit are covered and billed to New York State Fee-For-Service (FFS) program. They are defined as medications that go through a retail or specialty pharmacy, including self-administered injectable products. Pharmacy medications are subject to FFS's clinical criteria including (but not limited to) coverage, quantity limit, step therapy, and prior authorization. Pharmacy benefit information can be found here: https://www.emedny.org/info/fullform.pdf

Medicaid follows the same criteria as above with the following exceptions:

a. Members may be allowed immediate access without prior authorization to a 72-hour emergency supply of a medication for a member with a behavioral health condition experiencing an emergency condition or a 7day supply of a substance use medication (opioid withdrawal and/or stabilization).

b. Foster Care Transition fills
    a. Transition fills apply to ensure access to care for medications that require prior authorization. Prior authorizations that were approved in Medicaid Fee-For-Service (FFS) will not carry through to MVP Medicaid Managed Care.

b. A member is allowed a one-time fill up to a thirty (30) day supply within the first ninety (90) days of foster care placement as a transitional fill. This transition fill is not limited to new enrollees.
c. Transition fill allows exceptions to refill timeframes and to rapidly replace lost medications
d. Transition fill applies to DME replacement

## Medicare Variation

Refer to the Medicare Part D formulary for drugs that may be covered under the Part D benefit.

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## Exclusions

- Members without prescription drug coverage
- Exceptions for non-covered drugs that are not prior authorized are not covered.Any employer group contract not subject to the Plan's Formulary is exempt from this policy.

## References

| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Complete Wellness | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| USA Care PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| Healthy NY | Prior Auth |

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|---|---|
| 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 | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

**GABA-Receptor Modulators**

| | |
|---|---|
| **Type of Policy:** | **Drug Therapy** |
| **Prior Approval Date:** | **11/01/2023** |
| **Approval Date:** | **11/01/2024** |
| **Effective Date:** | **01/01/2025** |
| **Related Policies:** | Quantity Limits for Prescription Drugs |
| | Obstructive Sleep Apnea: Diagnosis |

## Drugs Requiring Prior Authorization

Xyrem® (sodium oxybate)

Sodium Oxybate solution

Xywav® (Calcium Oxybate, Magnesium Oxybate, Potassium Oxybate, Sodium Oxybate)

Refer to the MVP website for the Medicare Part D formulary for drugs that may covered under the Part D benefit.

## Overview

Narcolepsy is a chronic neurological disorder caused by the brain's inability to regulate sleep-wake cycles normally. At various times throughout the day people with narcolepsy experience fleeting urges to sleep. If the urge becomes overwhelming, patients fall asleep for periods lasting from a few seconds to several minutes. In rare cases, some people may remain asleep for an hour or longer. In addition to the most common symptom excessive daytime sleepiness (EDS), three other major symptoms frequently characterize narcolepsy: cataplexy (the sudden loss of voluntary muscle tone); vivid hallucinations during sleep onset or upon awakening; and brief episodes of total paralysis at the beginning or end of sleep. EDS can result from a wide range of medical conditions, including other sleep disorders such as sleep apnea, various viral or bacterial infections, mood disorders such as depression, and painful chronic illnesses such as congestive heart failure and rheumatoid arthritis that disrupt normal sleep patterns. Various medications can also lead to EDS, as can consumption of caffeine, alcohol, and nicotine. Finally, sleep deprivation has become one of the most common causes of EDS

among Americans. This lack of specificity increases the difficulty of arriving at an accurate diagnosis based on a consideration of symptoms alone. Specialized tests are essential in confirming a diagnosis of narcolepsy.

Xyrem® (sodium oxybate) is GHB (gamma-hydroxybutyrate), a known drug of abuse. Xyrem is indicated for the treatment of excessive daytime sleepiness and cataplexy in patients with narcolepsy. In Xyrem clinical trials, approximately 80% of patients maintained concomitant stimulant use. The package label black box warns that Xyrem is a central nervous system (CNS) depressant with abuse potential, and it should not be used with alcohol or other CNS depressants. Xyrem is only available through the Xyrem REMS Program, using a centralized pharmacy.

Xywav® is a mixture of oxybate salts, including calcium, magnesium, potassium, and sodium oxybates. The Xywav product differs from Xyrem, a sodium oxybate formulation, in that the oxybate electrolytes are balanced in the Xywav formulation, eliminating the need for monitoring in patient populations requiring a low sodium diet. In addition, to the indication for treatment of cataplexy or EDS in patients with narcolepsy, Xyway is indicated for the treatment of idiopathic hypersomnia (IH). IH is a rare and typically chronic neurologic sleep disorder and is unique from other disorders that also cause EDS. Furthermore, people with IH still experience EDS during the day despite sleeping a normal or longer than normal amount of time each night. Xywav is only available through the Xywav REMS Program, using a certified pharmacy.

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**Indications/Criteria**

A. Xyrem and Xywav for the treatment of cataplexy and excessive daytime sleepiness in members with narcolepsy may be considered for coverage when all of the following criteria are met:

- Member has a definitive diagnosis of narcolepsy based upon objective sleep studies; **AND**
- Member is at least 7 years old; **AND**
- Quantitatively documented symptoms of excessive daytime sleepiness and/or cataplexy; **AND**
- Documented intolerance, contraindication, or failure of a 3-month trial of the following:
    - For Adults 17 years of age and older:
        - For excessive daytime sleepiness (EDS)

- modafinil 200mg daily or solriamfetol (Sunosi) 150mg daily or armodafinil 150mg daily; **AND** a formulary amphetamine product

- For Pediatric members 7 years old up to 17 years old
  - For excessive daytime sleepiness (EDS)
    - Modafinil

B. Xywav for the treatment of idiopathic hypersomnia (IH) may be considered for coverage when the following criteria is met:
   - Member has a definitive diagnosis of idiopathic hypersomnia (IH) in adults including:
     - Chart notes documenting that other disorders or medications that can cause EDS have been ruled out such as narcolepsy type 1 and 2, insufficient sleep syndrome, obstructive sleep apnea, depression, and delayed sleep phase syndrome.
   - Documentation of clinical feature(s) supportive of IH
     - Unrefreshing sleep
     - Prolonged sleep time
     - Memory problems or attention deficit
     - Severe and prolonged sleep inertia
     - Automatic behaviors during periods of drowsiness
     - Autonomic symptoms (fainting, cold hands and feet, orthostatic hypotension)
   - Documentation of symptom severity
     - Epworth Sleepiness Scale (ESS) of ≥ 10 and/or idiopathic hypersomnia severity scale (IHSS).

**Initial approval** will be for 6 months

For members with a diagnosis of narcolepsy, **extension requests** will be approved up to 12 months if the member has a  continued therapy based on demonstrated response of decreasing cataplexy events and improvement in score for appropriate test (e.g. Epworth Sleepiness Scale, Clinical Global Impression of Change, etc.) for EDS.

For members with a diagnosis of IH, **extension requests** will be approved up to 12 months if the member has a continued therapy will be considered at 6-month intervals based on documentation of improvement measured by ESS score and/or IHSS score and clinical impression

**Exclusions**

- Concomitant use with sedative hypnotics (including anxiolytics), CNS depressants (including alcohol), sedating antidepressants
- History of GHB abuse
- Diagnosis of narcolepsy based solely on symptoms
- Doses greater than 9 grams per night

Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling

**References**


1. Narcolepsy Fact Sheet [Internet]. Bethesda (MD): National Institute of Neurological Disorders and Stroke; 2016 Apr 6 [cited 2016 Sep 9]. Available from: http://www.ninds.nih.gov/disorders/narcolepsy/detail_narcolepsy.htm
2. Xyrem® (sodium oxybate) Oral Solution. Prescribing Information. Palto Alto, CA: Jazz Pharmaceuticals Inc.; April 2015.
3. Kiran Maski, Lynn Marie Trotti, Suresh Kotagal, et al. Treatment of central disorders of hypersomnolence: an American Academy of Sleep Medicine clinical practice guideline. Journal of Clinical Sleep Medicine. September 2021; 17(9): 1881 93. Cataplexy. In: DRUGDEX® System [Internet database]. Greenwood Village, Colo: Thomson Reuters (Healthcare) Inc. Updated periodically.
4. Narcolepsy in Children: Management and Treatment. Cleveland Clinic. March 3, 2020. Accessed October 1, 2020. https://my.clevelandclinic.org/health/diseases/14307-narcolepsy-in-children/management-and-treatment
5. Xywav® calcium, magnesium, potassium, and sodium oxybates solution. Prescribing Information. Palto Alto, CA: Jazz Pharmaceuticals Inc.; April 2023.
6. Arnulf I, Leu-Semenescu S, Dodet P. Precision medicine for idiopathic hypersomnia. *Sleep Med Clin*. 2019;14(3):333-350.
7. Trotti LM. Idopathic hypersomnia. *Sleep Med Clin*. 2017;12(3):331-344.
8. Ali M, Auger RR, Slocumb NL, Morgenthaler TI. Idiopathic hypersomnia: clinical features and response to treatment. *J Clin Sleep Med*. 2009;5(6):562-568.

9. American Academy of Sleep Medicine. *International Classification of Sleep Disorders*. 3rd ed. Darien, IL:American Academy of Sleep Medicine; 2014.

10. Johns MW. A new method for measuring daytime sleepiness: the Epworth Sleepiness Scale. *Sleep*. 1991;14(6):540-545.

11. Dauvilliers Y, Evangelista E, Barateau L, et al. Measurement of symptoms in idiopathic hypersomnia: the Idiopathic Hypersomnia Severity Scale. *Neurology*. 2019;92(15):e1754-e1762.

| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Complete Wellness | Refer |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part |
| USA Care 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 | Refer to the MVP website for the Medicare Part B and Part |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part |
| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

**Gabapentin ER**

| | |
|---|---|
| **Type of Policy:** | **Drug Therapy** |
| **Prior Approval Date:** | **11/01/2023** |
| **Approval Date:** | **11/01/2024** |
| **Effective Date:** | **01/01/2025** |
| **Related Policies:** | **N/A** |

**Drug Requiring Prior Authorization (covered under the pharmacy benefit)**

Gralise® (gabapentin)
Gabapentin ER
Horizant® (gabapentin enacarbil)

Refer to the MVP website for the Medicare Part D formulary for drugs that may be covered under the Part D benefit.

**Overview**

Horizant (gabapentin enacarbil) is an oral medication used to treat primary restless legs syndrome (RLS) and postherpetic neuralgia (PHN) in adults. Gabapentin enacarbil is a prodrug of gabapentin and its therapeutic effects in RLS and PHN are attributable to gabapentin. The precise mechanism by which gabapentin is efficacious in RLS and PHN is unknown.

RLS is a sensorimotor disorder characterized by an urge to move the legs that is usually accompanied or caused by uncomfortable sensations in the legs that occurs primarily in the evening and night. RLS is also called Willis-Ekbom Disease. Patients with RLS often report daytime fatigue, decreased alertness and emotional distress due to sleep disturbances. Gabapentin enacarbil is a prodrug of gabapentin, an antiepileptic drug. The mechanism by which Horizant is effective for RLS is unknown.

Post-herpetic neuralgia (PHN) is a painful complication of acute herpes zoster infection which occurs in ~10 to 20% of herpes zoster patients. Horizant is a twice-daily formulation of gabapentin enacarbil and Gralise is a once-daily formulation indicated to treat PHN, also known as after-shingles pain. The exact mechanism by which Horizant

and Gralise exert their analgesic effects is not completely understood. In rats and mice gabapentin prevents pain-related responses of neuropathic pain.

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**Indications/Criteria**

A. Horizant for RLS will be considered when ALL of the following criteria are met:
- Member has a documented diagnosis of moderate to severe primary (idiopathic) RLS
- Other causes of movement disorder have been ruled out and RLS is definitively diagnosed.The member has a score of 11 or greater on the International Restless Legs Syndrome Rating Scale
- The member has failed a1-month trial or have a contraindication or intolerance to one of the following:
    - Ropinirole
    - Pramipexole

**Initial approval** will be for 6 months

**Extension requests** will be approved up to 12 months, if there is documentation that the member has continued benefit to therapy and improvement in score on the International Restless Legs Syndrome Rating Scale

B. Horizant or Gralise for PHN will be considered when ALL of the following criteria are met:
- PHN has persisted for at least three months after the rash and/or blisters have healed; AND
- Minimum baseline pain intensity score of at least 4 on an 11-point numerical pain rating scale ranging from 0 (no pain) to 10 (worst possible pain);
- Provider attestation that the member has a contraindication, intolerance, or failure to an adequate trial of each of the following medications
    - gabapentin immediate release at 1800mg in divided dose three times a day;
    - Lidocaine 5% patch

**Initial approval** will be limited to 6 months.

**Extension requests** will be approved up to 12 months if there is documentation of continued benefit and adequate pain relief.

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## Exclusions

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling  RLS secondary to other conditions (iron deficiency anemia, pregnancy, ESRD, etc.)
- Members with a movement disorder other than RLS, including periodic limb movement disorder
- Gralise
    - Creatinine Clearance less than 30ml/min
    - Members on hemodialysis
- Horizant for RLS
    - Combination therapy with dopamine agonists

---

## References


1. Horizant® (gabapentin enacarbil). Prescribing Information. Atlanta, GA: Arbor Pharmaceuticals, LLC April 2020.
2. 
3. National Institutes of Health. National Institute of Neurological Disorders and Stroke. Restless Legs Syndrome Fact Sheet. http://www.ninds.nih.gov/disorders/restless_legs/restless_legs.htm [Accessed December 27, 2012.]
4. 
5. Gralise (gabapentin).  Prescribing Information.  Newark, CA: Depomed, Inc. April 2020. Revised 04/2023.
6. Restless Legs Syndrome Rating Scale (nih.gov)


| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Complete Wellness | Refer |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part |

| | |
|---|---|
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part |
| USA Care 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 | Refer to the MVP website for the Medicare Part B and Part |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part |
| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

# Ganaxolone

**Type of Policy:** **Drug/Medical Therapy**
**Prior Approval Date:** **02/01/2023**
**Approval Date:** **02/01/2024**
**Effective Date:** **04/01/2024**

**Related Policies:** **NA**

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies.

## Drugs Requiring Prior Authorization under the pharmacy benefit

Ztalmy (ganaxolone) suspension

## Overview

Ganaxolone is a neuroactive steroid gamma-aminobutyric acid (GABA) A receptor positive modulator indicated for the treatment of seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD) in patients 2 years and older. CDD is a rare developmental epileptic encephalopathy (DEE) that causes both epileptic activity and severe developmental impairment, impacting cognitive, motor, speech, and visual function.

## Indications/Criteria

Ztalmy may be considered for coverage when all the following criteria are met:

- Ordered by or in consult with a neurologist.
- Member has a documented diagnosis of seizures associated with cyclin-dependent kinase like 5 deficiency disorder (CDD)
- Confirmed CDKL5 gene mutation
- Documentation of baseline monthly seizure frequency
- Documentation of a failure of at least two previous antiepileptic therapies

**Initial approval** will be for 6 months.

**Extension requests** will be approved for up to 12 months if the member has a continued benefit to therapy and documentation of reduction in monthly seizure frequency compared to baseline.

## Exclusions

The use of Ztalmy will not be covered for the following situations:

- Dosing, age, and/or frequency outside of the FDA approved package labeling

## References

1. Clinical Pharmacology. Ztalmy 50mg/ml suspension. Revised 03/29/2022. Accessed 01/07/2023.

| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Medicare Gold Giveback | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |

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|---|---|
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D |
| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

**Gaucher Disease Type 1 Treatment**

| | |
|---|---|
| **Type of Policy:** | **Drug/Medical Therapy** |
| **Prior Approval Date:** | **10/01/2023** |
| **Approval Date:** | **12/01/2024** |
| **Effective Date:** | **02/01/2025** |
| **Related Policies:** | **N/A** |

**Codes Requiring Prior Authorization (covered under the medical benefit)**

J1786 Cerezyme® (imiglucerase, 10 units)

J3385 Vpriv™ (Injection, velaglucerase alfa, 100 units)

J3060 Elelyso (Injection, taliglucerase alfa, 10 units)

**Drug Requiring Prior Authorization (covered under the pharmacy benefit)**

Cerdelga (eliglustat 84 mg oral capsules)

Zavesca® (miglustat 100 mg oral capsules)

Miglustat 100mg oral capsules

Refer to the Medicare Part D formulary for drugs that may be covered under the Part D benefit

**Overview**

Gaucher disease is an inherited metabolic disorder in which harmful quantities of a fatty substance called glucocerebroside accumulate in the spleen, liver, lungs, bone marrow, and sometimes in the brain. There are three types of Gaucher disease. **Type 1** is the most common. Members in this group usually bruise easily and experience fatigue due to anemia and low blood platelets. They also have an enlarged liver and spleen, skeletal disorders, and, in some instances, lung and kidney impairment. There are no signs of brain involvement. Symptoms can appear at any age. In **Type 2**, liver and spleen enlargement are apparent by 3 months of age. Members have extensive and progressive brain damage and usually die by 2 years of age. In **Type 3**, liver and spleen enlargement is variable, and signs of brain involvement such as seizures gradually become apparent.

All Gaucher members exhibit a deficiency of an enzyme called glucocerebrosidase that is involved in the breakdown and recycling of glucocerebroside. The buildup of this fatty material within cells prevents the cells and organs from functioning properly. Enzyme replacement therapy may reverse many of the complications of the disease in members with Type 1 disease. The agents identified in this policy are FDA approved only in type 1 Gaucher disease.

Medications that reverse or halt the clinical symptoms of Gaucher's Disease Type 1 are Cerezyme® (imiglucerase), Vpriv™ (velaglucerase alfa) and Elelyso® (taliglucerase alfa). Cerdelga (eliglustat) is a glucosylceramide synthase inhibitor approved for the long-term treatment of adults with Gaucher's disease type 1, whose dose is determined by establishing the member's CYP2D6 phenotype. Zavesca® (miglustat) is a glucosylceramide synthase inhibitor approved for adult members with mild to moderate Type 1 Gaucher Disease for whom enzyme replacement therapy is not a therapeutic option (e.g. due to allergy, hypersensitivity or poor venous access).

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**Indications/Criteria**

**Cerezyme (imiglucerase)**, **Vpriv (velaglucerase alfa),** and **Elelyso (taliglucerase alfa)** may be considered for coverage when the following criteria are met:

- Diagnosis of Gaucher's Disease Type 1 is confirmed by biochemical assay; **AND**
- Home administration should be evaluated for appropriateness; **AND**
- Member is experiencing symptomatic manifestations of the disease as evidenced by **one** of the following:
    - Documented skeletal disease (osteopenia, avascular osteosclerosis, marrow infiltration, lytic lesions)
    - Anemia (Hgb less than or equal to 11.5gm/dL females, Hgb less than or equal to 12.5gm/dL males or 1.0gm/dL below lower limit of normal for age and sex)
    - Thrombocytopenia (platelet count less than or equal to 120,000/mm
    - Hepatomegaly or splenomegaly
- Site of Care (Cerezyme & Elelyso)
    - Per the MVP Health Care Pharmacy Management Programs policy, Cerezyme and Elelyso are subject to Site of Care requirements and must be obtained through a preferred home infusion vendor. Prior Authorization and medical justification are required for Cerezyme or

Elelyso obtained and administered in other outpatient settings such as a provider's office or hospital facility
- MVP will allow 60 days after prior authorization approval for members to transfer to a preferred infusion site
- This requirement does not apply to MVP Medicare and Medicaid members

**Cerdelga (eliglustat)** may be considered for coverage when the following criteria are met:

- Diagnosis of Gaucher's Disease Type 1 is confirmed by biochemical assay; **AND**
- Confirmation of CYP2D6 metabolizer status as detected by an FDA-cleared test with a result of either extensive metabolizer, intermediate metabolizer, or poor metabolizer

**Miglustat** may be considered for coverage when the following criteria are met:

- Diagnosis of Gaucher's Disease Type 1 is confirmed by biochemical assay; **AND**
- Member is experiencing symptomatic manifestations of the disease; **AND**
- Member has a contraindication for use of enzyme replacement therapy such as allergy, hypersensitivity reaction or poor venous access
- For **brand name Zavesca**, documentation of failure or contraindication to miglustat

**Initial coverage**, when approved, will be for a period up to 1 year.

**Extension of therapy** will be up to a maximum of 3 years if the member has a continued benefit to therapy. Extension requests where the medication did not have the full desired effect or was considered a clinical failure will require clinical rationale for continuation.

**MVP Medicaid Variation**

**Extension** of therapy will be up to a maximum of 1 year

Medications that are a pharmacy benefit are covered and billed to New York State Fee-For-Service (FFS) program. They are defined as medications that go through a retail or specialty pharmacy, including self-administered injectable products. Pharmacy medications are subject to FFS's clinical criteria including (but not limited to) coverage, quantity limit, step therapy, and prior authorization. Pharmacy benefit information can be found here: https://www.emedny.org/info/fullform.pdf

## Exclusions

The use of imiglucerase (Cerezyme), velaglucerase alfa (Vpriv), taliglucerase alfa (Elelyso), Cerdelga (eliglustat), or Zavesca (miglustat) will **not be considered medically necessary** in the following situations:

- Indication, age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling
- Members with Type 2 or Type 3 Gaucher's Disease
- Asymptomatic Type 1 disease
- Carriers of Gaucher's Disease
- Combination use of any of these agents

The use of Zavesca (miglustat) will also **not be considered medically necessary** in the following situations:

- Severe disease defined as a hemoglobin concentration below 9 g/dL or a platelet count below 50 x $10^9$/L or active bone disease
- Adjusted CrCl < 30 mL/min/1.73$m^2$

The use of Cerdelga (eliglustat) will also **not be considered medically necessary** in the following situations:

- Extensive metabolizers (EMs):
    - Moderate or severe hepatic impairment
    - Taking a strong or moderate CYP2D6 inhibitor concomitantly with a strong or moderate CYP3A inhibitor Mild hepatic impairment taking a strong or moderate CYP2D6 inhibitor.
- Intermediate Metabolizers (IMs):
    - Taking a strong or moderate CYP2D6 inhibitor concomitantly with a strong or moderate CYP3A inhibitor
- Intermediate and Poor Metabolizers (PMs):
    - Any degree of renal impairment
    - Taking a strong CYP3A inhibitor
- CYP2D6 ultra-rapid metabolizer as detected by an FDA-cleared test
- Pre-existing cardiac disease, long QT syndrome, or concomitant use of Class IA and Class III antiarrhythmics

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## References

1. Cerezyme® (imiglucerase). Prescribing Information. Cambridge, MA: Genzyme Corporation; Apr 2018. Revised 07/2024.
2. Zavesca® (miglustat). Prescribing Information. South San Francisco, CA: Actelion Pharmaceuticals, Inc. Revised 08/2022.
3. Grabowski GA, Barton NW, Pastores G, et al.. Enzyme therapy in type 1 Gaucher disease: Comparative efficacy of mannose-terminated glucocerebriosidase from natural and recombinant sources. Ann Intern Med. 1995;122(1):33-9
4. National Institutes of Health Consensus Development Conference Report. Gaucher Disease: Current issues in diagnosis and treatment. 1995.
5. National Institute of Neurological Disorders and Stroke. National Institutes of Health, Gaucher's Disease information page..
6. Vpriv® (velaglucerase alfa for injection) Lexington, MA: Shire Human Genetic Therapies, Inc.; Dec 2020. Revised 07/2024.
7. Elelyso® (taliglucerase alfa). Prescribing Information. New York, NY: Pfizer Labs. Jul 2021. Revised 07/2024.
8. Grabowski GA. Phenotype, diagnosis, and treatment of Gaucher's disease. *Lancet*. Oct 4, 2008;372(9645):1263-71.
9. Cerdelga (eliglustat capsules). Prescribing Information. Waterford, Ireland: Genzyme Ltd. Revised 01/2024.

Dardis, A., Michelakakis, H., Rozenfeld, P. et al. Patient centered guidelines for the laboratory diagnosis of Gaucher disease type 1. Orphanet J Rare Dis 17, 442 (2022). https://doi.org/10.1186/s13023-022-02573-6. 12/21/2022

| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Complete Wellness | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| USA Care PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

# GLP-1 Receptor Agonists (prospective)

**Type of Policy:** Drug Therapy
**Prior Approval Date:** 08/01/2023
**Approval Date:** 02/01/2024
**Effective Date:** 04/01/2025
**Related Policies:** NA

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies.

## Drugs Requiring Prior Authorization under the pharmacy benefit

Adlyxin

Ozempic

Rybelsus

Trulicity

Victoza

Mounjaro

Byetta

Bydureon/ Bydureon BCISE

## Overview

Glucagon-like peptide-1 receptor agonists (GLP-1) is a class of anti-diabetic medications that exert their main effect by stimulating glucose-dependent insulin release from the pancreatic islets. Per current American Diabetic Association guidelines, they are considered additive therapy to metformin and lifestyle modifications (such as diet and

exercise). There are specific GLP-1 Receptor Agonists with an indication for weight loss (rather than Type 2 diabetes) which include Saxenda, Zepbound and Wegovy.

**Indications/Criteria**

GLP-1 Receptor Agonists may be considered for coverage when the following criteria is met:

- Documentation of a diagnosis of Type 2 diabetes **AND**
- Member has a 90 day supply of an antidiabetic medication in the past 180 days within their claims history or chart notes. Antidiabetic medications include:
    - Metformin
    - SGLT-2 Inhibitor (i.e Farxiga, Invokana, Invokamet, Jardiance, Steglatro)
    - DPP-4 (i.e Janumet, Januvia, Nesina, Onglyza, Tradjenta)
    - Sulfonylurea (i.e. glimepiride, glipizide, glyburide)
    - Thiazolidinediones (i.e. pioglitazone)
    - Basal insulin (i.e. Basaglar, Lantus, Levemir, Semglee, Tresiba)
    - Regular/Intermediate Insulin (i.e. Novolin R, Humulin R)
    - Rapid acting insulin (i.e Novolog, Humalog, Fiasp)
    - Insulin combinations (i.e Novolog Mix, Humalog Mix)
    - Glucagon

**Initial approval** will be for 6 months

**Extension requests** will be approved up to 12 months if the member continues to meet the coverage criteria within the policy.

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**Exclusions**

The use of any drugs listed in this policy will not be covered for the following situations:

- GLP-1 agonists that do not have an FDA approved indication for weight loss, will not be covered for weight loss.
- Medications that are on label for weight loss are subject to the "Weight loss products" criteria in the Quantity Limits for Prescription Drugs policy.
- Age, dose, frequency outside of FDA approved labeling

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**References**

1. American Diabetes Association. Diabetes Care; vol 44. Supplement 1; Jan 2021. 9. Pharmacologic Approaches to Glycemic Treatment: Standards of Medical Care in Diabetes—2021 (silverchair.com)

2. Glucagon-like peptide 1 based therapies for the treatment of type 2 diabetes mellitus. September 2022. Up to Date. Glucagon-like peptide 1-based therapies for the treatment of type 2 diabetes mellitus - UpToDate

| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Complete Wellness | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D |
| USA Care PPO | Refer to the MVP website for the Medicare Part B and Part D |
| 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 | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

**Golimumab**

| | |
|---|---|
| **Type of Policy:** | **Medical Therapy** |
| **Prior Approval Date:** | **03/01/2023** |
| **Approval Date:** | **02/01/2024** |
| **Effective Date:** | **04/01/2024** |
| **Related Policies:** | **Apremilast, Adalimumab, Infliximab, Risankizumab, Secukinumab, Tofacitinib, Upadacitinib, Ustekinumab, Ozanimod, Abatacept, Tocilizumab, Certolizumab** |

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies.

Refer to the MVP website for the Medicare Part B policies for coverage criteria of drugs covered under the medical benefit.

**Drugs Requiring Prior Authorization under the pharmacy benefit**

Simponi SQ (golimumab) is non-preferred under the pharmacy benefit

**Drugs Requiring Prior Authorization under the medical benefit**

J1602 Simponi Aria (injection, golimumab)

**Overview**

Golimumab is a TNF-alpha blocker (TNF blocker) available in both intravenous and subcutaneous formulations. It is FDA approved to treat moderately to severely active rheumatoid arthritis (RA), psoriatic arthritis (PsA), ankylosing spondylitis (AS), and polyarticular juvenile idiopathic arthritis (pJIA). Members should be screened for immunologic and infectious disease prior to initiating therapy.

**Medicaid Variation:** Medications that are a pharmacy benefit are covered and billed to New York State Fee-For-Service (FFS) program. They are defined as medications that go through a retail or specialty pharmacy, including self administered injectable products. Pharmacy medications are subject to FFS's clinical criteria including (but not limited to) coverage, quantity limit, step therapy, and prior authorization. Pharmacy benefit information can be found here: https://www.emedny.org/info/fullform.pdf

**Indications/Criteria**

A. For all indications, Simponi SQ (golimumab) is non-formulary and will only be considered for **pharmacy** coverage when:
    - Documented failure, contraindication or ineffective response to all preferred/formulary therapies for the specific indication.

B. For all indications, Simponi Aria (injection, golimumab) may be considered for **medical** coverage when:
    - Must be prescribed for an FDA approved indication **AND**
    - Must be ordered by or with consult from a rheumatologist/immunologist **AND**
    - Documentation identifies failure of **preferred** self-administered biologic therapies to treat the condition **AND**
    - Rationale and documentation is provided identifying why member or caregiver is unable to self-administer **AND**
    - Site of Care
        - Per the MVP Health Care Pharmacy Management Programs policy, Simponi Aria is subject to Site of Care requirements and must be obtained through a preferred home infusion vendor. Prior Authorization and medical justification is required for Simponi Aria obtained and administered in other outpatient settings such as a provider's office or hospital facility.
        - MVP will allow 60 days after prior authorization approval for members to transfer to a preferred infusion site.
        - This requirement does not apply to MVP Medicare and Medicaid members

C. **Rheumatoid Arthritis**
Golimumab may be considered for coverage for Rheumatoid Arthritis when the above criteria is met **AND**:

- Member has a diagnosis of moderate to severe active adult RA as defined by persistent or recurrent symptoms with documented synovitis and morning stiffness of significant duration to inhibit activities of daily living.
- Chart notes are provided documenting a failure to respond to a three-month trial of methotrexate at a maximally tolerated dose.
    - Failure is demonstrated by documentation of provider assessment without improvement in joint counts and/or physical symptoms and inflammatory markers while on therapy.
    - If the member has a contraindication or significant intolerance to methotrexate
        - Chart notes documenting a failure to respond to at least one other nonbiologic DMARDs at a maximally tolerated dose for at least 3 months **AND** documentation confirming why methotrexate cannot be used is required. If a trial of methotrexate is not appropriate due to alcohol use, chart notes must be provided indicating that the patient has been counseled on the need to abstain from alcohol use while taking methotrexate and is unwilling to abstain from alcohol use.

**Initial approval** for **6 months**.

**Extension requests** will be approved for 12 months if the member has a continued benefit to therapy **AND** there is medical necessity for use of the IV formulation instead of a self-administered formulation.
Extension requests where Simponi did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

D. **Ankylosing Spondylitis**
Golimumab may be considered for coverage for Ankylosing Spondylitis when the above criteria is met **AND**:
- Member has a diagnosis of moderate to severe AS
- Chart notes documenting failure of at least one NSAID at maximum tolerated dose AND documented significant clinical symptoms such as fatigue, spinal pain, arthralgia, inflammation of joints and tendons, morning stiffness duration and therapy AND insufficient response to at least one local corticosteroid injection in patients with symptomatic peripheral arthritis
    - **For members with pure axial manifestations** do not have to have a trial of nonbiologic disease modifying anti-rheumatic drugs (DMARDs)

**Initial approval** for **6 months**.

**Extension requests** will be approved for 12 months if the member has a continued benefit to therapy **AND** there is medical necessity for use of the IV formulation instead of a self-administered formulation.
Extension requests where Simponi did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

E. **Psoriatic Arthritis**
Golimumab may be considered for coverage for Psoriatic Arthritis when the above criteria is met **AND**:

- Member has a diagnosis of moderate to severe PsA as defined by three or more tender joints AND three or more swollen joints on two separate occasions at least one month apart
- Chart notes documenting failure of at least one NSAID at maximum tolerated dose unless the member has contraindications to NSAID therapy such as cardiovascular disease, peptic ulcer disease or renal disease **AND**
- Chart notes documenting failure to an adequate trial of at least one of the following nonbiologic disease modifying anti-rheumatic drugs (DMARDs): leflunomide, sulfasalazine, or methotrexate.
    - **Members with pure axial manifestations** do not have to have a trial of nonbiologic disease modifying anti-rheumatic drugs (DMARDs)
    - If a trial of methotrexate is not appropriate due to alcohol use, chart notes must be provided indicating that the patient has been counseled on the need to abstain from alcohol use while taking methotrexate and is unwilling to abstain from alcohol use.

**Initial approval** for **6 months**.

**Extension requests** will be approved for 12 months if the member has a continued benefit to therapy **AND** there is medical necessity for use of the IV formulation instead of a self-administered formulation.
Extension requests where Simponi did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

F. **Juvenile Idiopathic Arthritis**

Golimumab to treat Juvenile idiopathic arthritis will be reviewed on a case-by-case basis using the American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis.

**Initial approval** for **6 months**.

**Extension requests** will be approved for 12 months if the member has a continued benefit to therapy **AND** there is medical necessity for use of the IV formulation instead of a self-administered formulation.

Extension requests where Simponi did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing

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**Exclusions**

The use of Golimumab will not be covered for the following situations:

- Dosing, age, and/or frequency outside of the FDA approved package labeling
- Combination therapy that is not supported by current clinical guidelines
- Diagnosis of Multiple Sclerosis

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**References**

1. Clinical Pharmacology: Golimumab. Revised 09/30/2022. Accessed 01/05/2023
2. Simponi (golimumab) injection, for subcutaneous use. Prescribing information. Janssen Biotech, Inc. Horsham, PA. Revised September 2019.
3. Simponi ARIA (golimumab) injection. Prescribing information. Janssen Biotech, Inc. Horsham, PA. Revised February 2021.
4. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis & Rheumatology Vol. 71, No. 1, January 2019, pp 5–32 DOI 10.1002/art.40726. 2018 American College of Rheumatology/ National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis
5. 2021 American College of Rheumatology Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Oligoarthritis,

Temporomandibular Joint Arthritis, and Systemic Juvenile Idiopathic Arthritis. Arthritis and Rheumatology. Vol 74 No. 4 April 2022, pp553-569. Available at: https://www.rheumatology.org/Portals/0/Files/ACR-JIA%20Guideline-Oligo-TMJ-sJIA-EarlyView.pdf

6. Fraenkel et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care & Research Vol. 73, No. 7, July 2021, pp 924–939 DOI 10.1002/acr.24596. Available at: 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis (contentstack.io).
7. Ward Michael, Atul Deodhar et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondylosrthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. Arthritis and Rheumatology. Vol 71 (No. 10). October 2019, pp 1599-1613. Available at: https://www.rheumatology.org/Portals/0/Files/AxialSpA-Guideline-2019.pdf
8.

| Member Product | Medical Management Requirements* |
|---|---|
| **New York Products** | Prior Auth |
| 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 | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Medicare Gold Giveback | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |

| | |
|---|---|
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D |
| 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).** | |
| *© 2024 MVP Health Plan, Inc. All rights reserved. Descriptions contained within MVP's Medical Policies are not a guarantee of coverage. Each MVP Group or Subscriber Contract contains specific limitations, exclusions and requirements that may affect a Policy. If there is any discrepancy between your Group or Subscriber Contract and a Policy, your Group or Subscriber Contract shall in all cases govern.* | |

***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 |

**MVP Health Care Medical Policy**

**Medicare Part B: Golimumab**

| | |
|---|---|
| **Type of Policy:** | **Medical Therapy** |
| **Prior Approval Date:** | **11/01/2023** |
| **Approval Date:** | **02/01/2024** |
| **Effective Date:** | **04/01/2024** |
| **Related Policies:** | **Abatacept, Certolizumab, Infliximab, Risankizumab, Tocilizumab, Ustekinumab** |

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies for drugs that may be covered under the Part D benefit.

**Drugs Requiring Prior Authorization under the medical benefit**

J1602 Simponi Aria (injection, golimumab)

## Overview/Summary of Evidence

Golimumab is a TNF-alpha blocker (TNF blocker) available in both intravenous and subcutaneous formulations. It is FDA approved to treat moderately to severely active rheumatoid arthritis (RA), psoriatic arthritis (PsA), ankylosing spondylitis (AS), and polyarticular juvenile idiopathic arthritis (pJIA). Members should be screened for immunologic and infectious disease prior to initiating therapy.

## Indications/Criteria

A. For all indications, Simponi Aria (injection, golimumab) may be considered for **medical** coverage when:
   - Must be prescribed for an FDA approved indication **AND**
   - Must be ordered by or with consult from a rheumatologist/immunologist **AND**

- Member has coverage under Medicare Part B and meets the criteria below for a provider administered drug identified in this policy.

B. **Rheumatoid Arthritis**
Golimumab may be considered for coverage for Rheumatoid Arthritis when the above criteria is met **AND**:
    - Member has a diagnosis of moderate to severe active adult RA as defined by persistent or recurrent symptoms with documented synovitis and morning stiffness of significant duration to inhibit activities of daily living.
    - Chart notes are provided documenting a failure to respond to a three-month trial of methotrexate at a maximally tolerated dose.
        - Failure is demonstrated by documentation of provider assessment without improvement in joint counts and/or physical symptoms and inflammatory markers while on therapy.
        - If the member has a contraindication or significant intolerance to methotrexate
            - Chart notes documenting a failure to respond to at least one other nonbiologic DMARDs at a maximally tolerated dose for at least 3 months **AND** documentation confirming why methotrexate cannot be used is required. If a trial of methotrexate is not appropriate due to alcohol use, chart notes must be provided indicating that the patient has been counseled on the need to abstain from alcohol use while taking methotrexate and is unwilling to abstain from alcohol use.

**Initial approval** for **6 months**.

**Extension requests** will be approved for 12 months if the member has a continued benefit to therapy
**Extension requests** where Simponi did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

C. **Ankylosing Spondylitis**
Golimumab may be considered for coverage for Ankylosing Spondylitis when the above criteria is met **AND**:
    - Member has a diagnosis of moderate to severe AS
    - Chart notes documenting failure of at least one NSAID at maximum tolerated dose AND documented significant clinical symptoms such as fatigue, spinal

pain, arthralgia, inflammation of joints and tendons, morning stiffness duration and therapy AND insufficient response to at least one local corticosteroid injection in patients with symptomatic peripheral arthritis
    - **For members with pure axial manifestations** do not have to have a trial of nonbiologic disease modifying anti-rheumatic drugs (DMARDs)

**Initial approval** for **6 months**.

**Extension requests** will be approved for 12 months if the member has a continued benefit to therapy
**Extension requests** where Simponi did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

D. **Psoriatic Arthritis**
Golimumab may be considered for coverage for Psoriatic Arthritis when the above criteria is met **AND**:
- Member has a diagnosis of moderate to severe PsA as defined by three or more tender joints AND three or more swollen joints on two separate occasions at least one month apart
- Chart notes documenting failure of at least one NSAID at maximum tolerated dose unless the member has contraindications to NSAID therapy such as cardiovascular disease, peptic ulcer disease or renal disease **AND**
- Chart notes documenting failure to an adequate trial of at least one of the following nonbiologic disease modifying anti-rheumatic drugs (DMARDs): leflunomide, sulfasalazine, or methotrexate.
    - **Members with pure axial manifestations** do not have to have a trial of nonbiologic disease modifying anti-rheumatic drugs (DMARDs)
    - If a trial of methotrexate is not appropriate due to alcohol use, chart notes must be provided indicating that the patient has been counseled on the need to abstain from alcohol use while taking methotrexate and is unwilling to abstain from alcohol use.

**Initial approval** for **6 months**.

**Extension requests** will be approved for 12 months if the member has a continued benefit to therapy
**Extension requests** where Simponi did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

E. **Juvenile Idiopathic Arthritis**
Golimumab to treat Juvenile idiopathic arthritis will be reviewed on a case-by-case basis using the American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis.

**Initial approval** for **6 months**.

**Extension requests** will be approved for 12 months if the member has a continued benefit to therapy
**Extension requests** where Simponi did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing

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**Exclusions**

The use of Golimumab will not be covered for the following situations:

- Dosing, age, and/or frequency outside of the FDA approved package labeling
- Combination therapy that is not supported by current clinical guidelines
- Diagnosis of Multiple Sclerosis

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**References**

1. Clinical Pharmacology: Golimumab. Revised 09/30/2022. Accessed 01/05/2023.
2. Simponi ARIA (golimumab) injection. Prescribing information. Janssen Biotech, Inc. Horsham, PA. Revised February 2021.
3. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis & Rheumatology Vol. 71, No. 1, January 2019, pp 5–32 DOI 10.1002/art.40726. 2018 American College of Rheumatology/ National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis
4. 2021 American College of Rheumatology Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Oligoarthritis, Temporomandibular Joint Arthritis, and Systemic Juvenile Idiopathic Arthritis. Arthritis and Rheumatology. Vol 74 No. 4 April 2022, pp553-569. Available at:

https://www.rheumatology.org/Portals/0/Files/ACR-JIA%20Guideline-Oligo-TMJ-sJIA-EarlyView.pdf

5. Fraenkel et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care & Research Vol. 73, No. 7, July 2021, pp 924–939 DOI 10.1002/acr.24596. Available at: 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis (contentstack.io).
6. Ward Michael, Atul Deodhar et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondylosrthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. Arthritis and Rheumatology. Vol 71 (No. 10). October 2019, pp 1599-1613. Available at: https://www.rheumatology.org/Portals/0/Files/AxialSpA-Guideline-2019.pdf

**MVP Health Care Medical Policy**

**Gout Treatments**

**Type of Policy:** **Drug/Medical Therapy**
**Prior Approval Date:** **08/01/2023**
**Approval Date:** **08/01/2024**
**Effective Date:** **10/01/2024**
**Related Policies:**

Refer to the MVP Medicare website for the Medicare Part D Formulary and Part D policies for drugs that may be covered under the Part D benefit.

**Codes Requiring Prior Authorization (covered under the medical benefit)**

J2507 Injection, pegloticase, 1 mg (Krystexxa™)

**Drugs Requiring Prior Authorization (covered under the pharmacy benefit)**
Colcrys™ (colchicine tablets) if quantity exceeds 2 tablets per day
Gloperba (colchicine oral solution) if quantity exceeds 10mL per day
Mitigare (colchicine capsules) if quantity exceeds 2 capsules per day
Colchicine tablets/capsules if quantity exceeds 2 tablets/capsules per day
Uloric® (febuxostat) tablets (only brand Uloric requires prior authorization)

**Overview**

Gout is a complex form of arthritis characterized by sudden, severe flares of pain, redness, and tenderness in joints caused by urate crystals accumulating around the joint, causing inflammation and intense pain. Urate crystals can form when there are high levels of uric acid in the blood (hyperuricemia = uric acid levels of >6.8 mg/dL). Normally uric acid dissolves in the blood and passes through the kidneys into the urine but sometimes the body either produces too much uric acid or the kidneys excrete too little uric acid. There are two different therapies for treating gout; treating the acute attack and treating hyperuricemia associated with gout. For mild/moderate acute gout, monotherapy treatment is recommended with one of the following: non-steroidal anti-inflammatory drugs (NSAIDS), oral colchicine, or systemic corticosteroids. Combination

therapy can be considered for a severe acute attack. For the treatment of hyperuricemia associated with gout, it is recommended to start with allopurinol (or probenecid if adequate renal function and intolerant to allopurinol), febuxostat, and lastly, pegloticase (Krystexxa).

**Colcrys, Gloperba (colchicine**): A pain reliever that effectively reduces gout pain that is generally reserved for patients who cannot take NSAIDs. It is dosed 1.2 mg at first sign of flare and then 0.6 mg one hour later. Colchicine can cause intolerable side effects such as nausea, vomiting, or diarrhea. Colchicine may be effective for prophylaxis against acute flares when beginning urate lowering treatment[6]. Colcrys is also indicated for familial Mediterranean fever (FMF).

**Allopurinol**: A xanthine oxidase inhibitor indicated for the management of patients with signs and symptoms of primary or secondary gout. Dosing for patients with a creatinine clearance down to 10mL/min is available.

**Uloric (febuxostat)**: A xanthine oxidase inhibitor indicated for the chronic management of hyperuricemia in patients with gout. It is dosed 40 mg or 80 mg orally once daily continuously for frequent gouty flares and to prevent complications. Dosing for patients with a creatinine clearance less than 15mL/min is not available.

**Krystexxa (pegloticase**): A PEGylated uric acid specific enzyme which works by catalyzing the oxidation of uric acid to allantoin (an inert, water-soluble purine metabolite that is readily eliminated by renal excretion) and therefore lowers serum uric acid. It is indicated for the treatment of chronic gout (hyperuricemia) in adult patients who are inadequately controlled with xanthine oxidase inhibitors at the maximum dose or for whom these drugs are contraindicated. Administered as an 8 mg intravenous infusion every 2 weeks in a healthcare setting given over at least 120 minutes.

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## Indications/Criteria

**Colcrys (colchicine**) will be allowed up to the FDA labeled dose for up to 2 tablets per day. Gloperba (colchicine oral solution) will be allowed up to the FDA labeled dose for up to 10mL per day. Doses exceeding 2 tablets per day or 10mL per day for gout will not be covered. Doses exceeding 2 tablets per day for Familial Mediterranean fever (FMF) will require prior authorization.

ALL the following criteria must be met for coverage for **Uloric (brand** febuxostat):

- Recurrent acute gout flares; symptomatic gout with at least 2 gout flares in the previous 12 months or at least 1 gout tophus or gouty arthritis or radiographic damage due to gout

- CrCl >15 mL/min
- Failure of 90-day continuous trial of allopurinol and a trial of generic febuxostat therapy at the maximum medically appropriate dose or an intolerance to allopurinol or when treatment with allopurinol is advised against
- Serum uric acid level ≥ 6 mg/dL
- Consideration of cardiovascular health as there is a higher rate of cardiovascular death associated with febuxostat use in those with cardiovascular disease

ALL the following criteria must be met for coverage for **Krystexxa**:

- Failure of 90-day continuous trial of each of the following: allopurinol (dosed ≥ 600mg/day) AND Uloric/Febuxostat.
    - If either allopurinol or Uloric/febuxostat is contraindicated, failure of a 90-day continuous trial of probenecid (dosed ≥500mg twice a day) AND documentation of specific contraindication to allopurinol and Uloric/febsuxostat must be submitted in place of a trial.
- Recurrent acute gout flares[6]: symptomatic gout with at least 3 gout flares in the previous 18 months or at least 1 gout tophus or gouty arthritis
- Serum uric acid level ≥6 mg/dL
- If not used in combination with methotrexate, documentation confirming why methotrexate cannot be used is required. If a trial of methotrexate is not appropriate due to alcohol use, chart notes must be provided indicating that the patient has been counseled on the need to abstain from alcohol use while taking methotrexate and is unwilling to abstain from alcohol use
- Glucose-6-phosphate dehydrogenase (G6PD) Deficiency: Before starting Krystexxa, patients at higher risk for G6PD deficiency (e.g., those of African and Mediterranean ancestry) should be screened due to the risk of hemolysis and methemoglobinemia. Krystexxa is contraindicated in patients with G6PD deficiency

Initial approval up to 6 months. Continuation of therapy for brand Uloric, and Krystexxa for up to 12 months may be considered if documentation identifies improvement in symptoms and uric acid levels are less than 6mg/dL.

**Medicaid Variation:** Medications that are a pharmacy benefit are covered and billed to New York State Fee-For-Service (FFS) program. They are defined as medications that go through a retail or specialty pharmacy, including self administered injectable products. Pharmacy medications are subject to FFS's clinical criteria including (but not limited to) coverage, quantity limit, step therapy, and prior authorization. Pharmacy benefit information can be found here: https://www.emedny.org/info/fullform.pdf

## Exclusions

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling Uloric/Febuxostat in combination with azathioprine, mercaptopurine, or theophylline
- Uloric/Febuxostat used for the treatment of asymptomatic hyperuricemia
- If uric acid level increases to above 6 mg/dL after initiating treatment, continuation of Krystexxa is not a covered benefit due to an increased risk of anaphylaxis and infusion reactions particularly when 2 consecutive levels are observed
- Re-treatment with Krystexxa after stopping treatment for longer than 4 weeks is not covered due to immunogenicity and increased risk of anaphylaxis and infusion reactions

## References


1. Zyloprim® (allopurinol) Tablets. Prescribing Information. San Diego, CA: Prometheus Laboratories Inc. October 2003.
2. Probenecid Tablets. Prescribing Information. Corona, CA: Watson Laboratories, Inc. July 2003.
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| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Medicare Gold Giveback | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |

| | |
|---|---|
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D |
| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

**Government Programs Over-the-Counter (OTC) Drug Coverage**

(For Child Health Plus and select Essential Plan Members Only)

**Type of Policy:** **Drug Therapy**
**Prior Approval Date:** **12/01/2023**
**Approval Date:** **12/01/2024**
**Effective Date:** **02/01/2025**
**Related Policies:** **Enteral Therapy- New York**

**Codes: N/A**

## Overview

Child Health Plus and select Essential Plans cover certain OTC drugs and supplies as listed in this policy. Coverage for these products will be allowed at a participating pharmacy.

## Indications/Criteria

- Subject to applicable copayment
- Prescription must be filled by a participating pharmacy.
- A prescription for an OTC product described above must be written by a participating provider
- Coverage of OTC medications and quantities follow the New York State Medicaid Program Pharmacy Fee Schedule (4.1) for the MVP Medicaid, Child Health Plus and select Essential Plan products.
- A prescription for an OTC product described below must be written by a practitioner licensed and authorized to prescribe medications.
- The over-the-counter medications in the following classes are covered for Child Health Plus and select Essential Plan members:

  Enteral Nutrition*
  ANALGESIC AND ANTIPYRETIC
  ANTACID
  ANTI-DIARRHEAL
  ANTIHISTAMINE
  ANTI-VERTIGO
  ARTIFICIAL TEARS AND OCCULAR/ORAL LUBRICANTS
  CHRONIC RENAL DISEASE

COUGH AND COLD
DERMATOLOGICAL
FAMILY PLANNING
FECAL SOFTENER AND LAXATIVE
HEMATINIC
INSULIN
INSULIN, BIOSYNTHETIC HUMAN
PEDICULOCIDE
SMOKING CESSATION AGENTS
VITAMIN/MINERAL

**May require prior authorization per MVP Benefit Interpretation*
*[q]Quantity Limits may apply*

For detailed information on covered non-prescription/OTC drugs refer to the New York State Medicaid Pharmacy List of Reimbursable Drugs available at:
https://www.emedny.org/info/formfile.aspx

- Certain over the counter supplies are covered at the pharmacy based on the NYS Medicaid Pharmacy Services Fee Schedule. Examples of coverage are listed below and the full list is available at: Pharmacy_Fee_Schedule.xls (live.com)
    - Contraceptive Condoms
    - Diabetic supplies
    - Humidifiers/Vaporizers
    - Nebulizers and supplies
    - Ostomy supplies
    - Peak Flow meters
    - Spacers
    - Incontinence supplies
    - Diapers
    - Wound dressings
    - Enteral supplies
    - Breast pumps

**Exclusions/Limitations**

- Humidifiers and vaporizers are limited to 1 unit per year
- Nebulizers are limited to 1 unit per year. There are no limits on nebulizer supplies (i.e. masks)
- Peak Flow meters are limited to 1 unit every 6 months
- Spacers are limited to 1 unit every 6 months. There is no limit to replacement bags for certain products

- Requests for OTC products other than those listed as covered in the subscriber contract will be denied as a non-covered benefit.

## References

1. New York State Medicaid Program Pharmacy Procedure Codes. Version 2022-2. Pharmacy_Procedure_Codes.pdf (emedny.org)

2. New York State Pharmacy Fee Schedule October 12, 2022. Accessed on October 27, 2022. Available at: Pharmacy_Fee_Schedule.xls (live.com)

3. New York State Medicaid Fee-For-Service Program Pharmacy Manual Policy Guidelines. October 2022; Version 2022-2. Accessed on October 27, 2022. Available at: Pharmacy Policy Guidelines (emedny.org)

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| **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 | Covered (exception of some enterals) |
| MVP Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Covered (exception of some enterals) |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Complete Wellness | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| USA Care PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |

| | |
|---|---|
| MVP VT HMO | Not Covered |
| MVP VT Plus HMO | Not Covered |
| MVP VT HDHP 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

**Growth Hormone Therapy**

| | |
|---|---|
| **Type of Policy:** | **Drug Therapy** |
| **Prior Approval Date:** | **04/01/2024** |
| **Approval Date:** | **10/01/2024** |
| **Effective Date:** | **01/01/2025** |
| **Related Policies:** | **N/A** |

Refer to the MVP Medicare website for the Medicare Part D Formulary and Part D policies for drugs that may be covered under the Part D benefit.

**Drugs Requiring Prior Authorization (covered under the pharmacy benefit)**

Genotropin/Miniquick (somatropin)

Norditropin/Flexpro (somatropin)

Humatrope (somatropin)

Increlex (mecasermin)

Serostim (somatropin)

Zomacton (somatropin)

Omnitrope (somatropin)

Voxzogo (vosoritide)

**Overview**

Growth failure may be the result of growth hormone deficiency or primary insulin-like growth factor-1 (IGF-1) deficiency in children. The administration of growth hormone to children results in an acceleration in linear growth. Growth hormone deficiency in children ranges from complete absence of the hormone resulting in severe growth restriction, to a partial deficiency resulting in slightly short stature. Progressive weight loss and inappropriate deletion of lean body mass with paradoxical sparing of total body fat characterize HIV-associated wasting. If this condition is identified early, alternative treatments can be started, and growth hormone therapy may be avoided. Voxzogo (vosoritide) is a C type natriuretic peptide (CNP) analog approved for increasing linear growth in pediatric patients 5 years and older with achondroplasia and

open epiphyses. Achondroplasia is a genetic condition that causes short stature and disproportionate growth.

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**Indications/Criteria**

Norditropin/Flexpro, Humatrope, and Omnitrope are the preferred agents for appropriate labeled indications and must be used prior to non-preferred agents unless there is documented failure or contraindication.

**A. <u>For the following indications</u>**, the criteria listed in the chart below must be met in addition to:

- Must be ordered by or with consult from an endocrinologist
- Must have open growth plates

| **Criteria – all checked criteria must be met for coverage.** | **Growth Hormone Deficiency(children)** | **Chronic Kidney Disease** | **Turner Syndrome** | **Prader-Willi Syndrome (children)** | **IGF-1 Severe Deficiency or GH gene deletion with neutralizing antibodies (2-18 yrs old)** |
|---|---|---|---|---|---|
| A. Present height must be below the amount specified | Less than 3rd percentile **OR** more than 2 SD below 50th percentile for age/gender | Less than 3rd percentile **OR** more than 2 SD below 50th percentile for age/gender | Less than 5th percentile **OR** more than 2 SD below mid-parental height prediction | Less than 3rd percentile **OR** more than 2 SD below 50th percentile for age/gender | Less than 3rd percentile **OR** Standard deviation score <u>≤</u> - 3.0 |
| B. Growth velocity must be less than specified for age/gender | 10th percentile or greater than 2 SD below the mean (for growth velocity) | 10th percentile or greater than 2 SD below the mean (for growth velocity) | Growth velocity < 25% for bone age and bone age less than 14 years (for growth velocity) | X | |
| C. Lack of response to two different growth hormone provocative tests defined as a serum GH level of less than 10 ng/ml in children and adolescents; OR lack of | X | | | X | Normal or elevated growth hormone **AND** basal IGF-1 standard deviation score <u>≤</u> - 3.0 |

| | | | | | |
|---|---|---|---|---|---|
| response to one GH test AND IGF-I and IGF-BP3 levels more than 2 SD below the mean for bone age and gender.. | | | | | |
| D. Genetic testing confirming diagnosis. | | | | X | |

GHD = growth hormone deficiency; CRI = Growth restriction due to chronic renal insufficiency in children; TS = Turner's Syndrome in children; PWS = Prader-Willi Syndrome in children; IGF-1 = Severe Primary IGF-1 Deficiency in children.

- For pediatric members with confirmed Prader-Willi syndrome, documentation must include that the member does not have special risk factors such as severe obesity, history of respiratory impairment or sleep apnea or unidentified respiratory infection. Growth hormone therapy is contraindicated in these members.

  **Initial approval** will be up to 12 months

  **Extension requests** will be up to 12 months. Dose increases require a new prior authorization request. Dose increases will be considered only if the height and growth velocity is below normal for age/gender after a minimum of 6 months of therapy at a previously authorized dose.

**B. <u>Voxzogo (vosoritide)</u>**

- Voxzogo therapy may be considered for coverage when the following criteria is met:
- Documentation indicating a diagnosis of achondroplasia confirmed through genetic testing with results significant for a mutation of the GlyArg mutation of the FGFR3 gene such as c.1138G>A or c.1138G>C
- Documentation of recent annualized growth velocity (AGV)
- Member is 5 years of age or older
- Must have open growth plates and a current AGV ≥ 1.5cm/year
- Member has not received previous treatment with growth hormone, insulin-like growth factor 1 or anabolic steroids in the last 6 months
  - Member does not have a planned limb lengthening surgery. If the member had a limb lengthening surgery, it must have occurred at least 18 months prior to the Voxzogo request

- Must be ordered by or with consult from an endocrinologist, geneticist, or skeletal dysplasia specialist

**Initial requests** will be approved up to 6 months

**Extension requests** will be approved up to 12 months if documentation is provided indicating all the following:

- The member has open growth plates
- Current AGV ≥ 1.5cm/year and an increase in AGV
- Attestation that the member will not have limb lengthening surgery while take Voxzogo.

**C. <u>Small for Gestational Age (SGA)/Intrauterine Growth Restriction (IUGR)</u>**

Growth Hormone therapy may be considered for coverage for SGA/IUGR when the following criteria is met:

- Member's birth weight is less than 10$^{th}$ percentile for gestational age and gender or birth weight and/or length < - 2 standard deviation score (SDS) (≤ 3$^{rd}$ percentile) for gestational age and gender
- Member height is <-2.5 SDS at 2 years of age or height is <-2 SDS at age 3 to 4 years of age
- Member is at least two years of age and prepubertal at start of therapy
- Must be ordered by or with consult from an endocrinologist
- Must have open growth plates

**Initial approval** will be up to 12 months

**Extension requests** will be up to 12 months when documentation of prior height and current height with dates is provided. Dose increases require a new prior authorization request. Dose increases will be considered only if the height and growth velocity is below normal for age/gender after a minimum of 6 months of therapy at a previously authorized dose.

**D**. **<u>Adults with growth hormone deficiency</u>**

Growth Hormone therapy for adults with growth hormone deficiency may be considered for coverage when the following criteria is met:

- Documented diagnosis of growth hormone deficiency of adult onset from
    - hypopituitarism/pituitary disease,
    - hypothalamic disease,
    - pituitary hormone deficiencies (Adrenocorticotripic, thyroid-stimulating hormone, gonadotropin deficiency, prolactin)
    - pituitary surgery,
    - radiation, tumor,
    - brain injury **OR**;
    - Documented congenital or genetic defect
- Documented low serum insulin-like growth factor-1 (adjusted for age and gender)
- Lack of response to two separate growth hormone provocative tests
    - Defined as a serum GH level ≤4 mcg/L on the GHRH/arginine test and ≤ 5 mcg/L for the gold standard insulin tolerance test (ITT).
    - When GHRH is not available and an ITT is either contraindicated or not practical in a given patient, the glucagon stimulation test can be used (criteria defined by GH level ≤3 mcg/L) **OR;**
- Patients with irreversible hypothalamic-pituitary structural lesions and those with panhypopituitarism (≥3 pituitary hormone deficiencies) and serum IGF-I levels below the age- and sex-appropriate normal range when off GH therapy for at least 1 month. These patients should be deemed GH deficient and do not require further GH stimulation testing.

**AND** all the following must be met for coverage:

- Baseline IGF-1 level required with initial request.
- Current IGF-1 required for continuation of therapy.
- Must be ordered by an endocrinologist.
- Adults with childhood-onset GHD previously treated with GH replacement in childhood should be retested after final height is achieved and GH therapy discontinued for at least 1 month to establish their GH status before considering restarting GH therapy.

**Initial approval will be** up to 12 months

**Extension requests** will be up to 12 months and considered if dosing is adjusted to target an IGF-1 level within the age-adjusted reference range.

## E. Adults with AIDS Wasting/Cachexia (Serostim)

Growth Hormone therapy for adults with AIDS Wasting/Cachexia may be considered for coverage when the following criteria is met:

- Documentation of HIV diagnosis and current antiretroviral therapy.
    - Member is currently receiving highly active antiretroviral therapy (HAART) for at least one month with viral load reduced to <10,000 copies/ml.

- Must be ordered by physicians specializing in treating HIV patients.

- Documented unintentional weight loss of at least *10%* from baseline premorbid weight**,** or weight and amount that indicates significant weight loss has occurred (BMI <20kg/$m^2$)and wasting is not the result of an active, HIV-related opportunistic infection, TB or cancers or other preventable causes of weight loss. Member should be free from infection for 4-8 weeks before initiation of therapy.

- Currently receiving at least 100% of estimated caloric requirement on current nutritional regimen. Individuals receiving assisted enteral or parenteral nutrition must be weight stable for at least 2 months or have persistent weight loss despite such interventions

- Member has a trial, contraindication or intolerance to the following therapies: cyproheptadine, dronabinol and/or megestrol.

- Documentation that the member does not have the following:

    - Evidence of GI bleeding, obstruction, or malabsorption.
    - Experiencing acute critical illness due to complications following open heart or abdominal surgery, multiple accidental trauma, or acute respiratory failure
    - Active malignancy.
    - Systemic chemotherapy, interferon, anabolic steroids, or investigational agents within 30 days. Individuals with documented hypogonadism may be on replacement therapy with gonadal steroids if this was started at least 2 months prior.
    - Diabetes mellitus, diabetic retinopathy, or history of significant glucose intolerance which for the purposes of the protocol will be defined as a fasting blood glucose >200 mg/dl.

**Initial approval** will be limited to a 12-week period at a dose of no more than 6mg/day.

**Extension requests** will require that the weight has stabilized or there has been no further weight loss and that the member is currently on antiretroviral therapy.

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**Exclusions**

- Continued therapy for children for growth hormone and insulin-like growth factors will **not** be considered medically necessary for any of the following:
    1. No further growth expected, or final height is achieved (final height is not greater than mid-parental height)
    2. Bone age indicating growth is complete (defined as greater than or equal to 14 years in girls or 16 years in boys) and/or epiphyseal fusion is complete. Acromegalic changes are possible with the use of pediatric growth hormone dose in adolescents with fused epiphyseal plates and should be avoided[25]. Exceptions are granted if the provider submits radiographic documentation of open growth plates as required if bone age is greater than 14 years in girls or 16 years in boys.
    3. Renal transplantation (for chronic renal insufficiency)
    4. Height velocity is less than 2cm/year above baseline velocity.
    5. Prescription history or documentation identifies non-compliance with therapy.
    6. Current or predicted height without growth hormone therapy greater than or equal to mid-parental height

- In all cases, growth hormone will not be approved in the presence of an active malignant condition.
    1. If Growth Hormone Deficiency (GHD) results from an intracranial tumor, absence of tumor growth or tumor recurrence must be documented for at least 6 months prior to therapy initiation
- Indication, age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling
- Growth hormone therapy is not covered for Idiopathic Short Stature due to patients having normal growth hormone stimulation test results and the limited effectiveness of growth hormone therapy in ISS
- Growth hormone therapy is not covered for any indications other than those listed in Criteria section above
- Growth hormone therapy is not covered for catabolic illnesses (other than AIDS) or to improve muscle strength or exercise tolerability.
- Growth hormone is not indicated for members in a non-euthyroid state

- Treatment with insulin growth factors is not covered for secondary forms of IGF-1 deficiency such as growth hormone deficiency, malnutrition, hypothyroidism, or chronic treatment with pharmacologic doses of anti-inflammatory steroids.
- Insulin growth factors in combination with growth hormone is not covered.

**References**


1. Nutropin® (somatropin injection). Prescribing Information. South San Francisco, CA: Genentech Inc.; June 2014.
2. Genotropin® (somatropin injection). Prescribing Information. New York, NY: Pharmacia & Upjohn Company; Sept 2014.
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4. Humatrope® (somatropin for injection). Prescribing Information. Indianapolis, IN: Eli Lilly and Company; July 2014.
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6. Omnitrope® (somatropin for injection). Prescribing Information. Princeton, NJ: Sandoz; Aug 2014.
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9. Serostim® (somatropin for injection). Prescribing Information. Rockland, MA: EMD Serono, Inc.; Jun 2014
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| Member Product | Medical Management Requirements* |
|---|---|
| **New York Products** | Prior Authorization |
| 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 | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Authorization |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Medicare Gold Giveback | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D |
| 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 | 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).** | |
| *© 2024 MVP Health Plan, Inc. All rights reserved. Descriptions contained within MVP's Medical Policies are not a guarantee of coverage. Each MVP Group or Subscriber Contract contains specific limitations, exclusions and requirements that may affect a Policy. If there is any discrepancy between your Group or Subscriber Contract and a Policy, your Group or Subscriber Contract shall in all cases govern.* | |

***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 |

**MVP Health Care Medical Policy**

**Guselkumab**

| | |
|---|---|
| **Type of Policy:** | **Drug Therapy** |
| **Prior Approval Date:** | **10/01/2024** |
| **Approval Date:** | **06/01/2025** |
| **Effective Date:** | **08/01/2025** |
| **Related Policies:** | Adalimumab |
| | Apremilast |
| | Etanercept |
| | Infliximab |
| | Risankizumab |
| | Secukinumab |
| | Tofacitinib |
| | Upadacitinib |
| | Ustekinumab |
| | Zeposia |

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies.

**Drugs Requiring Prior Authorization under the medical benefit**

J1628 Tremfya 100MG/ML Solution J1628 Injection, guselkumab

**Drugs Requiring Prior Authorization under the pharmacy benefit**

Tremfya (guselkumab) One Press Patient-Controlled Injector
Tremfya (guselkumab) Prefilled Syringe

**Overview**
Guselkumab is a subcutaneously administered interleukin 23 (IL-23) blocker approved for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy and for treating psoriatic arthritis (PsA).

Members should be screened for immunologic and infectious disease prior to initiating therapy.

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**Medicaid Variation:** Medications that are a pharmacy benefit are covered and billed to New York State Fee-For-Service (FFS) program. They are defined as medications that go through a retail or specialty pharmacy, including self-administered injectable products. Pharmacy medications are subject to FFS's clinical criteria including (but not limited to) coverage, quantity limit, step therapy, and prior authorization. Pharmacy benefit information can be found here: https://www.emedny.org/info/fullform.pdf

**Indications/Criteria**

**A. For all indications, the following criteria must be met in addition to the specific diagnosis criteria below.**

- Prescription drugs covered under the pharmacy benefit must be self-administered. If office administration is being requested documentation must be provided identifying why the member or caregiver is unable to administer the medication

  Must be ordered by or with consult from an appropriate specialist: rheumatologist, immunologist, dermatologist, gastroenterologist, or colorectal surgeon
- Must be prescribed for an FDA approved indication

**B. Plaque Psoriasis**
Guselkumab may be considered for coverage for Plaque Psoriasis when the following criteria is met:

- The medication is ordered by or in consultation with a dermatologist
- A diagnosis of moderate to severe chronic plaque psoriasis and one of the following:
  - Crucial body areas (e.g. hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected OR

- At least 10% of the body surface area (BSA) is affected OR
- At least 3% of the body surface area (BSA) is affected AND the member meets any of the following criteria:
    - Member has had an inadequate response or intolerance to either phototherapy (e.g. UVB, PUVA) OR
    - Member has had an inadequate response or intolerance to pharmacologic treatment with methotrexate, cyclosporine, or acitretin

**Initial approval** duration will be 12 months

**Extension requests** will be approved for up to 3 years if the member has a continued benefit to therapy. Extension requests where the guselkumab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

## C. Psoriatic Arthritis (PsA)

Guselkumab may be considered for coverage for PsA when the following criteria is met:

- Member has a diagnosis of moderate to severe psoriatic arthritis as indicated by three or more tender joints AND three or more swollen joints on two separate occasions at least one month apart **AND**
- Chart notes are provided documenting a failure of at least one NSAID at maximum tolerated dose unless the member has contraindications to NSAID therapy such as cardiovascular disease, peptic ulcer disease or renal disease **AND**
- Chart notes documenting a failure to an adequate trial of at least one of the following nonbiologic disease modifying anti-rheumatic drugs (DMARDs): leflunomide, sulfasalazine, or methotrexate.
    - **Members with pure axial manifestations** do not have to have a trial of nonbiologic disease modifying anti-rheumatic drugs (DMARDs)
    - If a trial of methotrexate is not appropriate due to alcohol use and **both** leflunomide and sulfasalazine are not clinically appropriate, chart notes must be provided indicating that the member has been counseled on the need to abstain from alcohol use while taking methotrexate and is unwilling to abstain from alcohol use.

**Initial approval** duration will be 12 months

**Extension requests** will be approved for up to 3 years if the member has a continued benefit to therapy. Extension requests where the guselkumab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

**D. Ulcerative Colitis**

Guselkumab may be considered for coverage when the following criteria is met:

- A diagnosis of moderate to severe Ulcerative Colitis
- Chart notes are provided identifying inadequate response, intolerance, or contraindication to conventional therapy for maintenance of remission (i.e., anti-inflammatory aminosalicylates [e.g., mesalamine (5-ASA), sulfasalazine], 6-mercaptopurine, and azathioprine)
    - If conventional therapy is not considered medically appropriate, documentation must be provided.

**Initial approval** will be for **6 months.**

**Extensions requests** will be approved up to 12 months if the member has a continued benefit to therapy. Extension requests where guselkumab does not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

**E.** Crohn's Disease

Guselkumab may be considered for coverage when the following criteria is met:

- A diagnosis of moderate to severe Crohn's disease
- Documentation including the assessment of growth, nutrition, extraintestinal complications, therapy-induced complications and functional ability and any clinical signs and symptoms outlined in Crohn's Disease Activity Index (CDAI) such as frequent liquid stools >4/day, severity grade and frequency of abdominal pain, presence of an abdominal mass, general well-being, extra-intestinal symptoms (arthralgia, uveitis, erythema, stomatitis, abscess, fever >37.5 in the last week), taking opiates or diphenoxylate/atropine for diarrhea, anemia, and weight loss >10%
- Induction therapy is indicated for either the subcutaneous or intravenous.

**Initial approval** will be for 6 months.

**Extension requests** will be approved for up to 12 months if the member has a continued benefit to therapy. Extension requests where guselkumab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

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**Exclusions**

The use of guselkumab will not be covered for the following situations:

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling
- Combination therapy that is not supported by current guidelines

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**References**


1. Tremfya [package insert]. Horsham, PA: Janssen Biotech, Inc.; November 2023.
2. Reich K, Armstrong, AW, Foley P, et al. Efficacy and safety of guselkumab, an anti-interleukin-23 monoclonal antibody, compared with adalimumab for the treatment of patients with moderate to severe psoriasis with randomized withdrawal and retreatment: Results from the phase III, double-blind, placebo- and active comparator–controlled VOYAGE 2 trial. Am J Clin Dermatol. 2017;76(3):418-431.
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with pharmacological therapies: 2019 update. Ann Rheum Dis. 2020;79(6):700-712

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7. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. *Journal of Psoriasis and Psoriatic Arthritis*. 2019;4(1):31-58. doi:10.1177/2475530318812244
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| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Complete Wellness | Refer to the MVP website for the Medicare Part B and Part |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part |
| USA Care 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 | Refer to the MVP website for the Medicare Part B and Part |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part |
| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

**Hemophilia Factor**

| | |
|---|---|
| **Type of Policy:** | Medical Therapy |
| **Prior Approval Date:** | 10/01/2023 |
| **Approval Date:** | 04/01/2025 |
| **Effective Date:** | 06/01/2025 |
| **Related Policies:** | Hemophilia Gene Therapy |

## Codes Requiring Retrospective Review

**Must be obtained from Accredo Specialty Pharmacy, covered under the medical benefit. Please see Medicaid and Medicare Variations.**

| | |
|---|---|
| J7210 | Injection, Factor VIII (antihemophilic factor, recombinant), Afstyla, per IU |
| J7179 | Injection, von Willebrand factor (recombinant), Vonvendi, per IU |
| J7202 | Injection, Factor IX albumin fusion protein (recombinant), Idelvion, per IU |
| J7207 | Injection, Factor VIII (antihemophilic factor, recombinant), pegylated, per IU |
| J7209 | Injection, Factor VIII (antihemophilic factor, recombinant), Nuwiq, per IU |
| J7182 | Injection, Factor VIII (antihemophilic factor, recombinant), Novoeight, per IU |
| J7188 | Injection, factor VIII (antihemophilic factor, recombinant), Obizur, per IU |
| J7175 | Injection, Factor X (human), Coagadex, per IU |
| J7181 | Factor XIII (antihemophilic factor, recombinant), Tretten, per 10 IU |

| | |
|---|---|
| J7201 | Factor IX (antihemophilic factor, recombinant), Alprolix, per 1IU |
| J7200 | Factor IX (antihemophilic factor, recombinant), Rixubis, per IU |
| J7180 | Injection, factor XIII (antihemophilic factor, human), 1 IU |
| J7183 | Injection, von Willebrand factor complex (human), Wilate, 1 IU VWF:RCO |
| J7185 | Injection, factor VIII (antihemophilic factor, recombinant) (Xyntha), per IU |
| J7186 | Injection, antihemophilic factor VIII/Von Willebrand factor complex (human), per factor VIII I.U. |
| J7187 | Injection, Von Willebrand factor complex (Humate-P), per IU, VWF:RCO |
| J7189 | Factor VIIa (antihemophilic Factor, recombinant), per 1mcg |
| J7190 | Factor VIII (antihemophilic factor [human]) per IU |
| J7192 | Factor VIII (antihemophilic factor, recombinant) per IU, not otherwise specified (Kogenate) |
| J7193 | Factor IX (antihemophilic factor, purified, non-recombinant) per IU |
| J7194 | Factor IX, complex, per IU |
| J7195 | Factor IX (antihemophilic factor, recombinant) per IU (Benefix) |
| J7198 | Anti-inhibitor, per IU |
| J7199/J7203 | Hemophilia clotting factor, not otherwise classified (Adynovate, Rebinyn) |
| J7205 | Factor VIII, Fc fusion protein (recombinant), (Eloctate) |
| J7207 | Factor VIII, (antihemophilic factor, recombinant), pegylated, 1 IU |
| J7211 | Factor VIII, (antihemophilic factor, recombinant), (Kovaltry), 1 IU |
| J7208 | Factor VIII (antihemophilic factor, recombinant) pegylated-aucl (Jivi), 1 IU |
| J7170 | Emicizumab injection (Hemlibra) |
| J7204 | Factor VIII (antihemophilic factor, recombinant), Esperoct (glycopegylated-exei, per IU |
| J7214 | Factor viii/von willebrand factor complex, recombinant (Altuviiio), per factor viii i.u. |

## Overview

FDA approved indications for Factor VII

- Von Willebrand disease
- Classic Hemophilia

FDA Approved indications for Factor IX

- Factor IX deficiency (hemophilia B, Christmas disease)
- Bleeding in Patients with Antihemophilic Factor Inhibitors

## Indications/Criteria

Factor products listed above will be covered when medically necessary for FDA approved indications.

**Factor products must be obtained through Accredo Specialty Pharmacy.**

- Utilization is subject to retrospective review in accordance with FDA approved indication(s).
- Prior authorization and medical justification is required for factor products obtained or administered in other outpatient settings.
- Please see Medicaid and Medicare Variations.

## MVP Medicaid Variation

- Prior authorization is NOT required
- Provider must complete prior notification form
- Must be obtained through a contracted vendor
- Medications that are a pharmacy benefit are covered and billed to New York State Fee-For-Service (FFS) program. They are defined as medications that go through a retail or specialty pharmacy, including self administered injectable products. Pharmacy medications are subject to FFS's clinical criteria including (but not limited to) coverage, quantity limit, step therapy, and prior authorization. Pharmacy benefit information can be found here: https://www.emedny.org/info/fullform.pdf

## Medicare Variation

Refer to the MVP Medicare website for the Medicare Part D Formulary and Part D policies for drugs that may be covered under the Part D benefit.
Refer to the MVP Medicare website for Medicare Part B policies for drugs that may be covered under the Part B benefit.

## Exclusions

- Child Health Plus: blood factors prior to 04/01/2014 are not covered

## References

1. Clinical Pharmacology: Accessed 02/07/2025
2. New York State Department of Health. Clotting Factor Guidelines. Transition of Clotting Factor Products and Services from Medicaid Fee-For-Service to Medicaid Managed Care. Clotting Factor Guidelines (ny.gov)

| Member 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 | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Potential for Retrospective Review |
| MVP Child Health Plus | Potential for Retrospective Review |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Potential for Retrospective Review |
| MVP Complete Wellness | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| USA Care PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP VT HMO | Potential for Retrospective Review |
| MVP VT Plus HMO | Potential for Retrospective Review |
| MVP VT HDHP 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

**Medicare Part B: Hemophilia Factor**

| | |
|---|---|
| **Type of Policy:** | **Medical Therapy** |
| **Prior Approval Date:** | **11/01/2023** |
| **Approval Date:** | **04/01/2025** |
| **Effective Date:** | **06/01/2025** |
| **Related Policies:** | **N/A** |

Refer to the MVP Medicare website for the Medicare Part D Formulary and Part D policies for drugs that may be covered under the Part D benefit.

## Codes Requiring Retrospective Review

| | |
|---|---|
| J7210 | Injection, Factor VIII (antihemophilic factor, recombinant), Afstyla, per IU |
| J7179 | Injection, von Willebrand factor (recombinant), Vonvendi, per IU |
| J7202 | Injection, Factor IX albumin fusion protein (recombinant), Idelvion, per IU |
| J7207 | Injection, Factor VIII (antihemophilic factor, recombinant), pegylated, per IU |
| J7209 | Injection, Factor VIII (antihemophilic factor, recombinant), Nuwiq, per IU |
| J7182 | Injection, Factor VIII (antihemophilic factor, recombinant), Novoeight, per IU |
| J7188 | Injection, factor VIII (antihemophilic factor, recombinant), Obizur, per IU |
| J7175 | Injection, Factor X (human), Coagadex, per IU |
| J7181 | Factor XIII (antihemophilic factor, recombinant), Tretten, per 10 IU |
| J7201 | Factor IX (antihemophilic factor, recombinant), Alprolix, per 1IU |
| J7200 | Factor IX (antihemophilic factor, recombinant), Rixubis, per IU |
| J7180 | Injection, factor XIII (antihemophilic factor, human), 1 IU |
| J7183 | Injection, von Willebrand factor complex (human), Wilate, 1 IU VWF:RCO |
| J7185 | Injection, factor VIII (antihemophilic factor, recombinant) (Xyntha), per IU |

| | |
|---|---|
| J7186 | Injection, antihemophilic factor VIII/Von Willebrand factor complex (human), per factor VIII I.U. |
| J7187 | Injection, Von Willebrand factor complex (Humate-P), per IU, VWF:RCO |
| J7189 | Factor VIIa (antihemophilic Factor, recombinant), per 1mcg |
| J7190 | Factor VIII (antihemophilic factor [human]) per IU |
| J7192 | Factor VIII (antihemophilic factor, recombinant) per IU, not otherwise specified |
| J7193 | Factor IX (antihemophilic factor, purified, non-recombinant) per IU |
| J7194 | Factor IX, complex, per IU |
| J7195 | Factor IX (antihemophilic factor, recombinant) per IU |
| J7198 | Anti-inhibitor, per IU |
| J7199/J7203 | Hemophilia clotting factor, not otherwise classified (Adynovate, Rebinyn) |
| J7205 | Factor VIII, Fc fusion protein (recombinant), (Eloctate) |
| J7207 | Factor VIII, (antihemophilic factor, recombinant), pegylated, 1 IU |
| J7211 | Factor VIII, (antihemophilic factor, recombinant), (Kovaltry), 1 IU |
| J7208 | Factor VIII (antihemophilic factor, recombinant) pegylated-aucl (Jivi), 1 IU |
| J7170 | Emicizumab injection (Hemlibra) |
| J7204 | Factor VIII (antihemophilic factor, recombinant), Esperoct (glycopegylated-exei, per IU |
| J7214 | Factor viii/von willebrand factor complex, recombinant (Altuviiio), per factor viii i.u. |

## Overview

FDA approved indications for Factor VII

- Von Willebrand disease
- Classic Hemophilia

FDA Approved indications for Factor IX

- Factor IX deficiency (hemophilia B, Christmas disease)
- Bleeding in Patients with Antihemophilic Factor Inhibitors

## Indications/Criteria

Factor products listed above will be covered when medically necessary for FDA approved indications.

Utilization is subject to retrospective review in accordance with FDA approved indication(s).

Refer to Chapter 15 Section 50.5.5 of the Medicare Benefit Policy Manual for coverage details.

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**Exclusions**

- N/A

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**References**

1. Medicare Benefit Policy Manual. Chapter 15. Covered Medical and Other Health Services. Section 50.5.5 Hemophilia Clotting Factors. Revised 08/03/2023.

**MVP Health Care Medical Policy**

**Hemophilia Gene Therapy**

| | |
|---|---|
| **Type of Policy:** | **Drug Therapy** |
| **Prior Approval Date:** | **10/01/2023** |
| **Approval Date:** | **10/01/2024** |
| **Effective Date:** | **01/01/2025** |
| **Related Policies:** | **Hemophilia Factor** |

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies.

**Drugs Requiring Prior Authorization under the medical benefit**

J1411 Hemgenix (injection, etranacogene dezaparvovec-drlb)

J1412 Roctavian (injection, valoctocogene roxaparvovec)

**Overview**

**Hemgenix** is an adeno-associated virus vector-based gene therapy indicated for the treatment of adults with **hemophilia B** (congenital Factor IX deficiency) who currently use Factor IX prophylaxis therapy or have current/historical life-threatening hemorrhage or have repeated serious spontaneous bleeding episodes.
Hemgenix is designed to deliver a copy of a gene encoding the Padua variant of human coagulation Factor IX (hFIX-Padua). Hemgenix infusion results in cell transduction and increase in circulating Factor IX activity in patients with Hemophilia B.

**Roctavian** is an adeno-associated virus vector-based gene therapy indicated for the treatment of adults with **severe hemophilia A** (congenital factor VIII deficiency with factor VIII activity <1IU/dL) without pre-existing antibodies to adeno-associated virus serotype 5 (AAV5). Roctavian is designed to introduce a functional copy of a transgene encoding the B-domain deleted SQ form of human coagulation factor VIII (hFVIII-SQ). Transcription of this transgene occurs within the liver, using the liver-specific promotor,

which results in the expression of hFVIII-SQ. The expressed hFVIII-SQ replaces the missing coagulation factor VIII needed for effective hemostasis.

## Indications/Criteria

### A. Hemophilia A

Roctavian may be considered for coverage when **ALL** of the following criteria is met:

- Chart notes documenting that member has a confirmed diagnosis of severe hemophilia A (hereditary factor VIII deficiency with factor VIII activity <1IU/dL)
- Current chart notes documenting the **ALL** of the following tests:
    - No pre-existing antibodies to AAV5 as demonstrated using FDA approved companion diagnostic
    - Negative factor VIII inhibitor titer testing
    - Liver function tests [alanine aminotransferase (ALT), aspartate aminotransferase (AST), gamma-glutamyl transferase (GGT), alkaline phosphatase (ALP), total bilirubin and international normalized ration (INR)]
    - Ultrasound or laboratory assessments for liver fibrosis
        - See Exclusions section
- Provider attestation
    - Indicating evaluation for thrombosis and cardiovascular risk factors has been completed and will be monitored after Roctavian infusion
    - For members with pre-existing risk factors for hepatocellular carcinogenicity (cirrhosis, advanced hepatic fibrosis, hepatitis B or C, non-alcoholic fatty liver disease (NAFLD), chronic alcohol consumption, non-alcoholic steatohepatitis (NASH), advanced age), regular (annual) monitoring liver ultrasounds and alpha-fetoprotein testing following administration

Roctavian will be approved as **a one-time dose**. Requests for replacement due to lost or damaged product will not be covered. Coverage is contingent on eligibility at the time of infusion.

### B. Hemophilia B

Hemgenix may be considered for coverage when **ALL** of the following criteria is met:

- Chart notes documenting that member has a confirmed diagnosis of moderately severe or severe hemophilia B (hereditary factor IX deficiency)
- Current chart notes documenting the **ALL** of the following tests:
    - Negative factor IX inhibitor titer testing
        - If initial test is positive, there must be documentation of a re-test within 2 weeks
    - Documentation of liver health assessments including:
        - Enzyme testing [alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase (ALP) and total bilirubin)
        - Hepatic ultrasounds and elastography
- Current chart notes document one of the following:
    - Current use of Factor IX prophylaxis **OR**
    - Member has a current or historical life-threatening hemorrhage **OR**
    - Member has had repeated, serious spontaneous bleeding episodes
- Provider attestation
    - For members with pre-existing risk factors for hepatocellular carcinogenicity (cirrhosis, advanced hepatic fibrosis, hepatitis B or C, non-alcoholic fatty liver disease (NAFLD), chronic alcohol consumption, non-alcoholic steatohepatitis (NASH), advanced age), regular (annual) monitoring liver ultrasounds and alpha-fetoprotein testing following administration
    - Transaminase levels will be monitored once per week for 3 months after administration
    - Factor IX activity levels will be monitored regularly after Hemgenix administration

Hemgenix will be approved as **a one-time dose**. Requests for replacement due to lost or damaged product will not be covered. Coverage is contingent on eligibility at the time of infusion.

---

**Exclusions**

- Previous gene therapy treatment
- Member is biologically female
- Indication, age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling
- Roctavian

  - Member has known significant hepatic fibrosis (stage 3 or stage 4 on the Batts-Ludwig scale or equivalent)
  - Member has cirrhosis
  - Member has mannitol hypersensitivity
  - Active or uncontrolled infection (including chronic active hepatitis B)
  - Positive test for antibodies to AAV5
  - Positive test for factor VIII inhibitors
- Hemgenix
  - Member has active hepatitis B or C infection
  - Member has uncontrolled HIV infection
  - Positive initial test and re-test results for human factor IX inhibitors

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## References


1. U.S Food and Drug Administration. List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools). Content current as of 08/03/2023. Accessed 08/03/2023. List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools) | FDA
2. Roctavian (valotocogene roxaparvovec-rvox) suspension for intravenous infusion. BioMarin Pharmaceutical Inc. Novato CA. August 2023. 78bf2bcb-7068-4774-b962-a35c53704fc1_source__v.pdf (d34r3hkxgxjdtw.cloudfront.net)
3. Hemgenix (etranacogene dezaparvovec-drlb) suspension for intravenous infusion. CSL Behring LLC. King of Prussia, PA. November 2022. 2022-313 HEMGENIX.indd (cslbehring.com)
4. HOPE-B: Trial of AMT-061 in Severe or Moderately Severe Hemophilia B Patients CTG Labs - NCBI. (n.d.). Clinicaltrials.gov. Last updated: 2024-07-30


| Member Product | Medical Management Requirements* |
|---|---|
| **New York Products** | Prior Auth |
| 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 | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Medicare Gold Giveback | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |

| | |
|---|---|
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D |
| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

# Medicare Part B: Hemophilia Gene Therapy

**Type of Policy:** **Drug Therapy**
**Prior Approval Date:** **02/01/2024**
**Approval Date:** **10/01/2024**
**Effective Date:** **12/01/2024**
**Related Policies:** **Hemophilia Factor**

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies.

## Drugs Requiring Prior Authorization under the medical benefit

J1411 Hemgenix (injection, etranacogene dezaparvovec-drlb)

J1412 Roctavian (injection, valoctocogene roxaparvovec)

## Overview/Summary of Evidence

**Hemgenix** is an adeno-associated virus vector-based gene therapy indicated for the treatment of adults with **hemophilia B** (congenital Factor IX deficiency) who currently use Factor IX prophylaxis therapy or have current/historical life-threatening hemorrhage or have repeated serious spontaneous bleeding episodes.
Hemgenix is designed to deliver a copy of a gene encoding the Padua variant of human coagulation Factor IX (hFIX-Padua). Hemgenix infusion results in cell transduction and increase in circulating Factor IX activity in patients with Hemophilia B.

**Roctavian** is an adeno-associated virus vector-based gene therapy indicated for the treatment of adults with **severe hemophilia A** (congenital factor VIII deficiency with factor VIII activity <1IU/dL) without pre-existing antibodies to adeno-associated virus serotype 5 (AAV5). Roctavian is designed to introduce a functional copy of a transgene encoding the B-domain deleted SQ form of human coagulation factor VIII (hFVIII-SQ). Transcription of this transgene occurs within the liver, using the liver-specific promotor,

which results in the expression of hFVIII-SQ. The expressed hFVIII-SQ replaces the missing coagulation factor VIII needed for effective hemostasis.

## Indications/Criteria

### A. Hemophilia A

Roctavian may be considered for coverage when **ALL** of the following criteria is met:

- Chart notes documenting that member has a confirmed diagnosis of severe hemophilia A (hereditary factor VIII deficiency with factor VIII activity <1IU/dL).
- Current chart notes documenting the **ALL** of the following tests:
    - No pre-existing antibodies to AAV5 as demonstrated using FDA approved companion diagnostic
    - Negative factor VIII inhibitor titer testing
    - Liver function tests [alanine aminotransferase (ALT), aspartate aminotransferase (AST), gamma-glutamyl transferase (GGT), alkaline phosphatase (ALP), total bilirubin and international normalized ration (INR)]
    - Ultrasound or laboratory assessments for liver fibrosis
        - See Exclusions section
- Provider attestation
    - Indicating evaluation for thrombosis and cardiovascular risk factors has been completed and will be monitored after Roctavian infusion.
    - For members with pre-existing risk factors for hepatocellular carcinogenicity (cirrhosis, advanced hepatic fibrosis, hepatitis B or C, non-alcoholic fatty liver disease (NAFLD), chronic alcohol consumption, non-alcoholic steatohepatitis (NASH), advanced age), regular (annual) monitoring liver ultrasounds and alpha-fetoprotein testing following administration

Roctavian will be approved as a **one-time dose**. Requests for replacement due to lost or damaged product will not be covered. Coverage is contingent on eligibility at the time of infusion.

### B. Hemophilia B

Hemgenix may be considered for coverage when **ALL** of the following criteria is met:

- Chart notes documenting that member has a confirmed diagnosis of moderately severe or severe hemophilia B (hereditary factor IX deficiency)
- Current chart notes documenting the **ALL** of the following tests:
    - Negative factor IX inhibitor titer testing
        - If initial test is positive, there must be documentation of a re-test within 2 weeks
    - Documentation of liver health assessments including:
        - Enzyme testing [alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase (ALP) and total bilirubin)
        - Hepatic ultrasounds and elastography
- Current chart notes documenting one of the following:
    - Current use of Factor IX prophylaxis **OR**
    - Member has a current or historical life-threatening hemorrhage **OR**
    - Member has had repeated, serious spontaneous bleeding episodes
- Provider attestation
    - For members with pre-existing risk factors for hepatocellular carcinogenicity (cirrhosis, advanced hepatic fibrosis, hepatitis B or C, non-alcoholic fatty liver disease (NAFLD), chronic alcohol consumption, non-alcoholic steatohepatitis (NASH), advanced age), regular (annual) monitoring liver ultrasounds and alpha-fetoprotein testing following administration
    - Transaminase levels will be monitored once per week for 3 months after administration
    - Factor IX activity levels will be monitored regularly after Hemgenix administration

Hemgenix will be approved as a **one-time dose**. Requests for replacement due to lost or damaged product will not be covered. Coverage is contingent on eligibility at the time of infusion.

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**Exclusions**

- Previous gene therapy treatment
- Member is biologically female
- Indication, age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling
- Roctavian

  - Member has known significant hepatic fibrosis (stage 3 or stage 4 on the Batts-Ludwig scale or equivalent)
  - Member has mannitol hypersensitivity
  - Active or uncontrolled infection (including chronic active hepatitis B)
  - Positive test for antibodies to AAV5
  - Positive test for factor VIII inhibitors
- Hemgenix
  - Member has active hepatitis B or C infection
  - Member has uncontrolled HIV infection
  - Positive initial test and re-test results for human factor IX inhibitors

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**References**


1. U.S Food and Drug Administration. List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools). Content current as of 08/03/2023. Accessed 08/03/2023. List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools) | FDA

2. Roctavian (valotocogene roxaparvovec-rvox) suspension for intravenous infusion. BioMarin Pharmaceutical Inc. Novato CA. August 2023. 78bf2bcb-7068-4774-b962-a35c53704fc1_source__v.pdf (d34r3hkxgxjdtw.cloudfront.net)

3. Hemgenix (etranacogene dezaparvovec-drlb) suspension for intravenous infusion. CSL Behring LLC. King of Prussia, PA. November 2022. 2022-313 HEMGENIX.indd (cslbehring.com)

4. HOPE-B: Trial of AMT-061 in Severe or Moderately Severe Hemophilia B Patients CTG Labs - NCBI. (n.d.). Clinicaltrials.gov. Last updated: 2024-07-30

**MVP Health Care Medical Policy**

**Hepatitis C Treatment**

**Type of Policy:** **Drug Therapy**
**Prior Approval Date:** **12/01/2023**
**Approval Date:** **12/01/2024**
**Effective Date:** **02/01/2025**
**Related Policies:** **NA**

**Drugs Requiring Prior Authorization (covered under the pharmacy benefit)**

Harvoni® (ledipasvir/sofosbuvir) tablets, for oral use and oral pellets

Sovaldi™ (sofosbuvir) tablets, for oral use and oral pellets

Epclusa® (sofosbuvir/velpatasvir) tablets, for oral use and oral pellets

Mavyret™ (glecaprevir/pibrentasvir) tablets, for oral use and oral pellets

Vosevi™ tablets (sofosbuvir/velpatasvir/voxilaprevir)

Peg-Intron® injection, for subcutaneous use (pegylated interferon alpha-2b)

Pegasys® injection, for subcutaneous use (pegylated interferon alpha-2a)

ribavirin

ledipasvir/sofosbuvir

sofosbuvir/velpatasvir

Refer to the MVP website for the Medicare Part D formulary for drugs that may covered under the Part D benefit.

Refer to the MVP website for the Medicare Part B policies for coverage criteria of drugs covered under the medical benefit.

**Overview**

An estimated 2.7-3.9 million persons in the Unites States have chronic Hepatitis C virus (HCV). The course of HCV varies greatly in its course and outcome. Genotype 1, the most predominant form of HCV in the US, is also associated with lower response rates to therapy than genotypes 2 and 3.

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**Preferred Agents:**

The following medications below are preferred therapies: Documentation must be provided to support the use of other treatment regimens.

- **Epclusa**-Genotypes 1-6
- **Harvoni**-Genotypes 1, 4, 5, 6
- **Mavyret**-Genotype 1-6
- **Vosevi**-Genotypes 1-6

**Indications/Criteria**

The following information must be provided for all drugs:

- Test results identifying HCV-antibody, quantitative HCV PCR level (viral load), HCV genotype, and fibrosis score must be provided
- Documentation identifying if member is treatment naïve or experienced and previous treatment regimen
- Regimen for initial therapy or retreatment and duration of therapy will be based on the current American Association for the Study of Liver Disease (AASLD)/Infectious Disease Society of America (IDSA) guidance for the Testing, Managing, and Treating Hepatitis C. http://www.hcvguidelines.org/
- Preferred agents based on genotype must be used unless documentation is provided identifying a contraindication or intolerance

**Exclusions**

- Use of ribavirin during pregnancy
- Indication, age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling.
- Use with drugs that are contraindicated per package labeling
- Treatments not supported by the AASLD HCV: Recommendations for Testing, Managing, and Treating Hepatitis C guidelines

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## References


1. Boursier Jerome, Ledinghen Victor, et al. Comparison of Eight Diagnostic Algorithms for Liver Fibrosis in Hepatitis C: New Algorithms Are More Precise and Entirely Noninvasive. Hepatology, 2012; 55(1):58-67

2. Harvoni Tablets. Prescribing Information. Foster City, CA: Gilead Science, Inc.; October 2014
3. Vallet-Pichard A, Mallet V, et al. FIB-4: an inexpensive and accurate marker of fibrosis in HCV infection. Comparison with liver biopsy and fibrotest. Hepatology, 2007; 46(1):32-6
4. Borsoi Viana MS, Takei K, Collarile Tamaquti DC, et al. Use of AST platelet ratio index (APRI Score) as an alternative to liver biopsy for treatment indication in chronic hepatitis C. Ann Hepatol, 2009; 8(1):26-31New York State Department of Health: Hepatitis C (www.health.ny.gov/communicable/hepatitis/hepatitis_c) Hepatitis C - FAQs, Statistics, Data, & Guidelines | CDC What's New, Updates and Changes to the Guidance | HCV Guidance (hcvguidelines.org)HCV Testing and Linkage to Care | HCV Guidance (hcvguidelines.org). Last updated October 24, 2022.
5. Epclusa. Prescribing Information. Foster City, CA: Gilead Sciences, Inc. Last updated April 2022Harvoni. Prescribing Information. Foster City, CA: Gilead Science, Inc. Last updated March 2020
6. Solvaldi. Prescribing Information. Foster City, CA: Gilead Science, Inc. Last updated March 2020.Mavyret Tablets. Prescribing Information. North Chicago, IL: AbbVie Inc. Last updated October 2023
7. Vosevi Tablets. Prescribing Information. Foster City, CA: Gilead Science, Inc. Last updated November 2019
8. Peg-Intron®. Prescribing Information. Whitehouse Station, NJ: Merck Sharp & Dohme Corp ., a subsidiary of Merck & Co.. Last updated August 2019
9. Pegasys®. Prescribing Information. South San Francisco, CA: Hoffmann-La Roche, Inc. c/o Genentech, Inc.. Last updated March 2021
10. Treatment regimens for chronic hepatitis C virus genotype 1: UpToDate, Inc. 2014
11. Wenwen Jin, Zhonghua Lin, et al. Diagnostic accuracy of the aspartate aminotransferase-to-platelet ratio index for the prediction of hepatits B-related fibrosis: a leading meta-analysis. BMC Gastroenterology 2012, 12:14
12. AASLD/IDSA/IAS-USA. Recommendations for testing, managing, and treating Hepatitis C. http://www.hcvguidelines.org. Accessed November, 2017


| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Complete Wellness | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| USA Care PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

**Hereditary Angioedema**

| | |
|---|---|
| **Type of Policy:** | **Drug/Medical Therapy** *(administered by the pharmacy department)* |
| **Prior Approval Date:** | **10/01/2023** |
| **Approval Date:** | **12/01/2024** |
| **Effective Date:** | **02/01/2025** |

**Related Policies**:

Experimental or Investigational Procedures, Behavioral Health Services, Drugs & Treatments, Off-Label use of FDA Approved Drugs, Clinical Trials

Refer to the MVP Medicare website for the Medicare Part D Formulary and Part D policies for drugs that may be covered under the Part D benefit.

Refer to the MVP website for the Medicare Part B policies for coverage criteria of drugs covered under the medical benefit.

**Codes Requiring Prior Authorization (covered under the medical benefit)**

J0598 Cinryze® Injection, C1 esterase inhibitor (human), 10 units. (B/D coverage for Medicare dependent upon place of service)

J0597 Berinert® Injection, C1 esterase inhibitor (human), 10 units

J1290 Kalbitor® Injection, ecallantide, 1mg

J0596 Ruconest Injection, C1 esterase inhibitor recombinant), 10 units

**Drugs Requiring Prior Authorization (covered under the pharmacy benefit)**

Firazyr® (icatibant) – self-administered

Haegarda (C1 esterase inhibitor, human) –self administered

Takhzyro (lanadelumab-flyo)- self administered

**Overview**

Hereditary angioedema (HAE) is a genetic disorder caused by a deficiency or defective plasma protein C1 inhibitor. HAE is a chronic disease that is associated with acute attacks of swelling. Swelling can occur in the face, larynx, gastrointestinal tract, and limbs. The frequency and severity of attacks can vary significantly.

**Medicaid Variation:** Medications that are a pharmacy benefit are covered and billed to New York State Fee-For-Service (FFS) program. They are defined as medications that go through a retail or specialty pharmacy, including self-administered injectable products. Pharmacy medications are subject to FFS's clinical criteria including (but not limited to) coverage, quantity limit, step therapy, and prior authorization. Pharmacy benefit information can be found here: https://www.emedny.org/info/fullform.pdf

## Indications/Criteria

| **Brand Name** | Berinert® | Cinryze® | Firazyr® | Haegarda | Kalbitor® | Ruconest | Takhzyro |
|---|---|---|---|---|---|---|---|
| **Chemical Name** | C1 esterase inhibitor | C1 esterase inhibitor | icatibant | C1 esterase inhibitor | ecallantide | C1 esterase inhibitor | Lanadelumab -flyo |
| **Indication specific for HAE** | acute abdominal, facial, or laryngeal attacks | prophylaxis | acute attacks | prophylaxis | acute attacks | acute nonlaryngeal attacks | prophylaxis |
| **Administration** | IV | IV | SC<br>(self adm only – RX benefit) | SC<br>(self adm only – RX benefit) | SC<br>(Provider adm only – medical benefit) | IV | SC<br>(self adm only – RX benefit) |
| **Age restrictions** | ≥ 12 years | ≥ 6 years | ≥ 18 years | ≥ 6 years | ≥ 12 years | ≥ 13 years | ≥ 12 years |
| **Recommended Dose** | 20 units/kg IV | ≥ 12 years 1,000 Units IV every 3 or 4 days<br>6-11 years 500 units IV every 3 or 4 days | 30mg SC x1.<br>MDD=3 inj/24hrs | 60 units/kg SC twice weekly (every 3 or 4 days) | 30mg SC x1.<br>MDD=60mg/24hrs | <84 kg: 50 units/kg IV<br>≥84 kg: 4200 units IV<br>MDD= 2inj/24hr | 300mg SC every 2 weeks<br>Consider dosing once every 4 weeks when member is attack free for > 6 months |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Initial authorization & subsequent authorizations** | 3 months (1 injection per visit at recommended dose). | 3 months [10 doses (20 vials) per month for ≥ 12 years] or [10 doses (10 vials) per month for 6-11 years | 3 months [3 doses (3 prefilled syringes) per RX]. | 3 months [10 doses per month] | 3 months (2 doses per visit) | 3 months (2 doses per visit) | 3 months [2 doses (4 vials) per month]. |

Cinryze, Berinert, Firazyr, Haegarda, Kalbitor, Takhzyro and Ruconest may be considered for coverage when the following criteria are met:

- Ordered by an allergist, immunologist, or hematologist;
- Indication as listed in the table on page 1 of this policy;
- Laboratory data provided confirms diagnosis of HAE (i.e.C1-INH activity and serum complement factor 4 level below the reference range; serum C1q level within normal reference range);
- For short-term prophylaxis therapy, triggers (e.g. surgery, major dental work, etc.) of attacks have been prophylactically treated appropriately and severe HAE attacks* persist; OR contraindication (such as pregnancy or lactating) or severe intolerance to attenuated androgens (e.g. danazol);
- Provide family history of angioedema status;
- Provide current prescription history. (Medications that may trigger or worsen angioedema and should be avoided are estrogen contraceptives, hormone replacement therapy, and ACE-Inhibitors)[11];
- For medications indicated for prophylaxis, provider has documented the benefits of a prophylactic treatment strategy in addition to on-demand treatment considering individualized member factors OR provider has documented plans for as-needed use of short-term prophylaxis before medical procedures or other events at high risk of triggering HAE attacks.
- For Cinryze, Ruconest and Berinert

- Site of Care
  - Per the MVP Health Care Pharmacy Management Programs policy, Cinryze, Ruconest and Berinert are subject to Site of Care requirements and must be obtained through a preferred home infusion vendor. Prior Authorization and medical justification is required for Cinryze, Ruconest and Berinert obtained and administered in other outpatient settings such as a provider's office or hospital facility.
  - MVP will allow 60 days after prior authorization approval for members to transfer to a preferred infusion site.
  - This requirement does not apply to MVP Medicare and Medicaid members

*Severe attacks are defined as attacks that compromise the airway, compromise activities of daily living for at least 5 days per month, or last more than 72 hours.

**Continued authorization** may be provided for **Cinryze, Takhzyro and Haegarda** if the number of emergency room visits or hospitalizations due to a severe HAE attack has diminished.

**Continued authorization** may be provided for **Firazyr, Kalbitor, Ruconest or Berinert** if documentation identifies diminished symptoms, decreased severity of attack, reduced duration of attacks, and decreased hospitalizations.

## Exclusions

- Other types of angioedema are not covered (e.g. allergic, acquired, and medication-induced);
- More than one acute agent per authorization period;
- Refill of medication prior to use of current supply (i.e. stockpiling of medication is not covered);
- Medications that may trigger or worsen angioedema are currently being administered
- For Ruconest member with laryngeal attacks
- Indication, age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling

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| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Complete Wellness | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |

| | |
|---|---|
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| USA Care PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

**Select Hypnotics**

**Type of Policy:** **Drug Therapy**
**Prior Approval Date:** **04/01/2023**
**Approval Date:** **11/01/2024**
**Effective Date:** **01/01/2025**

**Related Policies:** **Refer to the MVP Medicare website for the Medicare Part D formulary and policies for drugs covered under the Part D benefit.**

## Drugs Requiring Prior Authorization (PA), Step Therapy (ST), and/or has Quantity Limitations (QL)

***Please see formulary for most up to date requirements**

| **Brand Name Non-Benzodiazepines** | **Chemical/ Generic Name** |
|---|---|
| Ambien® ST, PA, QL | zolpidem QL |
| Ambien CR® ST, PA, QL | zolpidem ER QL |
| Edluar™ ST, PA, QL | zolpidem SL ST, PA, QL |
| Intermezzo® | zolpidem SL ST, PA, QL |
| Sonata® | zaleplon QL |
| Lunesta® ST, PA, QL | eszopiclone QL |
| Rozerem® ST, PA, QL | ramelteon QL |
| Zolpimist™ ST, QL | zolpidem oral spray |
| **Brand Name Orexin Receptor Antagonist** | **Chemical/Generic Name** |
| Belsomra ST, QL | suvorexant |
| Dayvigo ST, QL | lemborexant |
| Quviviq ST, QL | daridorexant |

| Brand Name Benzodiazepines for Insomnia | Chemical/ Generic Name |
|---|---|
| Doral® QL | quazepam |
| Halcion® QL | triazolam QL |
| Prosom® | estazolam QL |
| Restoril® QL | temazepam QL |
| **Other Brand Name** | **Chemical/Generic Name** |
| Hetlioz PA | tasimelteon |
| Silenor® PA, QL | doxepin QL |

## Overview

Sleep disorders in the United States affect about one-third of the general population and are defined as a group of conditions that disturb normal sleep patterns. Sleep disorders can impair overall health, quality of life, and safety. Insomnia is one of the most prevalent sleep disorders and is defined as difficulty with falling asleep, staying asleep, sleep consolidation, duration of sleep, and/or quality, that occurs even with adequate opportunity for sleep, resulting in some form of daytime impairment. Hypnotics as well as Cognitive Behavioral Therapy (CBT) are common treatments for a variety of sleep disorders.

## Indications/Criteria

All **brand name** oral prescription **non-benzodiazepine** hypnotics, orexin receptor antagonists, and generic zolpidem sublingual require step therapy and may be medically necessary if:

- The member has experienced treatment failure or significant intolerance (e.g. sensitivity, drug allergy, adverse effect) to at least one generic non-benzodiazepine select hypnotics (not subject to the step edit)
- Coding will allow for coverage if there is at least one claim of a generic non-benzodiazepine hypnotic (not subject to the step edit) in the past 365 days

The use of BRAND **Silenor** may be medically necessary when:

- Documented failure or intolerance to **ALL** formulary non-benzodiazepine sleep medications

**Initial Approval** will be for 6 months

**Extension requests** will be approved for up to 12 months if the member has a continued benefit therapy. Extension requests where the medications did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

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The use of **Hetlioz** capsules may be medically necessary if all of the following are met:

- Provider attestation indicating that the member does NOT have severe hepatic impairment
- For Non-24-Hour Sleep-Wake Disorder in adults
    - Diagnosis of Non-24-Hour Sleep-Wake Disorder (non-entrained type circadian rhythm sleep- disorder, free running type)
    - Member is totally blind
    - History (within the last 3 months) of difficulty falling or staying asleep, daytime sleepiness, or difficulty awakening in the morning
- For Smith-Magenis Syndrome (SMS)
    - Diagnosis of Smith-Magenis Syndrome (SMS) with Nighttime Sleep Disturbances
    - Member is 16 years or older

The use of **Hetlioz** LQ Oral Suspension may be medically necessary if ALL the following are met:

- Diagnosis of Smith-Magenis Syndrome (SMS) with Nighttime Sleep Disturbances
- Member is 3-15 years of age

**Initial Approval** will be for 6 months

**Extension requests** will be approved for up to 12 months if the member has a continued benefit therapy. Extension requests where the medications did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

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**Quantity Limit Exceptions**

- Will be reviewed on a case-by-case basis and must meet the MVP Experimental/Investigational (E/I) Policy for use

**Initial Approval** will be up to 3 months

**Extension Request** will be approved for 6 months and the following documentation is required:

- Current re-evaluation of member demonstrating member need
- Risk versus benefit has been addressed
- Underlying issues have been assessed

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**Exclusions**

- Indication, age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling
- Current drug or alcohol abusers
- Use of concomitant medications that can potentiate insomnia including, but not limited, to CNS stimulants
- Combination use with other sleep medications including long-acting benzodiazepines
- Inadequate control of conditions, including initiating or adjusting medication therapy where appropriate, that may exacerbate insomnia
- Use of another hypnotic before completion of current supply
- Number of tablets per dose that exceed dose optimization strategies are not considered medically necessary. (That is, using multiple tablets per dose when there is an appropriate higher strength available. For example, drug A is available in 10mg and 20mg. Using 2 tablets of 10mg per dose is not considered medically necessary since there is a 20mg dose available.)

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| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Complete Wellness | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D |
| USA Care PPO | Refer to the MVP website for the Medicare Part B and Part D |
| 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 | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

# Idiopathic Pulmonary Fibrosis

**Type of Policy:** **Drug Therapy**
**Prior Approval Date:** **07/01/2023**
**Approval Date:** **07/01/2024**
**Effective Date:** **09/01/2024**
**Related Policies:** **NA**

## Drugs Requiring Prior Authorization

Pirfenidone tablets

Esbriet (pirfenidone) capsules/tablets

Ofev (nintedanib) capsules

Refer to the MVP website for the Medicare Part D formulary for drugs that may covered under the Part D benefit.

## Overview

Idiopathic pulmonary fibrosis (IPF) is a chronic, progressive fibrotic interstitial lung disease of unknown origin[1]. The tissue deep in the lungs becomes thick and scarred, resulting in an irreversible loss of the tissue's ability to transport oxygen. The most common symptoms are shortness of breath and cough. As the disease progresses, members can experience rapid, shallow breathing, unintended weight loss, fatigue or malaise, aching muscles and joints and clubbing of the fingers or toes.[2] IPF causes the same type of scarring and symptoms as other lung diseases, making it difficult to diagnose.

Esbriet and Ofev are both indicated for the treatment of IPF. Esbriet is a pyridone with an unknown mechanism of action.[3] Ofev is a kinase inhibitor, which inhibits multiple receptors implicated in the pathogenesis of IPF.[4]

## Indications/Criteria

Esbriet/Ofev will be considered medically necessary for Idiopathic Pulmonary Fibrosis when **ALL** the following criteria are met:

- Documented diagnosis of IPF with HRCT (high resolution computed tomography) **OR** pathological lung biopsy
    - Must rule out other causes of interstitial lung disease such as domestic and occupational environmental exposures, connective tissue disease, drug toxicity and/or infection.
- Liver function test prior to initiating treatment indicating AST/ALT and bilirubin are less than 5x ULN
- Prescribed by or in consultation with a pulmonologist
- FVC greater than or equal to 50% of predicted and a carbon monoxide diffusing capacity of 30 to 79% of predicted, prior to start of therapy

Initial coverage will be for 6 months. For continuation of therapy up to 12 months, documentation must identify improvement or maintenance of disease (less than a 10% decline in FVC) and LFTs within allowed bounds.

Ofev will be considered medically necessary for **Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD)** when **ALL** the following criteria are met:

- Confirmed diagnosis of SSc-ILD such as with HRCT (high resolution computed tomography) **AND**
- Prescribed by or in consultation with a pulmonologist

Ofev will be considered medically necessary for **Chronic Fibrosing Interstitial Lung Diseases (ILD) with a Progressive Phenotype** when **ALL** the following criteria are met:

- Confirmed diagnosis of Chronic Fibrosing ILD such as with HRCT (high resolution computed tomography) **AND**
- Presenting with clinical signs of progression (defined as FVC decline ≥ 10%, FVC decline ≥ 5% and < 10% with worsening symptoms or imaging, or worsening symptoms and worsening imaging all in the 24 months prior to screening) **AND**
- Prescribing physician is a pulmonologist or prescribed in consult with a pulmonologist

Initial coverage will be for 6 months. For continuation of therapy up to 12 months, must identify improvement or maintenance of disease and LFTs within allowed bounds.

**Exclusions**

- Esbriet - Severe hepatic impairment
- Dosing, age, and/or frequency outside of the FDA approved package labeling Ofev – Moderate to severe hepatic impairment
- Ofev – Pregnancy
- LFTs greater than 5x ULN
- End stage renal disease requiring dialysis

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| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Medicare Gold Giveback | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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).** |
|---|
| *© 2024 MVP Health Plan, Inc. All rights reserved. Descriptions contained within MVP's Medical Policies are not a guarantee of coverage. Each MVP Group or Subscriber Contract contains specific limitations, exclusions and requirements that may affect a Policy. If there is any discrepancy between your Group or Subscriber Contract and a Policy, your Group or Subscriber Contract shall in all cases govern.* |

***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 |

**MVP Health Care Medical Policy**

**Immunoglobulin Therapy**

**Type of Policy:** Medical Therapy
**Prior Approval Date:** 06/01/2023
**Approval Date:** 04/01/2024
**Effective Date:** 06/01/2024

**Related Policies:** Experimental or Investigational Procedures, Behavioral Health Services, Drugs & Treatments, Off-Label use of FDA Approved Drugs, Clinical Trials

Refer to the MVP website for the Medicare Part D formulary for drugs that may covered under the Part D benefit.

## Drugs Requiring Prior Authorization under the medical benefit

| Billing Code(s) | Medication |
|---|---|
| J1459 | Injection, immune globulin (Privigen), intravenous, non-lyophilized (e.g. liquid), 500 mg |
| J1552 | Injection, immune globulin (Alyglo), 500 mg |
| J1554 | Injection, immune globulin (Asceniv), 500 mg |
| J1556 | Injection, immune globulin (Bivigam), 500mg |
| J1555 | Injection, immune globulin (Cuvitru) |
| J1557 | Injection, immune globulin, (Gammaplex), intravenous, non-lyophilized (e.g. liquid), 500mg |
| J1561 | Injection, immune globulin (Gamunex-C, Gammaked), intravenous, non-lyophilized (e.g. liquid), 500 mg |

| | |
|---|---|
| J1566 | Injection, immune globulin, intravenous, lyophilized (e.g. powder), not otherwise specified, 500 mg (Only Carimune NF and Gammagard S/D should be billed using this code) |
| J1568 | Injection, immune globulin, (Octagam), intravenous, non-lyophilized (e.g. liquid), 500 mg |
| J1569 | Injection, immune globulin, (Gammagard), intravenous, non-lyophilized, (e.g. liquid), 500 mg |
| J1572 | Injection, immune globulin, (Flebogamma/Flebogamma DIF), intravenous, non-lyophilized (e.g. liquid), 500 mg |
| J1559 | Injection, immune globulin, (Hizentra), subcutaneous, 100 mg |
| J1575 | Injection, immune globulin, (HyQvia), subcutaneous 100 mg |
| J1576 | Injection, immune globulin,intravenuous, non-lyophilized (e.g. liquid), not otherwise specified, 500mg (Panzyga) |
| J1551 | Immune globulin (SCIg) (Cutaquig), subcutaneous, 100mg |
| J1558 | immune globulin (Xembify), subcutaneous, 100mg |

**Common Procedure Codes**
CPT Codes: 96365, 96366, 96367, 96368, 96374, 96375, 90284

# Overview

**Intravenous Immunoglobin Therapy (IVIG)**
The administration of Intravenous Immunoglobulin Therapy (IVIG) is used to provide antibodies in people who are susceptible to diseases for which there are no immunizations or who are immune deficient.

**Immune Globulin Subcutaneous (Human)**
The administration of Immune Globulin Subcutaneous (Human) is for the treatment of primary immune deficiency. Immune Globulin Subcutaneous (Human) supplies a broad spectrum of opsonizing and neutralizing IgG antibodies against a wide variety of bacterial agents.

This policy does not address other immunoglobulin preparations that at are used for pre or post exposure prophylaxis for specific infectious diseases, such as tetanus, rabies, hepatitis B, or cytomegalovirus.

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# Indications/Criteria

## A. Intravenous Immunoglobulin

- **For all indications, the following criteria must be met in addition to the specific diagnosis criteria below for intravenous immunoglobulin**.

  - Intravenous Immunoglobulin is to be administered in the home setting, with the exception of the first dose, which may be given in a supervised outpatient setting.

  - Documentation must be provided indicating medical necessity for administering intravenous immunoglobulin in places of service other than the home.

  - IVIG and SCIG must be obtained from a preferred contracted IVIG vendor.

  - Please see Medicaid, Child Health Plus and Vermont Variation regarding place of service and where to obtain.

### 1. Primary humoral immunodeficiency

Intravenous Immunoglobulin may be considered for coverage for a primary humoral immunodeficiency when the following criteria is met:

- Member has a documented diagnosis of one of the following disorders:
  - Congenital agammaglobulinemia
  - Common variable immunodeficiency (CVID)
  - Wiskott-Aldrich Syndrome
  - X-linked agammaglobulinemia
  - Severe combined immunodeficiency (SCID)
    - 
  - X-linked hyper-IgM syndrome

- Documentation of current gamma globulin levels prior to the initial treatment and identifies deficiency in levels (i.e <500mg/dL).
- Requests to maintain level above a trough range of 500-800mg/dL or more infusions more frequently than every 4 weeks must be submitted with appropriate supporting documentation.
- Documentation that the member demonstrates one of the following:
    - Recurrent severe infection and documented severe deficiency or absence of IgG subclass **OR**
        - 
    - Functional deficiency of humoral immunity as evidenced by documented failure to produce antibodies to specific antigens and a history of recurrent infections

**2. Immune thrombocytopenia purpura (ITP) criteria**

Intravenous Immunoglobulin may be considered for coverage for ITP (acute or chronic) when the following criteria is met:

- Acute ITP (treatment ≤ 5 consecutive days) for the treatment of:
    - Management of acute bleeding due to severe thrombocytopenia (platelet counts less than 30,000/µl; **or**
    - To increase platelet counts prior to splenectomy; **or**Severe thrombocytopenia (platelets less than 20,000/microliters) in members considered at risk for intracerebral hemorrhage.

- Chronic refractory ITP:
    - Prior treatment with corticosteroids and splenectomy; **and**
    - Duration of illness≥ 3 months; **and**
    - Age of 10 years or older; **and**
    - No concurrent illness/disease explaining thrombocytopenia **and**
    - Platelet count < 30,000/mcL **OR** Platelet count <50,000/mcL and significant bleeding symptoms or rapid increase in platelets is required **and**
    - 

**3. Chronic lymphocytic leukemia with associated hypogammaglobulinemia criteria:**

Intravenous Immunoglobulin may be considered for coverage for Chronic lymphocytic leukemia with associated hypogammaglobulinemia when the following criteria is met

- IVIG is being prescribed for prophylaxis of bacterial infection AND

- IgG level is less than 500mg/dL **OR**
- Documentation of specific antibody deficiency **AND** the presence or repeated bacterial infections within the past 12 months.

4. **Symptomatic human immunodeficiency virus (HIV)**
   Intravenous Immunoglobulin may be considered for coverage for HIV when the following criteria is met:
   - Chart notes identifying a HIV diagnosis
   - Documentation of recurrent infections
   - Documentation of IgG level <500mg/dl
   -
5. **Bone marrow transplant**
   Intravenous Immunoglobulin may be considered for coverage for bone marrow transplant when the following criteria is met:

   - Member is seropositive for cytomegalovirus (CMV) before transplantation or the patient and donor were seronegative and were undergoing allogeneic transplantation for hematologic neoplasms.
   - Documentation that member has a current IgG level <500mg/dL
   - May be covered up to 90 days only.

6. **Solid organ transplantation**
   Intravenous Immunoglobulin may be considered for coverage for solid organ transplant when the following criteria is met:

   - Chart notes identifying of a solid organ transplantation

7. **Kawasaki Disease (mucocutaneous lymph node syndrome)**
   Intravenous Immunoglobulin may be considered for coverage for Kawasaki Disease the following criteria is met:

   - Chart notes identifying a diagnosis of Kawasaki Disease

8. **Immune thrombocytopenic purpura in pregnancy.**
   For Immune thrombocytopenic purpura in pregnancy, Intravenous immunoglobulin is covered for any of the following:
      - Pregnant members who have previously delivered infants with autoimmune thrombocytopenia

- Pregnant members who have platelet counts less than 50,000/$mm^3$ during the current pregnancy
- Pregnant members with past history of splenectomy.

**9. Autoimmune mucocutaneous blistering diseases**

Intravenous Immunoglobulin may be considered for coverage for autoimmune mucocutaneous blistering diseases when the following criteria is met:

- Chart notes identifying that diagnosis has been confirmed by biopsy and pathology report
- Documentation that the condition is rapidly progressing, extensive and/or debilitating
- Documentation of a failure of standard therapy (i.e. corticosteroids, immunosuppressant agents)
- Approval will cover short-term use. Maintenance therapy is not a covered benefit.

**10. Scleromyxedema**

Intravenous Immunoglobulin may be considered for coverage for Scleromyxedema when the following criteria is met:

- Documentation of a diagnosis of scleromyxedema

**11. Humoral or vascular allograft rejection**

Intravenous Immunoglobulin may be considered for coverage for Humoral or vascular allograft rejection when the following criteria is met:

- Documentation of Humoral or vascular allograft rejection

**12. Hemolytic anemia**

Intravenous Immunoglobulin may be considered for coverage for Hemolytic anemia when the following criteria is met:

- Member is 18 years of age or younger
- Chart notes identifying a diagnosis of hemolytic anemia
- Members with hepatomegaly or hepatosplenomegaly will be considered for coverage on a case-by-case basis

**13. Polymyositis and dermatomyositis**

Intravenous Immunoglobulin may be considered for coverage for Polymyositis and dermatomyositis when the following criteria is met:

- Chart notes identifying that diagnosis is confirmed by objective test results such as electromyogram (EMG), muscle biopsy, and blood analysisDocumentation of a failure, contraindication, adverse effects or ineffective response to steroids or immunosuppressants
- 
- Documentation that IVIG will be used to decrease the doses of other drugs that are needed for treatment.

**14. Sensitized renal cell transplant**

Intravenous Immunoglobulin may be considered for coverage for Sensitized renal cell transplant when the following criteria is met:

- Chart notes identifying renal cell transplant

**15. Stiff-person syndrome**

Intravenous Immunoglobulin may be considered for coverage for Stiff-person syndrome when the following criteria is met:

- 
- Chart notes identifying diagnosis  of stiff-person syndrome
- Documentation of inadequate response to first-line treatment (benzodiazepines/baclofen)

**16. Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)**

Intravenous Immunoglobulin may be considered for coverage for CIDP when the following criteria is met:

- Chart notes identifying a diagnosis of CIDP confirmed by electrodiagnostic studies
- Documentation of progressive or relapsing/remitting disease
- Documentation of moderate to severe functional disability

**17.** Other supported diagnoses (such as acute and chronic inflammatory demyelinating polyradiculoneuropathy (CIDP), Guillain-Barre syndrome, myasthenia gravis, multifocal motor neuropathy (MMN))

- The request must meet the Experimental/Investigational policy and if appropriate:
    - Documentation of  difficulty with venous access for plasmapheresis; **or**

- Documentation is provided that other therapy has failed or is contraindicated such as steroids; **or**
- Documentation of rapidly progressive disease

**Initial approval** will be up to one treatment every 28-30 days up to 3 months unless otherwise noted for the diagnosis

**Extension requests** will be approved up to 6 months if the member has documentation of ALL the following:

- Current documentation that the member has continued benefit to therapy
- Current documentation demonstrating objective improvement
- Current documentation of appropriate laboratory reports

**B. <u>Subcutaneous Immune Globulin (SCIG): Gammaked, Gammagard, Gamunex-C, Hizentra, HyQvia, Cutaquig, and Xembify</u>**

Subcutaneous Immunoglobulin may be considered for coverage when the following criteria is met:

- Member meets the diagnosis criteria above AND subcutaneous IG is indicated for their diagnosis
- Current documentation indicating that intravenous IVIG is inappropriate
- Documentation that the member has a serum IgA level > 0.05g/L
- Documentation of no known antibodies to IgA
    a. Subcutaneous Immunoglobulin is contraindicated for IgA deficient patients with antibodies against IgA
- Attestation that the member does not have a history of severe systemic response to immune globulin preparations and
- Subcutaneous immunoglobulin is to be administered in the home setting, with the exception of the first dose, which may be given in a supervised outpatient setting.
    a. Chart notes must be provided documentation medical necessity for administering intravenous immunoglobulin in places of service other than the home.
    b. IVIG and SCIG must be obtained from a preferred contracted IVIG vendor.

- Please see Medicaid, Child Health Plus and Vermont Variation regarding place of service and where to obtain.

**Initial approval** will be up to one treatment every 28-30 days up to 3 months unless otherwise noted for the diagnosis

**Extension requests** will be approved up to 6 months if the member has documentation of ALL the following:

- Current documentation that the member has continued benefit to therapy
- Current documentation demonstrating objective improvement
- Current documentation of appropriate laboratory reports

**Medicaid Variation:**

- Members are not required to receive IVIG in the home setting.
- Medications that are a pharmacy benefit are covered and billed to New York State Fee-For-Service (FFS) program. They are defined as medications that go through a retail or specialty pharmacy, including self-administered injectable products. Pharmacy medications are subject to FFS's clinical criteria including (but not limited to) coverage, quantity limit, step therapy, and prior authorization. Pharmacy benefit information can be found here: https://www.emedny.org/info/fullform.pdf

**Child Health Plus Variation :** Members are not required to receive IVIG in the home setting.

**Vermont Variation**: Members are not required to receive IVIG in the home setting

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**Exclusions**

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling
- Diagnosis not supported by FDA approved package labeling or "MVP Health Care Experimental or Investigational Procedures, Behavioral Health Services, Drugs and Treatments, Off-Label use of FDA approved Drugs, and Clinical Trials" policy

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## References


1. National Government Services. Article for Intravenous Immune Globulin (IVIG) (A52446) – Related to LCD L33394. Original Article Effective Date 10/1/2005. Article Revision Effective Date 7/18/2021
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5. Common variable immunodeficiency, severe combined immunodeficiency (SCID), Wiskott-Aldrich syndrome, and X-linked agammaglobulinemia (n.d.). In The Merck Manuals Online Medical Library. Retrieved September 28, 2010, from http://www.merck.com/mmpe/index.html.
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7. Gammaked™, Immune Globulin Subcutaneous (Human), 10% Liquid. Prescribing information. Research Triangle Park, NC: Grifols Biotherapeutics, Inc.; September 2013.
8. Centers for Medicare & Medicaid Services. Article for Self-Administered Drug Exclusion List – Medical Policy Article (A47846). Original Article Effective Date 7/18/2008. Article Revision Effective Date 8/1/2014.
9. HyQvia [immune globulin infusion 10% (Human) with Recombinant Human Hyaluronidase] Solution for subcutaneous administration. Prescribing Information. Westlake Village, CA: Baxter Healthcare Corporation. April 2016.
10. Cuvitru [immune globulin subcutaneous (Human), 20% Solution]. Prescribing Information. Westlake Village, CA: Baxalta US Inc. September 2016.
11. Gamunex-C [immune globulin injection (Human), 10% caprylate/chromatography purified]. Prescribing Information. Grifols Therapeutics, Inc.; July 2014.
12. IVIG Toolkit. Eight guiding principles for effective use of IVIG for patients with primary immunodeficiency [Internet]. Milwaukee (WI): American Academy of Allergy, Asthma, and Immunology; 2011 Dec [cited 2016 Sep 19]. Available from http://www.aaaai.org/Aaaai/media/MediaLibrary/PDF%20Documents/Practice%20Resources/IVIG-guiding-principles.pdf
13. Panzyga [immune globulin intravenous, human-ifas 10% liquid preparation]. Prescribing Information. Octapharma USA, Inc. August 2018.

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15. Cutaquig (immune globulin subcutaneous (human)- hipp_ 16.5% solution. Prescribing Information. Octapharma. Hoboken, NJ. May 2020. https://www.fda.gov/media/119234/download
16. Cutaquig (Immune Globulin Subcutaneous (Human) – hipp) 16.5% solution. Prescribing Information. Octapharma USA Inc. Hoboken, NJ. November 2021.
17. Centers for Medicare & Medicaid Services. Local Coverage Determination (LCD) for Intravenous Immune Globulin (L33610) Original Effective Date 10/01/2015. Revision Effective Date 01/01/2023.
18. Centers for Medicare & Medicaid Services. Intravenous Immune Globulin – Policy Article (A52509) Original Effective Date 10/01/2015. Revision Effective Date: 01/01/2023.
19. Centers for Medicare & Medicaid Services. Local Coverage Determination (LCD) for External Infusion Pumps (L33794) Original Effective Date 10/01/2015. Revision Effective Date 04/01/2023.
20. Centers for Medicare & Medicaid Services. External Infusion Pumps – Policy Article (A52507). Original Effective Date 10/01/2015. Revision Effective Date 04/01/2023.
21. Stiff-Person Syndrome: A Treatment Update and New Directions - PMC (nih.gov)

| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Medicare Gold Giveback | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |

| | |
|---|---|
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D |
| 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 | 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).** | |
| *© 2024 MVP Health Plan, Inc. All rights reserved. Descriptions contained within MVP's Medical Policies are not a guarantee of coverage. Each MVP Group or Subscriber Contract contains specific limitations, exclusions and requirements that may affect a Policy. If there is any discrepancy between your Group or Subscriber Contract and a Policy, your Group or Subscriber Contract shall in all cases govern.* | |

***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 |

**MVP Health Care Medical Policy**

**Medicare Part B: Immunoglobulin Therapy**

| | |
|---|---|
| **Type of Policy:** | **Medical Therapy** |
| **Prior Approval Date:** | **01/01/2024** |
| **Approval Date:** | **04/01/2024** |
| **Effective Date:** | **06/01/2024** |

**Related Policies:** Experimental or Investigational Procedures, Behavioral Health Services, Drugs & Treatments, Off-Label use of FDA Approved Drugs, Clinical Trials

Refer to the MVP website for the Medicare Part D formulary for drugs that may covered under the Part D benefit.

**Drugs Requiring Prior Authorization under the medical benefit**

| Billing Code(s) | Medication |
|---|---|
| J1459 | Injection, immune globulin (Privigen), intravenous, non-lyophilized (e.g. liquid), 500 mg |
| J1554 | Injection, immune globulin (Asceniv), 500 mg |
| J1556 | Injection, immune globulin (Bivigam), 500mg |
| J1555 | Injection, immune globulin (Cuvitru) |
| J1557 | Injection, immune globulin, (Gammaplex), intravenous, non-lyophilized (e.g. liquid), 500mg |
| J1561 | Injection, immune globulin (Gamunex-C, Gammaked), intravenous, non-lyophilized (e.g. liquid), 500 mg |
| J1566 | Injection, immune globulin, intravenous, lyophilized (e.g. powder), not otherwise specified, 500 mg (Only Carimune NF and Gammagard S/D should be billed using this code) |
| J1568 | Injection, immune globulin, (Octagam), intravenous, non-lyophilized (e.g. liquid), 500 mg |

| | |
|---|---|
| J1569 | Injection, immune globulin, (Gammagard), intravenous, non-lyophilized, (e.g. liquid), 500 mg |
| J1572 | Injection, immune globulin, (Flebogamma/Flebogamma DIF), intravenous, non-lyophilized (e.g. liquid), 500 mg |
| J1559 | Injection, immune globulin, (Hizentra), subcutaneous, 100 mg |
| J1575 | Injection, immune globulin, (HyQvia), subcutaneous 100 mg |
| J1576 | Injection, immune globulin,intravenuous, non-lyophilized (e.g. liquid), not otherwise specified, 500mg (Panzyga) |
| J1551 | Immune globulin (SCIg) (Cutaquig), subcutaneous, 100mg |
| J1558 | immune globulin (Xembify), subcutaneous, 100mg |

(**Common Procedure Codes**
CPT Codes: 96365, 96366, 96367, 96368, 96374, 96375, 90284

**Overview/Summary of Evidence**

**Intravenous Immunoglobin Therapy (IVIG)**
The administration of Intravenous Immunoglobulin Therapy (IVIG) is used to provide antibodies in people who are susceptible to diseases for which there are no immunizations or who are immune deficient.

**Immune Globulin Subcutaneous (Human)**
The administration of Immune Globulin Subcutaneous (Human) is for the treatment of primary immune deficiency. Immune Globulin Subcutaneous (Human) supplies a broad spectrum of opsonizing and neutralizing IgG antibodies against a wide variety of bacterial agents.

This policy does not address other immunoglobulin preparations that at are used for pre or post exposure prophylaxis for specific infectious diseases, such as tetanus, rabies, hepatitis B, or cytomegalovirus.

**Indications/Criteria**

**Intravenous Immunoglobulin**

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- This policy is a supplement to Medicare National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs). Refer to the applicable NCD or LCD at www.cms.gov for the most up to date coverage guidance.
- IVIG and SCIG must be obtained from a preferred contracted IVIG vendor.

**Medicare Coverage:**

- Please refer to the current coverage guidelines at www.cms.gov.
- IVIG is covered under the Part B benefit in all treatment settings for Primary Immunodeficiency. Refer to LCD L33610 for Intravenous Immune Globulin and the accompanying Policy Article A52509 for coverage guidance.
    - Conditions not addressed in this policy will be reviewed on a case-by-case basis and must meet criteria for Experimental & Investigational therapies for coverage under Part B.
- Part B coverage of subcutaneous immune globulin administered in the home setting follows Medicare guidance under LCD 33794 for External Infusion Pumps. Please refer to LCD 33794 and the accompanying Policy Article A52507 for coverage guidance.
- Refer to the Medicare Part D formulary for drugs that may be covered under the Part D benefit.
- Medicare members are not required to receive IVIG in the home setting.

**Initial Coverage**

Initial coverage period will be for up to 3 months

**Extension of Therapy**

Continuation of therapy requests must be submitted along with documentation of all pertinent laboratory reports and objective evidence of improvement. Extensions of therapies will be for up to 6 months.

## Exclusions

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling

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## References


1. National Government Services. Article for Intravenous Immune Globulin (IVIG) (A52446) – Related to LCD L33394. Original Article Effective Date 10/1/2005. Article Revision Effective Date 7/18/2021
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**MVP Health Care Medical Policy**

**Infertility Drug Therapy (Commercial/Marketplace)**

**Type of Policy:** **Drug Therapy**
**Prior Approval Date:** **02/01/2024**
**Approval Date:** **02/01/2025**
**Effective Date:** **04/01/2025**

**Related Policies:**

**Infertility (Advanced Services) and In Vitro Fertilization (IVF)**

**Infertility Basic Services**

**Fertility Preservation Services**

**Experimental or Investigational Procedures**

## Drugs Requiring Prior Authorization (Covered under the pharmacy benefit – see grid for variations)

- J3355 Bravelle, (Injection, urofollitropin, 75 IU)
- J3490 Cetrotide (cetrorelix acetate for injection)
- J9218 Lupron (Leuprolide acetate, per 1 mg)
- J0725 Pregnyl, Novarel (Injection, chorionic gonadotropin, per 1,000 USP units)
- J3590 Ovidrel
- J3590 Menopur, Repronex (Injection, menotropins, 75 IU)
- J3490 Gonal-F (Injection, follitropin alfa, 75 IU)
- J3590 Follistim AQ (Injection, follitropin beta, 75 IU)
- J3490 Ganirelix (Injection, ganirelix acetate, 250 mcg)
- Clomid, Serophene (oral tablets, clomiphene 50mg)- quantity limit 30 tablets per 30 days. Prior Authorization required only if quantity limit is exceeded.

Refer to the Medicare Part D formulary for drugs that may be covered under the Part D benefit.

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**Overview**

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; **OR**
- The inability of opposite-sex partners to establish a clinical pregnancy after six months of regular, unprotected intercourse a person with internal reproductive organs 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.

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**Indications/Criteria**

1. For In-Vitro Fertilization (IVF):
    a. If the member's specific contract/benefit allows for IVF coverage under the NYS mandate **and** there is an approved medical case for the procedure, then please see the In-Vitro-Fertilization (IVF) and Preservation section and Table 1 within this policy.

2. For Fertility Preservation:
    a. If the member's specific contract/benefit allows for Fertility Preservation coverage under the NYS mandate **and** there is an approved medical case for the procedure then please see the In-Vitro-Fertilization (IVF) and Preservation section and Table 1 within this policy.

For all other covered procedures (such as Intrauterine Insemination (IUI), timed intercourse, etc): **Limitations for coverage are as follows:**

1. Coverage for additional infertility medications that exceed the limits defined in Table 1 will be considered on a case-by-case basis when the treating physician submits a revised treatment plan indicating the medical efficacy of such treatment.

2. Any drug not identified in this policy that is being used for infertility requires prior authorization. Off-label requests must meet criteria identified in the Experimental or Investigational Policy.

## Table 1

| **Drug/Drug Class** | **Drug Examples** | **Benefit Requirements** | **Coverage Description** |
|---|---|---|---|
| HCG (in combination or as monotherapy), | Pregnyl, Ovidrel, Novarel | *No prior authorization is required for up to 9 cycles per pregnancy*<br><br>Lifetime limit 18 cycles. No cycle limits for Fertility Preservation. | Drugs are covered for 9 cycles. |
| CLOMIPHENE | Clomid, Serophene | *No prior authorization is required for up to 6 cycles per pregnancy and within quantity limit (30 tablets/30 days)*<br><br>Lifetime limit 12 cycles.<br><br>No cycle limits for Fertility Preservation. | Drugs are covered for 6 cycles. |
| FSH-CONTAINING GONADOTROPIN PREPARATIONS | Bravelle, Gonal-F, Follistim AQ Repronex, Menopur | **IVF**: Prior authorization is required. Lifetime limit of 3 IVF cycles. | **IVF**: Drugs are covered for a lifetime limit of 3 IVF cycles (see IVF variation). Follistim AQ is the preferred recombinant FSH. |

| | | | |
|---|---|---|---|
| | | **All other covered procedures**: *No prior authorization is required for up to 9 cycles per pregnancy*<br><br>No cycle limits for Fertility Preservation. | **Fertility Preservation**: Drugs are covered with an approved Fertility preservation medical procedure case. Follistim AQ is the preferred recombinant FSH.<br><br>**All other covered procedures**: Drugs are covered for 9 cycles. Follistim AQ is the preferred recombinant FSH. |
| GnRH antagonists/GnRH agonists | Antigon/Ganirelix<br>Lupron/Leuprolide kit<br>Cetrotide | **IVF**: Prior authorization is required. Lifetime limit of 3 IVF cycles.<br><br>**All other covered procedures:** No prior authorization is required for up to 9 cycles per pregnancy<br>No cycle limits for Fertility Preservation. | **IVF**: Drugs are covered for a lifetime limit of 3 IVF cycles (see IVF Variation).<br><br>**Fertility Preservation**: Drugs are covered with an approved fertility preservation medical procedure case. Follistim AQ is the preferred recombinant FSH.<br><br>**All other covered procedures:** Drugs are covered for 9 cycles. |
| | | | |

## In-Vitro-Fertilization (IVF) and Fertility Preservation

### Indications/Criteria

Effective January 1, 2020 a NYS mandate requires that medications used for In vitro fertilization (IVF) and fertility preservation are covered by the member's **specific contract/benefit**.

1. IVF coverage applies to members with NY large group commercial insurance who are renewing their plan
    a. Medication coverage for IVF requires a current approved IVF medical procedure case documented in the member's file.
    b. Medication coverage for IVF is limited to 3 IVF cycles per lifetime. Please see Table 1 above.
        a. Note of cycle completion:
            i. Cycles started but not completed count towards the three-cycle limit.
            ii. Cycles paid out of pocket by the member or through another insurer do not count towards the three-cycle limit.
            iii. IVF treatment completed prior to January 1, 2020 do not count towards the three-cycle per lifetime limit.
2. Fertility Preservation coverage applies to members with a NY individual, small group or large group policies who are renewing their plan.
    a. Medication coverage for fertility preservation requires a current approved fertility preservation medical procedure case documented in the member's file.
    b. Please see Table 1 above.
3. **ASO variation**: Refer to ASO benefit grid for services/medications that may be covered

### Exclusions

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling

- Any drug prescribed in conjunction with any non-covered infertility procedure per the member's specific benefit, including frozen embryo transfer (FET), IVF, GIFT, ZIFT program, cycle or treatment

- In vitro fertilization (IVF) and Fertility Preservation are contract dependent. Some ASO products may have IVF coverage. Please consult the member'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.

- If covered, more than 3 cycles of IVF treatment are excluded

- Any drug prescribed for the treatment of infertility for members who are infertile due to a voluntary sterilization procedure

- External pump for the administration of infertility drugs other than GnRH will be considered only on a case-by-case-basis

- Infertility treatments and/or FDA-approved drugs not indicated by the NYS mandate

- Services, use, day supply exceeding the member's benefit

- Medications prescribed for an individual who is not a member of MVP

- Advanced services (including medications) for Healthy New York, MVP Medicaid, contracts. There is no coverage for basic or advanced services for the MVP Child Health Plus contract.

- Refer to each VT plans COC for coverage.

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| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS |
| MVP Complete Wellness | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| USA Care PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

**Infliximab**

**Type of Policy:** **Drug/Medical Therapy**
**Prior Approval Date:** **12/01/2023**
**Approval Date:** **10/01/2024**
**Effective Date:** **01/01/2025**

**Related Policies:** **Experimental or Investigational Procedures, Apremilast, Etanercept, Risankizumab, Adalimumab, Tofacitinib, Upadacitinib, Ustekinumab, Zeposia, Secukinumab**

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Refer to the MVP website for the Medicare Part D formulary for drugs that may covered under the Part D benefit.

Refer to the MVP website for the Medicare Part B policies for coverage criteria of drugs covered under the medical benefit.

**Codes Requiring Prior Authorization (covered under the medical benefit)**
J1745 Injection, infliximab, 10 mg (Remicade®/Infliximab)
Q5103 Injection, infliximab, 10mg (Inflectra)
Q5104 Injection, infliximab, 10mg (Renflexis)
Q5121 Infliximab, 10mg (Avsola)

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**Overview**
Infliximab (Remicade®/Infliximab, Inflectra, Avsola, Renflexis), bind specifically to human tumor necrosis factor alpha (TNF-α). TNF-α is a pro-inflammatory cytokine that is important in the induction of other inflammatory cytokines that initiate and maintain the tissue inflammatory response. Inhibiting the binding of TNFα to its receptors prevents the release of the pro-inflammatory cytokines that are involved in the body's immune and inflammatory responses. Patients who receive infliximab are at increased risk for developing *serious infection* that may result in hospitalization and/or death. Members should be screened for immunologic and infectious disease prior to initiating therapy.

**Medicaid Variation:** Medications that are a pharmacy benefit are covered and billed to New York State Fee-For-Service (FFS) program. They are defined as medications that go through a retail or specialty pharmacy, including self-administered injectable products. Pharmacy medications are subject to FFS's clinical criteria including (but not limited to) coverage, quantity limit, step therapy, and prior authorization. Pharmacy benefit information can be found here: https://www.emedny.org/info/fullform.pdf

## Indications/Criteria

**For all indications, the following criteria must be met in addition to the specific diagnosis criteria below.**

- Renflexis, and Inflectra are the preferred infliximab products. Approval for Avsola or Remicade/Infliximab will require documentation of medical necessity including side effects or drug failure of an adequate trial of Renflexis, and Inflectra.
- For all indications listed below the use of infliximab will require failure or contraindication to all preferred self-administered biologic therapies for the indication
- Must be ordered by or with consult from an appropriate specialist: rheumatologist/immunologist/dermatologist/ gastroenterologist/colorectal surgeon
- Initial approval for all indications will be for six months, continuation up to one year will require documentation of improved member status.
- Site of Care
    - Per the MVP Health Care Pharmacy Management Programs policy, Avsola, Inflectra, Remicade and Renflexis are subject to Site of Care requirements and must be obtained through a preferred home infusion vendor. Prior Authorization and medical justification is required for Avsola, Inflectra, Remicade and Renflexis obtained and administered in other outpatient settings such as a provider's office or hospital facility.
    - MVP will allow 60 days after prior authorization approval for members to transfer to a preferred infusion site.
    - This requirement does not apply to MVP Medicare and Medicaid members

## A. Ankylosing Spondylitis

For the treatment of active moderate to severe **ankylosing spondylitis** the following criteria must be met:

- Chart notes documenting failure of at least one trial of NSAIDS at maximum tolerated dose unless the member has contraindications to NSAID therapy such as cardiovascular disease, peptic ulcer disease or renal disease **AND**
- Chart notes are provided documenting significant clinical symptoms such as fatigue, spinal pain, arthralgia, inflammation of joints and tendons, and morning stiffness duration **AND**

Chart notes are provided documenting an insufficient response to at least one local corticosteroid injection in patients with symptomatic peripheral arthritis
**Initial approval** will be for 6 months

**Extension requests** will be approved for up to 12 months if the member has a continued benefit to therapy. Extension requests where the Infliximab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

## B. Crohn's Disease

For the treatment of moderate to severe active **Crohn's disease** confirmed by endoscopy (or capsule endoscopy when appropriate) the following criteria must be met:

- If the member is <18 years old , Pediatric Crohn's disease requests will be reviewed on a case-by-case basis. **OR**

- Documented failure or inadequate response to a 12-week trial of adalimumab **OR**

- Rationale accompanied by documentation is provided identifying why the member or caregiver is unable to self-administer adalimumab **OR**

- If adalimumab therapy is not appropriate, rationale for medical necessity of infliximab must be provided (i.e., contraindication, disease severity) and

will be reviewed on a case-by-case basis in accordance with current American College of Gastroenterology (ACG) guidelines.

**Initial approval** will be for 6 months

**Extension requests** will be approved for up to 12 months if the member has a continued benefit to therapy. Extension requests where the Infliximab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

**C. <u>Plaque Psoriasis</u>**

For the treatment of **plaque psoriasis** ALL the following criteria must be met:

- The medication must be ordered by or in consultation with a dermatologist
- A diagnosis of moderate to severe chronic plaque psoriasis and one of the following:
    - Crucial body areas (e.g. hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected OR
    - At least 10% of the body surface area (BSA) is affected OR
    - At least 3% of the body surface area (BSA) is affected AND the member meets any of the following criteria:
        - Member has had an inadequate response or intolerance to either phototherapy (e.g. UVB, PUVA) OR
        - Member has had an inadequate response or intolerance to pharmacologic treatment with methotrexate, cyclosporine, or acitretin

**Initial approval** will be for 6 months

**Extension requests** will be approved for up to 12 months if the member has a continued benefit to therapy. Extension requests where the Infliximab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

**D. <u>Psoriatic Arthritis</u>**

For the treatment of moderate to severe **psoriatic arthritis** the following criteria must be met**:**

- Member has a diagnosis of moderate to severe moderate to severe psoriatic arthritis as indicated by three or more tender joints AND three or more swollen joints on two separate occasions at least one month apart

- Chart notes documenting a of at least one NSAID at maximum tolerated dose unless the member has contraindications to NSAID therapy such as cardiovascular disease, peptic ulcer disease or renal disease **AND**

- Chart notes documenting a failure to respond to an adequate trial of at least one of the following nonbiologic disease modifying anti-rheumatic drugs (DMARDs): leflunomide, sulfasalazine, or methotrexate.
    - **Members with pure axial manifestations** do not have to have a trial of nonbiologic disease modifying anti-rheumatic drugs (DMARDs)If a trial of methotrexate is not appropriate due to alcohol use and both leflunomide and sulfasalazine are not clinically appropriate, chart notes must be provided indicating that the patient has been counseled on the need to abstain from alcohol use while taking methotrexate and is unwilling to abstain from alcohol use

**Initial approval** will be for 6 months

**Extension requests** will be approved for up to 12 months if the member has a continued benefit to therapy. Extension requests where the Infliximab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

## E. <u>Rheumatoid Arthritis</u>

- Member has a diagnosis of moderate to severe active adult **rheumatoid arthritis** as defined by persistent or recurrent symptoms with documented synovitis and morning stiffness of significant duration to inhibit activities of daily living **AND**

Chart notes documenting a failure to respond to one or more nonbiologic disease modifying anti-rheumatic drugs (DMARDs), one of which includes a three-month trial of maximally tolerated dose of methotrexate.

Failure is demonstrated by documentation of provider assessment without improvement in joint counts and/or physical symptoms and inflammatory markers while on therapy.

- If the member has a contraindication or significant intolerance to methotrexate Chart notes documenting a failure to respond to at least one other nonbiologic DMARDs at a maximally tolerated dose for at least 3 months **AND**Documentation confirming why methotrexate cannot be used is required. If a trial of methotrexate is not appropriate due to alcohol use, chart notes must be provided indicating that the patient has been counseled on the need to abstain from alcohol use while taking methotrexate and is unwilling to abstain from alcohol use.

- Must be given in combination with methotrexate unless the member has an acute, aggressive, very rapidly progressive intense inflammatory symmetrical arthritis disease as defined by their rheumatologist.

**Initial approval** will be for 6 months

**Extension requests** will be approved for up to 12 months if the member has a continued benefit to therapy. Extension requests where the Infliximab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

## F. Ulcerative Colitis

For the treatment of moderate to severe **Ulcerative Colitis** ALL the following criteria must be met:

- Chart notes are provided documenting an inadequate response to or an intolerance to conventional therapy (i.e.:, anti-inflammatory aminosalicylates [e.g. Mesalamine (5-ASA), sulfasalazine], 6-mercaptopurine, and azathioprine).

    - If conventional therapy is not considered medically appropriate, rationale for medical necessity of infliximab must be provided (i.e., contraindication, disease severity) and will be reviewed on a case-by-case basis in accordance with current American College of Gastroenterology (ACG) guidelines.
- Pediatric Ulcerative Colitis requests will be reviewed on a case-by-case basis in accordance with current American College of Gastroenterology (ACG) guidelines.

**Initial approval for all indications** will be for six months

**Extension requests** will be approved up to one year AND will require documentation of improved patient status and patient must continue to meet criteria identified above.

**G. Refractory granulomatosis with polyangiitis (Wegener's granulomatosis)**

- Infliximab requests for refractory granulomatosis with polyangiitis (Wegener's granulomatosis) in combination with corticosteroids will be reviewed on a case-by-case basis

**H.** Management of **Immune Checkpoint Inhibitor-Related Diarrhea/Colitis**:

For the treatment of moderate to severe **Immune Checkpoint Inhibitor-Related Diarrhea/Colitis** ALL of the following criteria must be met:

• Member has been receiving therapy with an immune checkpoint inhibitor (e.g., nivolumab, pembrolizumab, atezolizumab, avelumab, durvalumab, cemiplimab, etc.); AND

• Member has moderate (grade 2) to severe (grade 3-4) diarrhea or colitis related to their immunotherapy

- Continuation of therapy is not a covered

## Exclusions

Infliximab will not be considered medically necessary in the following members:

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling

- Members with a known hypersensitivity to murine proteins
- Members with heart failure (NYHA III/IV) at doses greater than 5mg/kg
- Infliximab in combination therapy with TNF blockers, other biologics, or interleukin-1 inhibitor.

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| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Medicare Gold Giveback | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D |
| 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 | 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).** | |
| *© 2024 MVP Health Plan, Inc. All rights reserved. Descriptions contained within MVP's Medical Policies are not a guarantee of coverage. Each MVP Group or Subscriber Contract contains specific limitations, exclusions and requirements that may affect a Policy. If there is any discrepancy between your Group or Subscriber Contract and a Policy, your Group or Subscriber Contract shall in all cases govern.* | |

***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 |

**MVP Health Care Medical Policy**

**Infliximab**

**Type of Policy:** **Drug/Medical Therapy**
**Prior Approval Date:** **12/01/2023**
**Approval Date:** **10/01/2024**
**Effective Date:** **01/01/2025**

**Related Policies:** **Experimental or Investigational Procedures, Apremilast, Etanercept, Risankizumab, Adalimumab, Tofacitinib, Upadacitinib, Ustekinumab, Zeposia, Secukinumab**

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Refer to the MVP website for the Medicare Part D formulary for drugs that may covered under the Part D benefit.

Refer to the MVP website for the Medicare Part B policies for coverage criteria of drugs covered under the medical benefit.

**Codes Requiring Prior Authorization (covered under the medical benefit)**
J1745 Injection, infliximab, 10 mg (Remicade®/Infliximab)
Q5103 Injection, infliximab, 10mg (Inflectra)
Q5104 Injection, infliximab, 10mg (Renflexis)
Q5121 Infliximab, 10mg (Avsola)

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**Overview**
Infliximab (Remicade®/Infliximab, Inflectra, Avsola, Renflexis), bind specifically to human tumor necrosis factor alpha (TNF-α). TNF-α is a pro-inflammatory cytokine that is important in the induction of other inflammatory cytokines that initiate and maintain the tissue inflammatory response. Inhibiting the binding of TNFα to its receptors prevents the release of the pro-inflammatory cytokines that are involved in the body's immune and inflammatory responses. Patients who receive infliximab are at increased risk for developing *serious infection* that may result in hospitalization and/or death. Members should be screened for immunologic and infectious disease prior to initiating therapy.

**Medicaid Variation:** Medications that are a pharmacy benefit are covered and billed to New York State Fee-For-Service (FFS) program. They are defined as medications that go through a retail or specialty pharmacy, including self-administered injectable products. Pharmacy medications are subject to FFS's clinical criteria including (but not limited to) coverage, quantity limit, step therapy, and prior authorization. Pharmacy benefit information can be found here: https://www.emedny.org/info/fullform.pdf

## Indications/Criteria

**For all indications, the following criteria must be met in addition to the specific diagnosis criteria below.**

- Renflexis, and Inflectra are the preferred infliximab products. Approval for Avsola or Remicade/Infliximab will require documentation of medical necessity including side effects or drug failure of an adequate trial of Renflexis, and Inflectra.
- For all indications listed below the use of infliximab will require failure or contraindication to all preferred self-administered biologic therapies for the indication
- Must be ordered by or with consult from an appropriate specialist: rheumatologist/immunologist/dermatologist/ gastroenterologist/colorectal surgeon
- Initial approval for all indications will be for six months, continuation up to one year will require documentation of improved member status.
- Site of Care
    - Per the MVP Health Care Pharmacy Management Programs policy, Avsola, Inflectra, Remicade and Renflexis are subject to Site of Care requirements and must be obtained through a preferred home infusion vendor. Prior Authorization and medical justification is required for Avsola, Inflectra, Remicade and Renflexis obtained and administered in other outpatient settings such as a provider's office or hospital facility.
    - MVP will allow 60 days after prior authorization approval for members to transfer to a preferred infusion site.
    - This requirement does not apply to MVP Medicare and Medicaid members

## A. Ankylosing Spondylitis

For the treatment of active moderate to severe **ankylosing spondylitis** the following criteria must be met:

- Chart notes documenting failure of at least one trial of NSAIDS at maximum tolerated dose unless the member has contraindications to NSAID therapy such as cardiovascular disease, peptic ulcer disease or renal disease **AND**
- Chart notes are provided documenting significant clinical symptoms such as fatigue, spinal pain, arthralgia, inflammation of joints and tendons, and morning stiffness duration **AND**

Chart notes are provided documenting an insufficient response to at least one local corticosteroid injection in patients with symptomatic peripheral arthritis
**Initial approval** will be for 6 months

**Extension requests** will be approved for up to 12 months if the member has a continued benefit to therapy. Extension requests where the Infliximab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

## B. Crohn's Disease

For the treatment of moderate to severe active **Crohn's disease** confirmed by endoscopy (or capsule endoscopy when appropriate) the following criteria must be met:

- If the member is <18 years old , Pediatric Crohn's disease requests will be reviewed on a case-by-case basis. **OR**

- Documented failure or inadequate response to a 12-week trial of adalimumab **OR**

- Rationale accompanied by documentation is provided identifying why the member or caregiver is unable to self-administer adalimumab **OR**

- If adalimumab therapy is not appropriate, rationale for medical necessity of infliximab must be provided (i.e., contraindication, disease severity) and

will be reviewed on a case-by-case basis in accordance with current American College of Gastroenterology (ACG) guidelines.

**Initial approval** will be for 6 months

**Extension requests** will be approved for up to 12 months if the member has a continued benefit to therapy. Extension requests where the Infliximab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

**C. <u>Plaque Psoriasis</u>**

For the treatment of **plaque psoriasis** ALL the following criteria must be met:

- The medication must be ordered by or in consultation with a dermatologist
- A diagnosis of moderate to severe chronic plaque psoriasis and one of the following:
    - Crucial body areas (e.g. hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected OR
    - At least 10% of the body surface area (BSA) is affected OR
    - At least 3% of the body surface area (BSA) is affected AND the member meets any of the following criteria:
        - Member has had an inadequate response or intolerance to either phototherapy (e.g. UVB, PUVA) OR
        - Member has had an inadequate response or intolerance to pharmacologic treatment with methotrexate, cyclosporine, or acitretin

**Initial approval** will be for 6 months

**Extension requests** will be approved for up to 12 months if the member has a continued benefit to therapy. Extension requests where the Infliximab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

**D. <u>Psoriatic Arthritis</u>**

For the treatment of moderate to severe **psoriatic arthritis** the following criteria must be met**:**

- Member has a diagnosis of moderate to severe moderate to severe psoriatic arthritis as indicated by three or more tender joints AND three or more swollen joints on two separate occasions at least one month apart

- Chart notes documenting a of at least one NSAID at maximum tolerated dose unless the member has contraindications to NSAID therapy such as cardiovascular disease, peptic ulcer disease or renal disease **AND**

- Chart notes documenting a failure to respond to an adequate trial of at least one of the following nonbiologic disease modifying anti-rheumatic drugs (DMARDs): leflunomide, sulfasalazine, or methotrexate.
    - **Members with pure axial manifestations** do not have to have a trial of nonbiologic disease modifying anti-rheumatic drugs (DMARDs)If a trial of methotrexate is not appropriate due to alcohol use and both leflunomide and sulfasalazine are not clinically appropriate, chart notes must be provided indicating that the patient has been counseled on the need to abstain from alcohol use while taking methotrexate and is unwilling to abstain from alcohol use

**Initial approval** will be for 6 months

**Extension requests** will be approved for up to 12 months if the member has a continued benefit to therapy. Extension requests where the Infliximab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

## E. <u>Rheumatoid Arthritis</u>

- Member has a diagnosis of moderate to severe active adult **rheumatoid arthritis** as defined by persistent or recurrent symptoms with documented synovitis and morning stiffness of significant duration to inhibit activities of daily living **AND**

Chart notes documenting a failure to respond to one or more nonbiologic disease modifying anti-rheumatic drugs (DMARDs), one of which includes a three-month trial of maximally tolerated dose of methotrexate.

Failure is demonstrated by documentation of provider assessment without improvement in joint counts and/or physical symptoms and inflammatory markers while on therapy.

- If the member has a contraindication or significant intolerance to methotrexate Chart notes documenting a failure to respond to at least one other nonbiologic DMARDs at a maximally tolerated dose for at least 3 months **AND**Documentation confirming why methotrexate cannot be used is required. If a trial of methotrexate is not appropriate due to alcohol use, chart notes must be provided indicating that the patient has been counseled on the need to abstain from alcohol use while taking methotrexate and is unwilling to abstain from alcohol use.

- Must be given in combination with methotrexate unless the member has an acute, aggressive, very rapidly progressive intense inflammatory symmetrical arthritis disease as defined by their rheumatologist.

**Initial approval** will be for 6 months

**Extension requests** will be approved for up to 12 months if the member has a continued benefit to therapy. Extension requests where the Infliximab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

## F. Ulcerative Colitis

For the treatment of moderate to severe **Ulcerative Colitis** ALL the following criteria must be met:

- Chart notes are provided documenting an inadequate response to or an intolerance to conventional therapy (i.e.:, anti-inflammatory aminosalicylates [e.g. Mesalamine (5-ASA), sulfasalazine], 6-mercaptopurine, and azathioprine).

    - If conventional therapy is not considered medically appropriate, rationale for medical necessity of infliximab must be provided (i.e., contraindication, disease severity) and will be reviewed on a case-by-case basis in accordance with current American College of Gastroenterology (ACG) guidelines.
- Pediatric Ulcerative Colitis requests will be reviewed on a case-by-case basis in accordance with current American College of Gastroenterology (ACG) guidelines.

**Initial approval for all indications** will be for six months

**Extension requests** will be approved up to one year AND will require documentation of improved patient status and patient must continue to meet criteria identified above.

**G. Refractory granulomatosis with polyangiitis (Wegener's granulomatosis)**

- Infliximab requests for refractory granulomatosis with polyangiitis (Wegener's granulomatosis) in combination with corticosteroids will be reviewed on a case-by-case basis

**H.** Management of **Immune Checkpoint Inhibitor-Related Diarrhea/Colitis**:

For the treatment of moderate to severe **Immune Checkpoint Inhibitor-Related Diarrhea/Colitis** ALL of the following criteria must be met:

• Member has been receiving therapy with an immune checkpoint inhibitor (e.g., nivolumab, pembrolizumab, atezolizumab, avelumab, durvalumab, cemiplimab, etc.); AND

• Member has moderate (grade 2) to severe (grade 3-4) diarrhea or colitis related to their immunotherapy

- Continuation of therapy is not a covered

## Exclusions

Infliximab will not be considered medically necessary in the following members:

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling

- Members with a known hypersensitivity to murine proteins
- Members with heart failure (NYHA III/IV) at doses greater than 5mg/kg
- Infliximab in combination therapy with TNF blockers, other biologics, or interleukin-1 inhibitor.

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**References**


1. Remicade® (infliximab) Injection. Prescribing Information. Malvern, PA: Centocor, Inc.; October 2021.
2. ACG Clinical Guideline: Ulcerative Colitis in Adults. The American Journal of Gastroenterology: March 2019 - Volume 114 - Issue 3 - p 384-413 doi: 10.14309/ajg.0000000000000152. Accessed: ACG Clinical Guideline: Ulcerative Colitis in Adults : Official journal of the American College of Gastroenterology | ACG (lww.com)Centers for Medicare & Medicaid Services. Article for infliximab (e.g., Remicade™) – Related to LCD L25820) – Medical Policy Article A46764. Original Article Effective Date 3/1/2008. Article Revision Effective Date 9/1/2014. Available at www.ngsmedicare.com
3. National Government Services Inc. Article for infliximab (e.g. Remicade) – Related to LCD L25820 (A46764). (Article revision effective date 10/17/2011).
4. Avsola (infliximab) injection. Prescribing Information. Thousand Oaks, CA: Amgen Inc.; September 2021.
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6. Joseph D. Feuerstein, Edith Y. Ho et al. AGA Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn's Disease. June 2021. Volume 160; Issue 7: p2696-2508. AGA Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn's Disease - Gastroenterology (gastrojournal.org).
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8. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of

Psoriatic Arthritis. *Journal of Psoriasis and Psoriatic Arthritis*. 2019;4(1):31-58. doi:10.1177/2475530318812244

| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Medicare Gold Giveback | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D |
| 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 | 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).** | |
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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 |

**MVP Health Care Medical Policy**

**Medicare Part B: Infliximab**

**Type of Policy:** **Drug/Medical Therapy**
**Prior Approval Date:** **1/01/2024**
**Approval Date:** **10/01/2024**
**Effective Date:** **12/01/2024**
**Related Policies:** **Experimental or Investigational Procedures, Risankizumab, Ustekinumab, Secukinumab**

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Refer to the MVP website for the Medicare Part D formulary for drugs that may covered under the Part D benefit.

**Codes Requiring Prior Authorization (covered under the medical benefit)**
J1745 Injection, infliximab, 10 mg (Remicade®/Infliximab)
Q5103 Injection, infliximab, 10mg (Inflectra)
Q5104 Injection, infliximab, 10mg (Renflexis)
Q5121 Infliximab, 10mg (Avsola)

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**Overview/Summary of Evidence**
Infliximab (Remicade®/Infliximab, Inflectra, Avsola, Renflexis), bind specifically to human tumor necrosis factor alpha (TNF-α). TNF-α is a pro-inflammatory cytokine that is important in the induction of other inflammatory cytokines that initiate and maintain the tissue inflammatory response. Inhibiting the binding of TNFα to its receptors prevents the release of the pro-inflammatory cytokines that are involved in the body's immune and inflammatory responses. Patients who receive infliximab are at increased risk for developing *serious infection* that may result in hospitalization and/or death. Members should be screened for immunologic and infectious disease prior to initiating therapy.

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## Indications/Criteria

**For all indications, the following criteria must be met in addition to the specific diagnosis criteria below.**

- Must be ordered by or with consult from an appropriate specialist: rheumatologist/immunologist/dermatologist/ gastroenterologist/colorectal surgeon
- Initial approval for all indications will be for six months, continuation up to one year will require documentation of improved member status.

### A. Ankylosing Spondylitis

For the treatment of active moderate to severe **ankylosing spondylitis** the following criteria must be met:

- Chart notes documenting failure of at least one trial of NSAIDS at maximum tolerated dose unless the member has contraindications to NSAID therapy such as cardiovascular disease, peptic ulcer disease or renal disease **AND**
- Chart notes documenting significant clinical symptoms such as fatigue, spinal pain, arthralgia, inflammation of joints and tendons, and morning stiffness duration **AND**

Chart notes documenting an insufficient response to at least one local corticosteroid injection in patients with symptomatic peripheral arthritis

**Initial approval** will be for 6 months

**Extension requests** will be approved for up to 12 months if the member has a continued benefit to therapy. Extension requests where the Infliximab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

### B. Crohn's Disease

For the treatment of active moderate to severe **Crohn's disease** confirmed by endoscopy (or capsule endoscopy when appropriate) the following criteria must be met:

- If member is <18 years old, Pediatric Crohn's disease requests will be reviewed on a case-by-case basis **OR**

- Documented failure or inadequate response to a 12-week trial of adalimumab **OR**

- Rationale, accompanied by documentation, identifying why the member or caregiver is unable to self-administer adalimumab.

- If adalimumab is not appropriate, rationale for medical necessity of infliximab must be provided (i.e., contraindication, disease severity) and will be reviewed on a case-by-case basis in accordance with current American College of Gastroenterology (ACG) guidelines.

**Initial approval** will be for 6 months

**Extension requests** will be approved for up to 12 months if the member has a continued benefit to therapy. Extension requests where Infliximab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

## C. Plaque Psoriasis

For the treatment of active **plaque psoriasis** ALL the following criteria must be met:

- The medication must be ordered by or in consultation with a dermatologist
- A diagnosis of moderate to severe chronic plaque psoriasis and one of the following:
    - Crucial body areas (e.g. hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected OR
    - At least 10% of the body surface area (BSA) is affected OR
    - At least 3% of the body surface area (BSA) is affected AND the member meets any of the following criteria:
        - Member has had an inadequate response or intolerance to either phototherapy (e.g. UVB, PUVA) OR
        - Member has had an inadequate response or intolerance to pharmacologic treatment with methotrexate, cyclosporine, or acitretin

**Initial approval** will be for 6 months

**Extension requests** will be approved for up to 12 months if the member has a continued benefit to therapy. Extension requests where Infliximab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

**D. <u>Psoriatic Arthritis</u>**

For the treatment of moderate to severe active **psoriatic arthritis** the following criteria must be met**:**

- Member has a diagnosis of moderate to severe psoriatic arthritis as indicated by three or more tender joints AND three or more swollen joints on two separate occasions at least one month apart.

- Chart notes documenting at least one NSAID at the maximum tolerated dose, unless the member has contraindications to NSAID therapy such as cardiovascular disease, peptic ulcer disease or renal disease **AND**

- Chart notes documenting a failure to respond to an adequate trial (at least 3 months of which 2 months is at standard target dose) of at least one of the following DMARDs: leflunomide, sulfasalazine, or methotrexate.

  **Members with pure axial manifestations** do not have to have a trial of nonbiologic disease modifying anti-rheumatic drugs (DMARDs)

  - If a trial of methotrexate is not appropriate due to alcohol use and both leflunomide and sulfasalazine are not clinically appropriate, chart notes must be provided indicating that the patient has been counseled on the need to abstain from alcohol use while taking methotrexate and is unwilling to abstain from alcohol use.

**Initial approval** will be for 6 months

**Extension requests** will be approved for up to 12 months if the member has a continued benefit to therapy. Extension requests where Infliximab did not have

the full desired effect or considered a clinical failure will require clinical rationale for continuing.

## E. Rheumatoid Arthritis

- Member has a diagnosis of active moderate to severe adult **rheumatoid arthritis** as defined by persistent or recurrent symptoms with documented synovitis and morning stiffness of significant duration to inhibit activities of daily living **AND**
- Chart notes documenting a failure to respond to one or more nonbiologic disease modifying anti-rheumatic drugs (DMARDs), one of which includes a three-month trial of maximally tolerated dose of methotrexate.
    - Failure is demonstrated by documentation of provider assessment without improvement in joint counts and/or physical symptoms and inflammatory markers while on therapy.
    - If the member has a contraindication or significant intolerance to methotrexate
        - Chart notes documenting a failure to respond to at least one other nonbiologic DMARDs at a maximally tolerated dose for at least 3 months **AND**
        - Documentation confirming why methotrexate cannot be used is required. If a trial of methotrexate is not appropriate due to alcohol use, chart notes must be provided indicating that the patient has been counseled on the need to abstain from alcohol use while taking methotrexate and is unwilling to abstain from alcohol use.

- Must be given in combination with methotrexate unless the member has an acute, aggressive, very rapidly progressive intense inflammatory symmetrical arthritis disease as defined by their rheumatologist OR the member has a significant intolerance or contraindication to methotrexate, as indicated above.

**Initial approval** will be for 6 months

**Extension requests** will be approved for up to 12 months if the member has a continued benefit to therapy. Extension requests where Infliximab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

**F. <u>Ulcerative Colitis</u>**

For the treatment of active moderate to severe **Ulcerative Colitis** ALL the following criteria must be met:

- Chart notes are provided documenting an inadequate response to or an intolerance to conventional therapy (i.e.:, anti-inflammatory aminosalicylates [e.g. Mesalamine (5-ASA), sulfasalazine], 6-mercaptopurine, and azathioprine).
    - If conventional therapy is not appropriate, rationale for medical necessity of infliximab must be provided (i.e., contraindication, disease severity) and will be reviewed on a case-by-case basis in accordance with current American College of Gastroenterology (ACG) guidelines.
- Pediatric Ulcerative Colitis requests will be reviewed on a case-by-case basis in accordance with current American College of Gastroenterology (ACG) guidelines.

**Initial approval for all indications** will be for 6 months
**Extension requests** will be approved up to 12 months if the member has a continued benefit to therapy. Extension requests where Infliximab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

**G. Refractory granulomatosis with polyangiitis (Wegener's granulomatosis)**

- Infliximab requests for refractory granulomatosis with polyangiitis (Wegener's granulomatosis) in combination with corticosteroids will be reviewed on a case-by-case basis

**H.** Management of **Immune Checkpoint Inhibitor-Related Diarrhea/Colitis**:

• Member has been receiving therapy with an immune checkpoint inhibitor (e.g., nivolumab, pembrolizumab, atezolizumab, avelumab, durvalumab, cemiplimab, etc.); AND

• Member has moderate (grade 2) to severe (grade 3-4) diarrhea or colitis related to their immunotherapy

- Continuation of therapy is not a covered benefit

Approval will be covered for infliximab 5mg/kg up to a maximum of 2 doses only within one month.

**Exclusions**

Infliximab will not be considered medically necessary in the following members:

- Indication, age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling.
    - Members with a known hypersensitivity to murine proteins
    - Members with heart failure (NYHA III/IV) at doses greater than 5mg/kg
    - Infliximab in combination therapy with TNF blockers, other biologics, or interleukin-1 inhibitor.

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**References**

1. Remicade® (infliximab) Injection. Prescribing Information. Malvern, PA: Centocor, Inc.; October 2021.
2. Avsola (infliximab) injection. Prescribing Information. Thousand Oaks, CA: Amgen Inc.; September 2021.
3. Joseph Feuerstein, Kim Isaacs et al. AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis. January 2020. Volume 158; Issue 5: p1450-1461. AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis - Gastroenterology (gastrojournal.org) Accessed September 27, 2021.
4. Joseph D. Feuerstein, Edith Y. Ho et al. AGA Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn's Disease. June 2021. Volume 160; Issue 7: p2696-2508. AGA Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn's Disease - Gastroenterology (gastrojournal.org).

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## MVP Health Care Medical Policy

**Intestinal Antibiotics**

| | |
|---|---|
| **Type of Policy:** | **Drug Therapy** |
| **Prior Approval Date:** | **10/01/2022** |
| **Approval Date:** | **10/01/2023** |
| **Effective Date:** | **12/01/2023** |
| **Related Policies:** | **NA** |

### Drugs Requiring Prior Authorization

Aemcolo (rifamycin) 194mg tablets

Refer to the MVP website for the Medicare Part D formulary for drugs that may covered under the Part D benefit.

### Overview

Aemcolo is indicated for travelers' diarrhea caused by noninvasive strains of Escherichia coli. Untreated bacterial diarrhea lasts 3–5 days. Antibiotic selection is based on the likelihood that an invasive organism is present and on antibiotic resistance patterns. These factors are determined largely by travel destination. First-line antibiotics for treatment or as empiric therapy include those of the quinolone class, such as ciprofloxacin or levofloxacin. An alternative to quinolones in known resistance locations (e.g., Thailand) is azithromycin. Since it is often difficult for travelers to distinguish between invasive and noninvasive diarrhea, the overall usefulness of rifamycin as empiric self-treatment remains to be determined. At this time, prophylactic antibiotics should not be recommended for most travelers.

### Indications/Criteria

**1. Traveler's diarrhea**

- Aemcolo may be covered for the treatment of traveler's diarrhea when all the following criteria are met:
    - Members ≥18 years old
    - Moderate to severe distressing symptoms of travelers' diarrhea are present and proven or strongly suspected to be caused by Escherichia coli based upon symptoms and travel destination. (When culture and susceptibility information are available, culture must identify E. coli and susceptible to rifamycin.); **AND**
    - Failure or intolerance to at least one quinolone such as ciprofloxacin or levofloxacin; **OR**
    - If contraindication or resistance to quinolones, then failure of azithromycin is required unless contraindicated.
    - Initial approval limited to 1 month, 12 tablets.

## Exclusions

- For travelers' diarrhea:
    1. Dose/frequency exceeding the package label.
    2. Diarrhea complicated by fever or blood in the stool or diarrhea due to pathogens other than Escherichia coli.
    3. Excludes diarrhea associated with antibiotics
    4. Prophylactic use
    5. Travel purposes
    6. Aemcolo: more than 12 tablets per episode

Dosing and/or frequency exceeding the FDA approved package labeling

- Non-FDA approved use

## References


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5. Aemcolo (rifamycin) delayed released tablets. Prescribing Information. Dublin, Ireland: Cosmo Technologies, Ltd. November 2018.


| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Medicare Preferred Gold HMO POS | Refer to Part D coverage |
| MVP Medicare Secure HMO POS | Refer to Part D coverage |
| MVP Medicare Secure Plus HMO POS | Refer to Part D coverage |
| MVP Medicare WellSelect PPO | Refer to Part D coverage |

| | |
|---|---|
| MVP Medicare WellSelect Plus PPO | Refer to Part D coverage |
| MVP Medicare Patriot Plan PPO | Refer to Part D coverage |
| MVP DualAccess D-SNP HMO | Refer to Part D coverage |
| MVP DualAccess Complete D-SNP HMO | Refer to Part D coverage |
| MVP DualAccess Plus D-SNP HMO | Refer to Part D coverage |
| UVM Health Advantage Select PPO | Refer to Part D coverage |
| UVM Health Advantage Secure PPO | Refer to Part D coverage |
| UVM Health Advantage Preferred PPO | Refer to Part D coverage |
| Healthy NY | Prior Auth |
| MVP Premier | Prior Auth |
| MVP Premier Plus | Prior Auth |
| MVP Premier Plus HDHP | Prior Auth |
| MVP Secure | Refer to Part D coverage |
| 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 | Refer to Part D coverage |
| MVP Medicare Secure Plus HMO POS | Refer to Part D coverage |
| UVM Health Advantage Select PPO | Refer to Part D coverage |
| UVM Health Advantage Secure PPO | Refer to Part D coverage |
| UVM Health Advantage Preferred PPO | Refer to Part D coverage |
| 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 | Refer to Part D coverage |
| 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).** | |
| *© 2023 MVP Health Plan, Inc. All rights reserved. Descriptions contained within MVP's Medical Policies are not a guarantee of coverage. Each MVP Group or Subscriber Contract contains specific limitations, exclusions and requirements that may affect a Policy. If there is any discrepancy between your Group or Subscriber Contract and a Policy, your Group or Subscriber Contract shall in all cases govern.* | |

***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 |

**MVP Health Care Medical Policy**

**Irritable Bowel Syndrome**

| | |
|---|---|
| **Type of Policy:** | **Drug Therapy** |
| **Prior Approval Date:** | **10/01/2023** |
| **Approval Date:** | **12/01/2024** |
| **Effective Date:** | **02/01/2025** |
| **Related Policies:** | **N/A** |

## Drugs Requiring Prior Authorization

Lotronex (alosetron oral tablet) - brand and generic

Viberzi (eluxadoline oral tablet)

## Overview

Irritable bowel syndrome is a common gastrointestinal problem that affects the large intestine. It causes cramping, bloating and changes in bowel habits. In some people it manifests as constipation (IBS-C), and others as diarrhea (IBS-D). In some cases, it can alternate between the two.

Irritable Bowel Syndrome is diagnosed by meeting the Rome IV Diagnostic Criteria:

- Recurrent abdominal pain on average at least 1 day/week in the last 3 months associated with two or more of the following:
    - Symptom improvement with defecation
    - Symptom onset associated with a change in frequency of stool
    - Symptom onset associated with a change in form (appearance) of stool

Irritable Bowel Syndrome is classified as diarrhea predominant (IBS-D) by the Bristol Stool Form

Scale:

- Loose or watery stools for ≥ 25% of bowel movements
- Hard or lumpy stools for < 25% of bowel movements

Viberzi® (eluxadoline) is a mu-opioid receptor agonist, indicated in adults for the treatment of irritable bowel syndrome with diarrhea (IBS-D). It should not be used in members without a gallbladder, with known or suspected biliary duct obstruction, or sphincter of Oddi, alcoholism, alcohol abuse, alcohol addiction, or drink more than 3 alcoholic beverages/day, a history of pancreatitis, structural diseases of the pancreas, including known or suspected pancreatic duct obstruction, severe hepatic impairment (Child-Pugh Class C), a history of chronic or severe constipation or sequelae from constipation, or known or suspected mechanical gastrointestinal obstruction disease or dysfunction.

Lotronex® (alosetron) is a 5-HT3 antagonist used in members of the female sex with severe IBS-D. It should only be used in members who have been experiencing diarrhea as their main symptom and have had inadequate response to other treatments. Alosetron should not be used in members of the male sex as it is seen to be ineffective. It should not be initiated in members with constipation, used in members with a history of chronic or severe constipation or sequelae from constipation, intestinal obstruction, stricture, toxic megacolon, gastrointestinal perforation, and/or adhesions; ischemic colitis, impaired intestinal circulation, thrombophlebitis, or hypercoagulable state, Crohn's disease or ulcerative colitis, diverticulitis, severe hepatic impairment, or use with concomitant fluvoxamine.

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**Indications/Criteria**

Coverage criteria for **all** medications in this policy:

- Member must have a diagnosis of IBS, as defined by the Rome IV criteria, and sub-classified as diarrhea-predominant IBS (IBS-D) using the Bristol Stool Form Scale **AND**
- Use of conventional therapy is not appropriate or **one** conventional agent was ineffective **AND** Conventional therapy includes:
    - Antidiarrheal agents (Loperamide)
    - Antispasmodics (dicyclomine, hyoscyamine)
    - Tricyclic Antidepressants (amitriptyline, nortriptyline, or imipramine)
- Must be prescribed by or in consultation with a gastroenterologist

Additional coverage criteria for **alosetron** are as follows:

- Diagnosed with severe IBS with symptoms for at least 6 months (with one of the following present):
    - Frequent and severe abdominal pain
    - Frequent bowel urgency or fecal incontinence
    - Disability or restriction of daily activities due to IBS

**AND**

- Rule out any anatomic or biochemical abnormalities in GI tract **AND**
- Member must be of the biologically female sex **AND**
- For **brand Lotronex,** members must meet the above criteria **AND** have had an adverse reaction or failed therapy with alosetron.

**Initial coverage** approval will be up to **6 months**

**Extension of therapy** will be up to **12 months** if the member has a continued benefit to therapy. Extension requests where the medication did not have the full desired effect or was considered a clinical failure will require clinical rationale for continuation

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**Exclusions**

- Indication, age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling.
- None of the medications identified in this policy will be covered when used in combination with one another.
- Viberzi:
    - Concurrent use with narcotic or opioid agents
    - Members without a gallbladder
    - Known or suspected biliary duct obstruction, or sphincter of Oddi disease or dysfunction
    - Alcoholism, alcohol abuse, alcohol addiction, or drink more than 3 alcoholic beverages/day
    - A history of pancreatitis; structural diseases of the pancreas, including known or suspected pancreatic duct obstruction
    - Severe hepatic impairment (Child-Pugh Class C)
    - A history of chronic or severe constipation or sequelae from constipation, or known or suspected mechanical gastrointestinal obstruction
- Alosetron:
    - Member taking concurrent fluvoxamine
    - Member with constipation

- History of chronic or severe constipation or sequelae from constipation; intestinal obstruction, stricture, toxic megacolon, gastrointestinal perforation, and/or adhesions; ischemic colitis; impaired intestinal circulation, thrombophlebitis, or hypercoagulable state; Crohn's disease or ulcerative colitis; diverticulitis; severe hepatic impairment

---

**References**


1. Lacy BE. Diagnosis and treatment of diarrhea-predominant irritable bowel syndrome. Int J Gen Med. 2016; 9:7-17.
2. Xifaxan® (rifaximin) Tablets. Prescribing Information. Morrisville, NC: Salix Pharmaceuticals, Inc. Revised 10/2023
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7. Rome IV Criteria Section C1 Irritable Bowel Syndrome Diagnostic Criteria. Rome IV Criteria - Rome Foundation (theromefoundation.org). 2021. Accessed 8/8/2023.
8. LOTRONEX (alosetron hydrochloride) Tablets. Prescribing Information. Roswell, GA: Sebela Pharmaceuticals Inc. Revised 4/2019.
9. Lembo, Anthony et al. AGA Clinical Practice Guideline on the Pharmacological Management of Irritable Bowel Syndrome With Diarrhea. Gastroenterology, Volume 163, Issue 1, 137 – 151. Updated 7/2022

| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Complete Wellness | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| USA Care PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

**Izervay**

| | |
|---|---|
| **Type of Policy:** | **Drug Therapy** |
| **Prior Approval Date:** | 04/01/2024 |
| **Approval Date:** | 04/01/2025 |
| **Effective Date:** | 06/01/2025 |
| **Related Policies:** | Syfovre |

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies.

## Drugs Requiring Prior Authorization under the medical benefit

J2782 Izervay (Avacincaptad Pegol) Solution for Intravitreal Injection

## Overview

Izervay (Avacincaptad Pegol) solution for intravitreal injection is a complement C5 inhibitor which is FDA approved for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD).

## Indications/Criteria

**Medicaid Variation:** Medications that are a pharmacy benefit are covered and billed to New York State Fee-For-Service (FFS) program. They are defined as medications that go through a retail or specialty pharmacy, including self administered injectable products. Pharmacy medications are subject to FFS's clinical criteria including (but not limited to) coverage, quantity limit, step therapy, and prior authorization. Pharmacy benefit information can be found here: https://www.emedny.org/info/fullform.pdf

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**Geographic atrophy (GA) secondary to age-related macular degeneration (AMD)**

Izervay may be considered for coverage for Geographic atrophy (GA) secondary to age-related macular degeneration (AMD) when all of following criteria is met:

- Chart notes confirming a diagnosis of geographic atrophy secondary to age-related macular degeneration
- Prescribed and administered by an ophthalmologist
- Baseline best-corrected visual acuity (BCVA) is between 20/25 and 20/320
- Member is not currently utilizing any other intravitreal complement inhibitor therapies confirmed by claims history

**Initial approval** for 6 months

**Extension requests** for Izervay may be covered for 12 months, 12 doses per eye, if the following is met:

- Member continues to meet initial approval criteria above
- Documentation that the member is tolerating the medication well (absence of adverse effects such as endophthalmitis, increased intraocular pressure, etc.)
- Documentation of objective test results supporting slowed progression and clinical benefit compared to baseline such as visual function test results, optical coherence tomography (OCT), and/or fundus autofluorescence photographs (FAF)
- Extension requests where Izervay did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing

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**Exclusions**

**Geographic atrophy (GA) secondary to age-related macular degeneration (AMD)**

The use of Izervay will not be covered for the following situations:

- Members with ocular or periocular infections
- Members with active intraocular inflammation
- Dosing, age, and/or frequency exceeding the FDA approved package labeling.
- GA secondary to a condition other than AMD such as Stargardt disease in either eye
- Member is currently utilizing another intravitreal compliment inhibitor

---

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## References


1. Avacincaptad Pegol. In: Specific Lexicomp Online Database [database on the Internet]. Hudson (OH): Lexicomp Inc.: publication year [updated 9 Feb. 2024; cited 14 Feb. 2024]. Available from: http://online.lexi.com. Subscription required to view.
2. Izervay (avacincaptad pegol intravitreal solution) NDA 217225. FDA. Revised February 2025 label (fda.gov)
3. Gaffe GJ, Westby K, Csaky KG, et al. C5 Inhibitor avacincaptad pegol for geographic atrophy due to age related macular degeneration: a randomized pivotal phase 2/3 trial. Ophthalmology. 2021; 128: 576-586.


| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Complete Wellness | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| USA Care PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

**Medicare Part B: Izervay**

| | |
|---|---|
| **Type of Policy:** | **Drug Therapy** |
| **Prior Approval Date:** | **04/01/2024** |
| **Approval Date:** | **04/01/2025** |
| **Effective Date:** | **06/01/2025** |
| **Related Policies:** | Syfovre |

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies.

## Drugs Requiring Prior Authorization under the medical benefit

J2782 Izervay (Avacincaptad Pegol) Solution for Intravitreal Injection

## Overview/Summary of Evidence

Izervay (Avacincaptad Pegol) solution for intravitreal injection is a complement C5 inhibitor which is FDA approved for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD).

## Indications/Criteria

### Geographic atrophy (GA) secondary to age-related macular degeneration (AMD)

Izervay may be considered for coverage for Geographic atrophy (GA) secondary to age-related macular degeneration (AMD) when all of following criteria is met:

- Chart notes confirming a diagnosis of geographic atrophy secondary to age-related macular degeneration
- Prescribed and administered by an ophthalmologist

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- Baseline best-corrected visual acuity (BCVA) is between 20/25 and 20/320
- Member is not currently utilizing any other intravitreal complement inhibitor therapies confirmed by claims history

**Initial approval** for 6 months

**Extension requests** for Izervay may be covered for 12 months, 12 doses per eye, if the following is met:

- Member continues to meet initial approval criteria above
- Documentation that the member is tolerating the medication well (absence of adverse effects such as endophthalmitis, increased intraocular pressure, etc.)
- Documentation of objective test results supporting slowed progression and clinical benefit compared to baseline such as visual function test results, optical coherence tomography (OCT), and/or fundus autofluorescence photographs (FAF)
- Extension requests where Izervay did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing

---

**Exclusions**

**Geographic atrophy (GA) secondary to age-related macular degeneration (AMD)**

The use of Izervay will not be covered for the following situations:

- Members with ocular or periocular infections
- Members with active intraocular inflammation
- Dosing, age, and/or frequency exceeding the FDA approved package labeling.
- GA secondary to a condition other than AMD such as Stargardt disease in either eye
- Member is currently utilizing another intravitreal complement inhibitor

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**References**


1. Avacincaptad Pegol. In: Specific Lexicomp Online Database [database on the Internet]. Hudson (OH): Lexicomp Inc.: publication year [updated 9 Feb. 2024; cited 14 Feb. 2024]. Available from: http://online.lexi.com. Subscription required to view.
2. Izervay (avacincaptad pegol intravitreal solution) NDA 217225. FDA. Revised 8/2023. label (fda.gov)


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3. Gaffe GJ, Westby K, Csaky KG, et al. C5 Inhibitor avacincaptad pegol for geographic atrophy due to age related macular degeneration: a randomized pivotal phase 2/3 trial. Ophthalmology. 2021; 128: 576-586.
4. Izervay (avacincaptad pegol intravitreal solution). Prescribing Information. Iveric Bio, Inc. Parsippany, NJ. Revised 8/2023.

**MVP Health Care Medical Policy**

**Jynarque**

**Type of Policy:** **Drug Therapy**
**Prior Approval Date:** **02/01/2024**
**Approval Date:** **02/01/2025**
**Effective Date:** **04/01/2025**
**Related Policies:** **Genetic and Molecular Diagnostic Testing**

## Drugs Requiring Prior Authorization (covered under the pharmacy benefit)

Jynarque (tolvaptan oral tablets)

## Overview

Tolvaptan is an oral selective vasopressin V2-receptor antagonist. Jynarque is FDA approved to slow kidney function decline in patients with rapidly progressing autosomal dominant polycystic kidney disease (ADPKD). For ADPKD, Jynarque requires routine liver function monitoring and is available through the Jynarque REMs program.

## Indications/Criteria

Patient must meet all the following criteria for initiating therapy:

- Prescribed by or in consult with a nephrologist
- Diagnosis of autosomal dominant polycystic kidney disease (ADPKD) confirmed by ultrasound OR genetic testing if imaging is not available or adequate.
- Total kidney volume (TKV) classification of 1C or higher by Mayo Clinical Imaging Classification Criteria
- Documentation of eGFR between 25 and 65ml/min/1.73m$^2$.
- Chart notes identifying symptoms of ADPKD (such as hypertension and flank pain)

- Documentation of the following labs:
  - Blood sodium concentration
  - ALT
  - AST
  - Bilirubin

**Initial approval** will be for a duration of 3 months.

**Subsequent extensions** for 6 months will be granted if the following are met**:**

- Documentation of continued monitoring of AST, ALT and bilirubin monthly for the first 18 months and every 3 months thereafter.
- Documentation of stability of eGFR level above 25 mL/min/1.73 m2
- Documentation that patient has not initiated dialysis

**Exclusions**

- Age, dose, frequency, outside of the FDA package label.
- Previous history, signs or symptoms of significant liver impairment or injury (not including uncomplicated polycystic liver disease).
- Combination use with strong CYP3A inhibitors
- Inability to sense or respond to thirst
- Uncorrected abnormal blood sodium concentrations, hypovolemia
- Urinary outflow obstruction
- Anuria
- Members who have progressed to end-stage renal disease.

**References**

1. Jynarque (tolvaptan tablets for oral use) [prescribing information]. Tokyo, Japan. Otsuka Pharmaceutical Co.
   Available at: https://www.otsuka-us.com/sites/g/files/qhldwo2966/files/media/static/JYNARQUE-PI.pdf
2. Ravine D, Gibson RN, Walker RG, Sheffield LJ, Kincaid-Smith P, Danks DM. Evaluation of ultrasonographic diagnostic criteria for autosomal dominant polycystic kidney disease 1. Lancet. 1994;343(8901):824-827.
3. Belibi FA, Edelstein CL. Unified ultrasonographic diagnostic criteria for polycystic kidney disease. J Am Soc Nephrol. 2009;20(1):6-8

| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Complete Wellness | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| USA Care PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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).** | |
| *© 2025 MVP Health Plan, Inc. All rights reserved. Descriptions contained within MVP's Medical Policies are not a guarantee of coverage. Each MVP Group or Subscriber Contract contains specific limitations, exclusions and requirements that may affect a Policy. If there is any discrepancy between your Group or Subscriber Contract and a Policy, your Group or Subscriber Contract shall in all cases govern.* | |

***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 |

**MVP Health Care Medical Policy**

**Lenmeldy**

| | |
|---|---|
| **Type of Policy:** | Medical Therapy (administered by the pharmacy department) |
| **Prior Approval Date:** | NA |
| **Approval Date:** | 06/01/2024 |
| **Effective Date:** | 06/01/2024 |
| **Related Policies:** | Orphan Drug(s) and Biologicals |

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies.

## Drugs Requiring Prior Authorization under the medical benefit

J3490 Lenmeldy (Atidarsagene Autotemcel)

## Overview

Lenmeldy is an autologous hematopoietic stem cell-based gene therapy indicated for the treatment of children with pre-symptomatic late infantile (PSLI), pre-symptomatic early juvenile (PSEJ) or early symptomatic early juvenile (ESEJ) metachromatic leukodystrophy (MLD). MLD is a rare, autosomal recessive, life-limiting lysosomal storage disease. It is caused by mutations in the arylsulfatase A (ARSA) gene or sphingolipid activator protein B (SAPB) gene which leads to accumulation of sulfatides throughout the body. Sulfatides accumulation is toxic to the nervous system and leads to gait abnormalities, speech regression, functional loss, cognitive loss, and seizures. Atidarsagene autotemcel is intended for one time administration to add functional copies of the ARSA gene into the patient's own hematopoietic stem cells (HSCs).

## Indications/Criteria

### Metachromatic Leukodystrophy

Lenmeldy may be considered for coverage when:

- Member has a confirmed diagnosis of pre-symptomatic late infantile (PSLI) or pre-symptomatic early juvenile (PSEJ) or early symptomatic early juvenile (ESEJ) metachromatic leukodystrophy (MLD). Diagnosis is confirmed by:
    - Genetic confirmation of mutation in ARSA gene
    - Biochemical testing
        - Sulfatase enzyme activity
        - Urinary sulfatide excretion
    - Brain MRI
        - An MRI can show the presence and absence of myelin. Brain injury accumulates as the disease progresses. An initial MRI in pediatric members can appear normal. Pediatric cases with an initial normal MRI will be reviewed on a case-by-case basis.
- Prescribed by or in consultation with Neurologist or Geneticist
- Chart notes documenting that the member does not have liver or renal impairment which is documented with current renal and liver function tests
- Documentation that the member will not receive live vaccines 6 weeks prior to myeloablative conditioning for Lenmeldy and until hematological recovery following treatment with Lenmeldy
- For female members, a negative serum pregnancy test must be confirmed
- Provider confirmation that member will not use prophylactic HIV anti-retroviral medications at least one month prior to mobilization or for the expected direction of time needed for the elimination of the medications.
    - Note: Anti-retroviral medications may interfere with the manufacturing of Lenmeldy
    - Note: if a child requires anti-retrovirals for HIV prophylaxis, initiation of Lenmeldy treatment should be delayed until confirmation of a negative test for HIV.
- Treatment centers administering Lenmeldy must be appropriately certified to do so. Please see link for treatment centers: LENMELDY(TM) (atidarsagene autotemcel) – Now Available
- Provider confirmation that the manufacturer requirement for a collection of unmanipulated back-up $CD34^+$ cells of at least $2.0 \times 10^6$ $CD34^+$ cells/kg is met
- Provider confirmation that full myeloablative conditioning would occur prior to Lenmeldy administration
- Chart notes documenting that the member has a current negative screening for the following: HIV-1, HIV-2, HBV, HCV, HTLV-1, HTLV-2, CMV and mycoplasma infection. Documentation must indicate that the member does not have active HIV-1, HIV-2, HBV, HCV, HTLV-1, HTLV-2, CMV and mycoplasma infection.

- Current documentation that the member does not have any active bacterial, viral, fungal, or parasitic infection(s)

Lenmeldy will be approved as a one-time dose within 6 months. Requests for replacement due to lost or damaged product will not be covered. Coverage is contingent on eligibility at the time of infusion.

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**Exclusions**

The use of Lenmeldy will not be covered for the following situations:

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling
- Diagnosis of late juvenile metachromatic leukodystrophy (MLD).
- Members with renal impairment
- Members with hepatic impairment
- Member has been previously treated with Lenmeldy
- Member is pregnant or planning to become pregnant
- Member has tested positive for or has active HIV-1, HIV-2, HBV, HCV, HTLV-1, HTLV-2, CMV and mycoplasma infection
- Members with active bacterial, viral, fungal, or parasitic infections
- Use in combination with other autologous genome edited hematopoietic stem cell-based gene therapies

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**References**

1. Lenmeldy suspension for intravenous infusion. Orchard Therapeutics. Boston, MA. Revised March 2024. USPI_final_3-18-24.pdf (orchard-tx.com)

2. Metachromatic Leukodystrophy. The Cleveland Clinic. Revised February 6, 2023. Accessed April 23, 2024. Metachromatic Leukodystrophy: What It Is, Causes & Symptoms (clevelandclinic.org)

3. Metachromatic Leukodystrophy. National Organization for Rare Disorders. Reviewed March 18, 2024. Accessed April 23, 2024. Metachromatic Leukodystrophy - Symptoms, Causes, Treatment | NORD (rarediseases.org)

| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Medicare Gold Giveback | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

**Medicare Part B: Lenmeldy**

| | |
|---|---|
| **Type of Policy:** | Medical Therapy (administered by the pharmacy department) |
| **Prior Approval Date:** | NA |
| **Approval Date:** | 06/01/2024 |
| **Effective Date:** | 06/01/2024 |
| **Related Policies:** | Medicare Part B: Orphan Drug(s) and Biologicals |

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies.

## Drugs Requiring Prior Authorization under the medical benefit

J3490 Lenmeldy (Atidarsagene Autotemcel)

## Overview

Lenmeldy is an autologous hematopoietic stem cell-based gene therapy indicated for the treatment of children with pre-symptomatic late infantile (PSLI), pre-symptomatic early juvenile (PSEJ) or early symptomatic early juvenile (ESEJ) metachromatic leukodystrophy (MLD). MLD is a rare, autosomal recessive, life-limiting lysosomal storage disease. It is caused by mutations in the arylsulfatase A (ARSA) gene or sphingolipid activator protein B (SAPB) gene which leads to accumulation of sulfatides throughout the body. Sulfatides accumulation is toxic to the nervous system and leads to gait abnormalities, speech regression, functional loss, cognitive loss, and seizures. Atidarsagene autotemcel is intended for one time administration to add functional copies of the ARSA gene into the patient's own hematopoietic stem cells (HSCs).

## Indications/Criteria

### Metachromatic Leukodystrophy

Lenmeldy may be considered for coverage when:

- Member has a confirmed diagnosis of pre-symptomatic late infantile (PSLI) or pre-symptomatic early juvenile (PSEJ) or early symptomatic early juvenile (ESEJ) metachromatic leukodystrophy (MLD). Diagnosis is confirmed by:
    - Genetic confirmation of mutation in ARSA gene
    - Biochemical testing
        - Sulfatase enzyme activity
        - Urinary sulfatide excretion
    - Brain MRI
        - An MRI can show the presence and absence of myelin. Brain injury accumulates as the disease progresses. An initial MRI in pediatric members can appear normal. Pediatric cases with an initial normal MRI will be reviewed on a case-by-case basis.
- Prescribed by or in consultation with Neurologist or Geneticist
- Chart notes documenting that the member does not have liver or renal impairment which is documented with current renal and liver function tests
- Documentation that the member will not receive live vaccines 6 weeks prior to myeloablative conditioning for Lenmeldy and until hematological recovery following treatment with Lenmeldy
- For female members, a negative serum pregnancy test must be confirmed
- Provider confirmation that member will not use prophylactic HIV anti-retroviral medications at least one month prior to mobilization or for the expected direction of time needed for the elimination of the medications.
    - Note: Anti-retroviral medications may interfere with the manufacturing of Lenmeldy
    - Note: if a child requires anti-retrovirals for HIV prophylaxis, initiation of Lenmeldy treatment should be delayed until confirmation of a negative test for HIV.
- Treatment centers administering Lenmeldy must be appropriately certified to do so. Please see link for treatment centers: LENMELDY(TM) (atidarsagene autotemcel) – Now Available
- Provider confirmation that the manufacturer requirement for a collection of unmanipulated back-up $CD34^+$ cells of at least $2.0 \times 10^6$ $CD34^+$ cells/kg is met
- Provider confirmation that full myeloablative conditioning would occur prior to Lenmeldy administration
- Chart notes documenting that the member has a current negative screening for the following: HIV-1, HIV-2, HBV, HCV, HTLV-1, HTLV-2, CMV and mycoplasma infection. Documentation must indicate that the member does not have active HIV-1, HIV-2, HBV, HCV, HTLV-1, HTLV-2, CMV and mycoplasma infection.

- Current documentation that the member does not have any active bacterial, viral, fungal, or parasitic infection(s)

Lenmeldy will be approved as a one-time dose within 6 months. Requests for replacement due to lost or damaged product will not be covered. Coverage is contingent on eligibility at the time of infusion.

---

**Exclusions**

The use of Lenmeldy will not be covered for the following situations:

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling
- Diagnosis of late juvenile metachromatic leukodystrophy (MLD).
- Members with renal impairment
- Members with hepatic impairment
- Member has been previously treated with Lenmeldy
- Member is pregnant or planning to become pregnant
- Member has tested positive for or has active HIV-1, HIV-2, HBV, HCV, HTLV-1, HTLV-2, CMV and mycoplasma infection
- Members with active bacterial, viral, fungal, or parasitic infections
- Use in combination with other autologous genome edited hematopoietic stem cell-based gene therapies

---

**References**

1. Lenmeldy suspension for intravenous infusion. Orchard Therapeutics. Boston, MA. Revised March 2024. USPI_final_3-18-24.pdf (orchard-tx.com)

2. Metachromatic Leukodystrophy. The Cleveland Clinic. Revised February 6, 2023. Accessed April 23, 2024. Metachromatic Leukodystrophy: What It Is, Causes & Symptoms (clevelandclinic.org)

3. Metachromatic Leukodystrophy. National Organization for Rare Disorders. Reviewed March 18, 2024. Accessed April 23, 2024. Metachromatic Leukodystrophy - Symptoms, Causes, Treatment | NORD (rarediseases.org)

**MVP Health Care Medical Policy**

**Luxturna**

**Type of Policy:** **Drug Therapy**
**Prior Approval Date:** **04/01/2024**
**Approval Date:** **04/01/2025**
**Effective Date:** **06/01/2025**
**Related Policies:** **N/A**

## Drug Requiring Prior Authorization (covered under the medical benefit)

J3398 Luxturna (voretigene neparvovec-rzyl) intraocular suspension

Refer to the MVP website for the Medicare Part D formulary for drugs that may be covered under the Part D benefit.

Refer to the MVP website for the Medicare Part B policies for coverage criteria of drugs covered under the medical benefit.

## Overview

Luxturna is an adeno-associated virus vector-based gene therapy indicated as an orphan drug for the treatment of patients with confirmed biallelic *RPE65* mutation-associated retinal dystrophy. Treatment with Luxturna includes one dose per eye per lifetime.

## Indications/Criteria

Luxturna will be considered for coverage when ALL the following are met:

- Prescribed and administered by an ophthalmologist or retinal surgeon with experience providing sub-retinal injections
- Member is at least 12 months of age but not greater than 64 years of age
- Member has a confirmed diagnosis of biallelic *RPE65* mutation-associated retinal dystrophy
- Chart notes document genetic testing to confirm mutation in both copies of the RPE65 gene
- Member must have viable retinal cells, as defined by:

    - an area in the retina within the posterior pole of greater than 100 µm thickness shown on OCT (optical coherence tomography): OR
    - ≥ 3-disc areas of retina without atrophy or pigmentary degeneration within the posterior pole; OR
    - remaining visual field within 30 degrees of fixation as measured by a III4e isopter or equivalent
- Treatment with Luxturna must be done separately in each eye on separate days, with at least six days between surgical procedures
- The member must not have had treatment with Luxturna previously in the intended eye
- The facility at which Luxturna is administered must be appropriately certified to do so. More information on this can be found here: https://luxturnahcp.com/about-luxturna/treatment-centers/

If approved, coverage will be provided for a maximum of 1 injection per eye per lifetime. Coverage of lost, damaged, or mishandled product will not be covered. Coverage is contingent on eligibility at the time of administration.

**Exclusions**

- Dose and/or frequency exceeding the package label
- Member is pregnant
- Member has previous administration of gene therapy vector
- Use of retinoid compounds or precursors that could potentially interact with the biochemical activity of the *RPE65* enzyme (individuals must discontinue use of these compounds for 18 months prior to Luxturna administration)
- Prior intraocular surgery within 6 months

**Medicaid Variation**

Luxturna will be considered for coverage when all the following are met:

- The member must have a retinal dystrophy due to confirmed mutations (on genetic testing) in both copies of the RPE65 gene
- The member must have viable retinal cells as determined by the treating physician(s)
- The member must be 12 months of age or older
- Treatment with Luxturna must be done separately in each eye on separate days, with at least six days between surgical procedures.
- Luxturna must be administered by a surgeon experienced in performing intraocular surgery

- The member must not have had treatment with Luxturna previously in the intended eye

The facility at which Luxturna is administered must be appropriately certified to do so. More information on this can be found here: https://luxturnahcp.com/about-luxturna/treatment-centers/

## References


1. Luxturna (voretigene neparvovec-ryzel) prescribing information. Philadelphia, PA: Spark Therapeutics, Inc. 2017. Revised 05/2022.

2. A Safety and Efficacy Study in Subjects with Leber Congenital Amaurosis (LCA) Using Adeno-Associated Viral Vector to Deliver the Gene for Human RPE65 to the Retinal Pigment Epithelium (RPE) [AAV2-hRPE65v2-301]. Available online at: https://www.clinicaltrials.gov/ct2/show/NCT00999609?term=voretigene+neparvovec-rzyl&rank=1

3. New York State Medicaid Update. March 2018; Vol 34: Number 3. Available at: New York Medicaid Update, Volume 34 Number 3, March 2018 (ny.gov)

4. Russel S, Bennet J, Wellman JA, et al. Efficacy and safety of voretigene neparvovec (AAV2-hRPE65v2) in patients with RPE65-mediated inherited retinal dystrophy: a randomized, controlled, open-label phase 3 trial. Lancet 2017; 390:849-860.


| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Complete Wellness | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| USA Care PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

**Medicare Part B: Luxturna**

| | |
|---|---|
| **Type of Policy:** | **Drug Therapy** |
| **Prior Approval Date:** | **04/01/2024** |
| **Approval Date:** | **04/01/2025** |
| **Effective Date:** | **06/01/2025** |
| **Related Policies:** | **N/A** |

## Drug Requiring Prior Authorization (covered under the medical benefit)

J3398 Luxturna (voretigene neparvovec-rzyl) intraocular suspension

Refer to the MVP website for the Medicare Part D formulary for drugs that may be covered under the Part D benefit.

## Overview/Summary of Evidence

Luxturna is an adeno-associated virus vector-based gene therapy indicated as an orphan drug for the treatment of patients with confirmed biallelic *RPE65* mutation-associated retinal dystrophy. Treatment with Luxturna includes one dose per eye per lifetime.

## Indications/Criteria

Luxturna will be considered for coverage when ALL the following are met:

- Prescribed and administered by an ophthalmologist or retinal surgeon with experience providing sub-retinal injections
- Member is at least 12 months of age but not greater than 64 years of age
- Member has a confirmed diagnosis of biallelic *RPE65* mutation-associated retinal dystrophy
- Chart notes document genetic testing to confirm mutation in both copies of the RPE65 gene
- Member must have viable retinal cells, as defined by:
    - an area in the retina within the posterior pole of greater than 100 µm thickness shown on OCT (optical coherence tomography): OR
    - ≥ 3-disc areas of retina without atrophy or pigmentary degeneration within the posterior pole; OR

    - remaining visual field within 30 degrees of fixation as measured by a III4e isopter or equivalent
- Treatment with Luxturna must be done separately in each eye on separate days, with at least six days between surgical procedures
- The Member must not have had treatment with Luxturna previously in the intended eye
- The facility at which Luxturna is administered must be appropriately certified to do so. More information on this can be found here: https://luxturnahcp.com/about-luxturna/treatment-centers/

If approved, coverage will be provided for a maximum of 1 injection per eye per lifetime. Coverage of lost, damaged, or mishandled product will not be covered. Coverage is contingent on eligibility at the time of administration.

## Exclusions

- Dose and/or frequency exceeding the package label
- Member is pregnant
- Member has previous administration of gene therapy vector
- Use of retinoid compounds or precursors that could potentially interact with the biochemical activity of the *RPE65* enzyme (individuals must discontinue use of these compounds for 18 months prior to Luxturna administration)
- Prior intraocular surgery within 6 months

## References

1. Luxturna (voretigene neparvovec-ryzel) prescribing information. Philadelphia, PA: Spark Therapeutics, Inc. 2017. Revised 05/2022.

2. A Safety and Efficacy Study in Subjects with Leber Congenital Amaurosis (LCA) Using Adeno-Associated Viral Vector to Deliver the Gene for Human RPE65 to the Retinal Pigment Epithelium (RPE) [AAV2-hRPE65v2-301]. Available online at: https://www.clinicaltrials.gov/ct2/show/NCT00999609?term=voretigene+neparvovec-rzyl&rank=1

3. 3. Russel S, Bennet J, Wellman JA, et al. Efficacy and safety of voretigene neparvovec (AAV2-hRPE65v2) in patients with RPE65-mediated inherited retinal dystrophy: a randomized, controlled, open-label phase 3 trial. Lancet 2017; 390:849-860.

**MVP Health Care Medical Policy**

**Lyfgenia (Lovotibeglogene Autotemcel)**

| | |
|---|---|
| **Type of Policy:** | Drug Therapy (administered by the pharmacy department) |
| **Prior Approval Date:** | NA |
| **Approval Date:** | 06/01/2024 |
| **Effective Date:** | 06/01/2024 |
| **Related Policies:** | Casgevy, Adakveo |

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies.

**Drugs Requiring Prior Authorization under the medical benefit**

J3590 Lyfgenia (Lovotibeglogene Autotemcel)

**Overview**

Lyfgenia (Lovotibeglogene Autotemcel)as is an intravenous, one-time autologous genome edited hematopoietic stem cell-based gene therapy for patients with sickle cell disease suffering from vaso-occlusive crisis. A vaso occlusive crisis is a potentially life-threatening complication caused when sickled red blood cells hinder blood flow causing pain, and lack of oxygen delivery to tissue. Lyfgenia is manufactured specifically for an individual using their own blood stem cells. The treatment course consists of multiple phases including cell mobilization and apheresis to collect CD34+ cells for manufacturing, myeloablative conditioning, and finally the modified cells are returned to

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the patient via IV infusion. The hematopoietic cells (HCs) are transduced ex-vivo with a BB305 lentiviral vector encoding a modified β-globin gene. Following IV infusion, the modified CD34+ hematopoietic cells engraft in the bone marrow and differentiate to produce red blood cells that combine with α-globin to produce HbA which is modified adult hemoglobin. This then reduces intracellular and total hemoglobin S (HbS) levels ultimately limiting the sickling of red blood cells and potential for a vaso-occlusive crisis from occurring.

**Medicaid Variation:** Medications that are a pharmacy benefit are covered and billed to New York State Fee-For-Service (FFS) program. They are defined as medications that go through a retail or specialty pharmacy, including self-administered injectable products. Pharmacy medications are subject to FFS's clinical criteria including (but not limited to) coverage, quantity limit, step therapy, and prior authorization. Pharmacy benefit information can be found here: https://www.emedny.org/info/fullform.pdf

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**Indications/Criteria**

**A. Sickle Cell Disease (SCD) with recurrent vaso-occlusive crises**

Lyfgenia will be considered for coverage for SCD with recurrent vaso-occlusive crises when ALL of the following criteria is met:

- Prescribed by a board-certified hematologist
- Lyfgenia must be administered at a Qualified Treatment Center. Please see the link for treatment centers: LYFGENIA™ (lovotibeglogene autotemcel) Qualified Treatment Center Locator
- Chart notes documenting a diagnosis of sickle cell disease (SCD), with either βS/βS or βS/β0 or βS/β+ genotype.
    - Lyfgenia has not been studied in member's with more than two α-globin gene deletions
- Documentation that that the member has not received a prior allogeneic or autologous HSC transplant AND is not being considered for other gene or investigational therapies for SCD.
- Member is ≥ 12 years old
- Chart notes documenting ≥ 4 severe vaso-occlusive crises in the 2 years prior to screening while adhering to previous SCD therapy, defined as any of the following:

    - An episode of acute pain with no medically determined cause other than vaso-occlusion, lasting more than 2 hours
    - Acute chest syndrome (ACS)
    - Acute hepatic sequestration
    - Acute splenic sequestration
    - Vaso-occlusive episode requiring a hospitalization or multiple visits to an emergency department/urgent care over 72 hours and receiving intravenous medications at each visit Acute chest syndrome
    - priapism requiring any level of medical attention
- Member has failed to match with a hematopoietic stem cell donor
- Chart notes documenting that the member has tried and failed other sickle cell disease treatment (such as hydroxyurea, Adakveo, Oxbryta, Endari) up to the maximally indicated dose for ≥6 months. Documentation must include dates of use.
- Chart notes documenting that the member does not have advanced liver impairment or renal impairment which is documented with current renal and liver function tests
    - Renal impairment (defined as creatinine clearance ≤70mL/min/1.73m$^2$)
    - Examples of advanced liver impairment
        - Alanine transaminase > 3 times upper limit of normal
        - Direct bilirubin value > 2.5 times upper limit of normal
        - Baseline prothrombin time (international normalized ratio [INR]) > 1.5 times upper limit of normal
        - Cirrhosis
        - Bridging fibrosis
        - Active hepatitis
- For female members, a negative serum pregnancy test must be confirmed
- Documented provider attestation confirming that the member is an appropriate candidate for hematopoietic stem cell (HSC) transplantation
- Chart notes documenting that the member has a current negative screening for the following: HIV-1, HIV-2. Documentation must indicate that the member does not have active HIV-1 or HIV-2.
- Current documentation that the member does not have any active bacterial, viral, fungal, or parasitic infection(s)

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Lyfgenia will be approved as a one-time dose within 6 months. Requests for replacement due to lost or damaged product will not be covered. Coverage is contingent on eligibility at the time of infusion.

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**Exclusions**

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling
- Use in combination with other autologous genome edited hematopoietic stem cell-based gene therapies such as Casgevy
- Members with renal deficiency
- Members with hepatic deficiency
- Member is pregnant or planning to become pregnant
- Member not an appropriate candidate for hematopoietic stem cell transplantation
- Member has received prior allogeneic or autologous HSC transplant
- Member has tested positive for or has active HIV-1, HIV-2
- Members with active bacterial, viral, fungal, or parasitic infections
- Members with more than two α-globin gene deletions

---

**References**


1. bluebirdbio. (2024, February). Lyfgenia (Lovotibeglogene Autotemcel) | now FDA approved. https://www.lyfgenia.com
2. bluebirdbio. (2023, December). Lyfgenia (Lovotibeglogene Autotemcel) Package Insert. LYFGENIA_Prescribing_Information.pdf (bluebirdbio.com)
3. *A study evaluating the safety and efficacy of BB1111 in severe sickle cell disease - full text view*. ClinicalTrials.gov. (n.d.). https://classic.clinicaltrials.gov/ct2/show/NCT02140554?term=02140554&draw=2&rank=1


| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Medicare Gold Giveback | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
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| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

**Medicare Part B: Lyfgenia (Lovotibeglogene Autotemcel)**

| | |
|---|---|
| **Type of Policy:** | Drug Therapy (administered by the pharmacy department) |
| **Prior Approval Date:** | NA |
| **Approval Date:** | 06/01/2024 |
| **Effective Date:** | 06/01/2024 |
| **Related Policies:** | Casgevy, Adakveo |

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies.

**Drugs Requiring Prior Authorization under the medical benefit**

J3590 Lyfgenia (Lovotibeglogene Autotemcel)

**Overview**

Lyfgenia (Lovotibeglogene Autotemcel)as is an intravenous, one-time autologous genome edited hematopoietic stem cell-based gene therapy for patients with sickle cell disease suffering from vaso-occlusive crisis. A vaso occlusive crisis is a potentially life-threatening complication caused when sickled red blood cells hinder blood flow causing pain, and lack of oxygen delivery to tissue. Lyfgenia is manufactured specifically for an individual using their own blood stem cells. The treatment course consists of multiple phases including cell mobilization and apheresis to collect CD34+ cells for manufacturing, myeloablative conditioning, and finally the modified cells are returned to

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the patient via IV infusion. The hematopoietic cells (HCs) are transduced ex-vivo with a BB305 lentiviral vector encoding a modified β-globin gene. Following IV infusion, the modified CD34+ hematopoietic cells engraft in the bone marrow and differentiate to produce red blood cells that combine with α-globin to produce HbA which is modified adult hemoglobin. This then reduces intracellular and total hemoglobin S (HbS) levels ultimately limiting the sickling of red blood cells and potential for a vaso-occlusive crisis from occurring.

**Medicaid Variation:** Medications that are a pharmacy benefit are covered and billed to New York State Fee-For-Service (FFS) program. They are defined as medications that go through a retail or specialty pharmacy, including self-administered injectable products. Pharmacy medications are subject to FFS's clinical criteria including (but not limited to) coverage, quantity limit, step therapy, and prior authorization. Pharmacy benefit information can be found here: https://www.emedny.org/info/fullform.pdf

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**Indications/Criteria**

**A. Sickle Cell Disease (SCD) with recurrent vaso-occlusive crises**

Lyfgenia will be considered for coverage for SCD with recurrent vaso-occlusive crises when ALL of the following criteria is met:

- Prescribed by a board-certified hematologist
- Lyfgenia must be administered at a Qualified Treatment Center. Please see the link for treatment centers: LYFGENIA™ (lovotibeglogene autotemcel) Qualified Treatment Center Locator
- Chart notes documenting a diagnosis of sickle cell disease (SCD), with either βS/βS or βS/β0 or βS/β+ genotype.
    - Lyfgenia has not been studied in member's with more than two α-globin gene deletions
- Documentation that that the member has not received a prior allogeneic or autologous HSC transplant AND is not being considered for other gene or investigational therapies for SCD.
- Member is ≥ 12 years old
- Chart notes documenting ≥ 4 severe vaso-occlusive crises in the 2 years prior to screening while adhering to previous SCD therapy, defined as any of the following:

    - An episode of acute pain with no medically determined cause other than vaso-occlusion, lasting more than 2 hours
    - Acute chest syndrome (ACS)
    - Acute hepatic sequestration
    - Acute splenic sequestration
    - Vaso-occlusive episode requiring a hospitalization or multiple visits to an emergency department/urgent care over 72 hours and receiving intravenous medications at each visit Acute chest syndrome
    - priapism requiring any level of medical attention
- Member has failed to match with a hematopoietic stem cell donor
- Chart notes documenting that the member has tried and failed other sickle cell disease treatment (such as hydroxyurea, Adakveo, Oxbryta, Endari) up to the maximally indicated dose for ≥6 months. Documentation must include dates of use.
- Chart notes documenting that the member does not have advanced liver impairment or renal impairment which is documented with current renal and liver function tests
    - Renal impairment (defined as creatinine clearance ≤70mL/min/1.73m$^2$)
    - Examples of advanced liver impairment
        - Alanine transaminase > 3 times upper limit of normal
        - Direct bilirubin value > 2.5 times upper limit of normal
        - Baseline prothrombin time (international normalized ratio [INR]) > 1.5 times upper limit of normal
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        - Bridging fibrosis
        - Active hepatitis
- For female members, a negative serum pregnancy test must be confirmed
- Documented provider attestation confirming that the member is an appropriate candidate for hematopoietic stem cell (HSC) transplantation
- Chart notes documenting that the member has a current negative screening for the following: HIV-1, HIV-2. Documentation must indicate that the member does not have active HIV-1 or HIV-2.
- Current documentation that the member does not have any active bacterial, viral, fungal, or parasitic infection(s)

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Lyfgenia will be approved as a one-time dose within 6 months. Requests for replacement due to lost or damaged product will not be covered. Coverage is contingent on eligibility at the time of infusion.

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**Exclusions**

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling
- Use in combination with other autologous genome edited hematopoietic stem cell-based gene therapies such as Casgevy
- Members with renal deficiency
- Members with hepatic deficiency
- Member is pregnant or planning to become pregnant
- Member not an appropriate candidate for hematopoietic stem cell transplantation
- Member has received prior allogeneic or autologous HSC transplant
- Member has tested positive for or has active HIV-1, HIV-2
- Members with active bacterial, viral, fungal, or parasitic infections
- Members with more than two α-globin gene deletions

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| Member Product | Medical Management Requirements* |
|---|---|
| **New York Products** | |
| HMO | Prior Auth |

| | |
|---|---|
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| MVP Secure | Prior Auth |
| MVP EPO | Prior Auth |
| MVP EPO HDHP | Prior Auth |
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| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

**Lyme Disease/IV Antibiotic Treatment**

**Type of Policy:** **Medical Therapy**
**Prior Approval Date:** **12/01/2023**
**Approval Date:** **12/01/2024**
**Effective Date:** **02/01/2025**
**Related Policies:** **N/A**

## Codes Requiring Prior Authorization when used for the treatment of Lyme Disease (covered under the medical benefit)

J0696 (ceftriaxone, per 250mg)

J0698 (cefotaxime, per gram)
J2540 (penicillin G potassium, up to 600,000 units)

Refer to the Medicare Part D formulary for drugs that may be covered under the Part D benefit.

Refer to the MVP website for the Medicare Part B policies for coverage criteria of drugs covered under the medical benefit.

## Overview

Lyme disease is a multisystem illness due to infection with the tick-borne spirochete, Borrelia burgdorferi. Lyme disease can occur in 3 stages: an early localized stage, a disseminated stage, and a late stage. The early localized stage is generally characterized by the bull's eye rash, which forms at the site of the tick bite. The disseminated stage typically occurs in the first few weeks to 6 months after infection. Lyme disease that is untreated and progressed for more than 6 months is late-stage disease. Late-stage Lyme disease may manifest as encephalitis, encephalomyelitis, arthritis, neuropathies and cerebral arteritis. Oral antibiotic therapy (ex. doxycycline, amoxicillin or cefuroxime axetil) is the standard of care for members in early localized and early disseminated

stages without neurologic or cardiac symptoms, and therapy is recommended for 14 to 21 days. Intravenous antibiotics are indicated for treatment of late-stage disease or for disseminated disease with neurologic or cardiac involvement, and therapy is recommended for 14 to 28 days.

Currently there is a two-step process for testing blood for Lyme disease bacteria. The common first step is ELISA (enzyme-linked immunosorbent assay) which can detect IgM antibodies to Borrelia burgdorferi. If the ELISA result is negative, an alternative diagnosis should be considered, or if the member has signs and symptoms consistent with Lyme disease for < 30 days, consider retesting after 4-6 weeks of initial symptoms. As of August 2019, the CDC has updated their guidelines for diagnosis. If the ELISA result is positive or indeterminate, perform the Western Blot or a second FDA cleared enzyme immunoassay. Clearance by FDA indicates "that test performance has been evaluated and is substantially equivalent to or better than a legally marketed predicate test". Results are considered positive only if both the ELISA and the Western Blot or second enzyme immunoassay are positive[8,10].

## Indications/Criteria and Documentation Requirements

MVP will provide coverage for the use of intravenous antibiotics for Lyme disease, when all the following criteria are met:

A. Current lab results indicating a positive (or equivocal) enzyme immunoassay (e.g. ELISA)

B. Current lab results indicating a positive w striped type western immune blot test **OR** a second positive enzyme immunoassay which includes:
    - For Western Immunoblot test:
        - For signs or symptoms >30 days an IgG immunoblot that includes:
        - IgG immunoblot must have at least five of the following 10 bands present:
            - 18 kDa
            - 21 kDa (OspC)*
            - 28 kDa
            - 30 kDa
            - 39 kDa (BmpA)
            - 41 kDa (Fla)

- 45 kDa
- 58 kDa (not GroEL)
- 66 kDa
- 93 kDa

- For signs or symptoms ≤ 30 days, the above criteria for an IgG Western Blot must be met **AND** an IgM western immunoblot must have at least two of the following bands present:
    - 24 kDa (OspC)*
    - 39 kDa (BmpA)
    - 41 kDa (Fla)

C. Contraindication or intolerance to all appropriate first-line oral antibiotic therapy at recommended maximum dosages except for the following:
    - Neurologic early Lyme Disease
    - Lyme-Disease Related parenchymal involvement of the brain or spinal cord
    - Refer to the IDSA guidelines Clinical Practice Guidelines by the Infectious Diseases Society of America (IDSA), American Academy of Neurology (AAN), and American College of Rheumatology (ACR): 2020 Guidelines for the Prevention, Diagnosis and Treatment of Lyme Disease | Clinical Infectious Diseases | Oxford Academic

D. Documentation includes signs or symptoms of early disseminated Lyme disease or late Lyme disease with one of the following:
    1. Neurologic early Lyme Disease: Neurologic disease manifested by meningitis, cranial neuropathy, radiculoneuropthy or with other peripheral nervous system manifestations with clinical and laboratory evidence (e.g. lymphocytic cerebrospinal fluid pleocytosis, CSF elevation)
    2. Lyme-Disease Related parenchymal involvement of the brain or spinal cord: evident by MRI imaging or focal findings on neurologic examination
    3. Carditis (early Lyme disease)
        - Examples: Atrioventricular (AV) heart block and/or myopericarditis associated with early Lyme disease.
    4. Lyme arthritis with persistent joint swelling with no or minimal response to an initial course of oral antibiotic treatment

- Documentation of serum antibody testing OR
- For seropositive members , PCR applied to synovial fluid or tissue

5. Late neurologic disease affecting the central or peripheral nervous system. (Retreatment is not recommended unless relapse is shown by reliable objective measures.) Retreatment is not recommended and the prospective, controlled clinical trials have demonstrated little benefit from prolonged antibiotic therapy. Due to a lack of efficacy supported in peer reviewed literature, long term (>28 days) antibiotic therapy is not considered medically necessary.

E. Chart notes from appropriate specialists (e.g. rheumatologist, cardiologist, neurologist), in the absence of neurologic or cardiac manifestations, that have ruled out underlying conditions that may have the similar symptoms as Lyme disease.

F. Treatment with IV antibiotics is supported by medical guidelines or peer reviewed literature and meets MVP Clinical Coverage Criteria for medical necessity.

**Medicaid Variation:** Medications that are a pharmacy benefit are covered and billed to New York State Fee-For-Service (FFS) program. They are defined as medications that go through a retail or specialty pharmacy, including self-administered injectable products. Pharmacy medications are subject to FFS's clinical criteria including (but not limited to) coverage, quantity limit, step therapy, and prior authorization. Pharmacy benefit information can be found here: https://www.emedny.org/info/fullform.pdf

## Exclusions

- Additional or prolonged courses of antibiotic therapy have not been demonstrated to benefit individuals and may expose them to significant risk from adverse effects of the medications.
- Indication, age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling
- Intravenous antibiotic therapy in excess of 28 days.
- Members with a positive ELISA test but unconfirmed by striped type immunoblot tests approved by the FDA and currently recommended by CDC
- Treatment of post-Lyme disease or post-Lyme disease syndrome (symptomatic therapy is recommended)
- Additional therapy after recommended treatment for members with persistent or recurring nonspecific symptoms (i.e. fatigue, pain or cognitive impairment) who lack objective evidence of reinfection or treatment failure

- Prophylaxis of Lyme disease in the absence of clinical symptoms.
- Treatment with IV antibiotics for non-specific symptoms (fatigue, headache, etc.)

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**References**


1. Halperin JJ, Shapiro ED, Logigian E, Belman AL, Dotevall L, Wormser GP, Krupp L, Gronseth G, Bever CT Jr. Practice parameter: treatment of nervous system Lyme disease (an evidence-based review). Report of the Quality Standards Subcommittee of the American Academy of Neurology. Neurology 2007 Jul 3; 69:1-12.
2. Medline Plus. A service of U.S. National Library of Medicine, National Institutes of Health. Lyme disease. August 2011. Available: www.nlm.nih.gov/medlineplus/ency/article/001319.htm.
3. Centers for Disease Control and Prevention (CDC). Lyme disease, diagnosis and treatment, laboratory testing, understanding the immunoblot test. Available: www.cdc.gov
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5. Mead P, Petersen J, Hinckley A. Updated CDC Recommendation for Serologic Diagnosis of Lyme Disease. Morbidity and Mortality Weekly Report; 2019 Aug; 68(32). https://www.cdc.gov/mmwr/volumes/68/wr/pdfs/mm6832a4-H.pdf
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| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Complete Wellness | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| USA Care PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

**Medicare Part B: Lyme Disease/IV Antibiotic Treatment**

**Type of Policy:** **Medical Therapy**
**Prior Approval Date:** **NA**
**Approval Date:** **12/01/2024**
**Effective Date:** **02/01/2025**
**Related Policies:** **N/A**

## Codes Requiring Prior Authorization when used for the treatment of Lyme Disease (covered under the medical benefit)

J0696 (ceftriaxone, per 250mg)

J0698 (cefotaxime, per gram)
J2540 (penicillin G potassium, up to 600,000 units)

Refer to the Medicare Part D formulary for drugs that may be covered under the Part D benefit.

Refer to the MVP website for the Medicare Part B policies for coverage criteria of drugs covered under the medical benefit.

Please refer to relevant CMS LCDs/NCDs/Policy Articles for most up to date Medicare Part B guidance if available.

## Overview

Lyme disease is a multisystem illness due to infection with the tick-borne spirochete, Borrelia burgdorferi. Lyme disease can occur in 3 stages: an early localized stage, a disseminated stage, and a late stage. The early localized stage is generally characterized by the bull's eye rash, which forms at the site of the tick bite. The disseminated stage

typically occurs in the first few weeks to 6 months after infection. Lyme disease that is untreated and progressed for more than 6 months is late-stage disease. Late-stage Lyme disease may manifest as encephalitis, encephalomyelitis, arthritis, neuropathies and cerebral arteritis. Oral antibiotic therapy (ex. doxycycline, amoxicillin or cefuroxime axetil) is the standard of care for members in early localized and early disseminated stages without neurologic or cardiac symptoms, and therapy is recommended for 14 to 21 days. Intravenous antibiotics are indicated for treatment of late-stage disease or for disseminated disease with neurologic or cardiac involvement, and therapy is recommended for 14 to 28 days.

Currently there is a two-step process for testing blood for Lyme disease bacteria. The common first step is ELISA (enzyme-linked immunosorbent assay) which can detect IgM antibodies to Borrelia burgdorferi. If the ELISA result is negative, an alternative diagnosis should be considered, or if the member has signs and symptoms consistent with Lyme disease for < 30 days, consider retesting after 4-6 weeks of initial symptoms. As of August 2019, the CDC has updated their guidelines for diagnosis. If the ELISA result is positive or indeterminate, perform the Western Blot or a second FDA cleared enzyme immunoassay. Clearance by FDA indicates "that test performance has been evaluated and is substantially equivalent to or better than a legally marketed predicate test". Results are considered positive only if both the ELISA and the Western Blot or second enzyme immunoassay are positive[8,10].

## Indications/Criteria and Documentation Requirements

MVP will provide coverage for the use of intravenous antibiotics for Lyme disease, when all the following criteria are met:

A. Current lab results indicating a positive (or equivocal) enzyme immunoassay (e.g. ELISA)

B. Current lab results indicating a positive w striped type western immune blot test **OR** a second positive enzyme immunoassay which includes:

- For Western Immunoblot test:
  - For signs or symptoms >30 days an IgG immunoblot that includes:
  - IgG immunoblot must have at least five of the following 10 bands present:
    - 18 kDa
    - 21 kDa (OspC)*

- 28 kDa
- 30 kDa
- 39 kDa (BmpA)
- 41 kDa (Fla)
- 45 kDa
- 58 kDa (not GroEL)
- 66 kDa
- 93 kDa

- For signs or symptoms ≤ 30 days, the above criteria for an IgG Western Blot must be met **AND** an IgM western immunoblot must have at least two of the following bands present:
  - 24 kDa (OspC)*
  - 39 kDa (BmpA)
  - 41 kDa (Fla)

C. Contraindication or intolerance to all appropriate first-line oral antibiotic therapy at recommended maximum dosages except for the following:
   - Neurologic early Lyme Disease
   - Lyme-Disease Related parenchymal involvement of the brain or spinal cord
   - Refer to the IDSA guidelines Clinical Practice Guidelines by the Infectious Diseases Society of America (IDSA), American Academy of Neurology (AAN), and American College of Rheumatology (ACR): 2020 Guidelines for the Prevention, Diagnosis and Treatment of Lyme Disease | Clinical Infectious Diseases | Oxford Academic

D. Documentation includes signs or symptoms of early disseminated Lyme disease or late Lyme disease with one of the following:
   1. Neurologic early Lyme Disease: Neurologic disease manifested by meningitis, cranial neuropathy, radiculoneuropthy or with other peripheral nervous system manifestations with clinical and laboratory evidence (e.g. lymphocytic cerebrospinal fluid pleocytosis, CSF elevation)
   2. Lyme-Disease Related parenchymal involvement of the brain or spinal cord: evident by MRI imaging or focal findings on neurologic examination
   3. Carditis (early Lyme disease)

- Examples: Atrioventricular (AV) heart block and/or myopericarditis associated with early Lyme disease.

4. Lyme arthritis with persistent joint swelling with no or minimal response to an initial course of oral antibiotic treatment
    - Documentation of serum antibody testing OR
    - For seropositive members , PCR applied to synovial fluid or tissue
5. Late neurologic disease affecting the central or peripheral nervous system. (Retreatment is not recommended unless relapse is shown by reliable objective measures.) Retreatment is not recommended and the prospective, controlled clinical trials have demonstrated little benefit from prolonged antibiotic therapy. Due to a lack of efficacy supported in peer reviewed literature, long term (>28 days) antibiotic therapy is not considered medically necessary.

E. Chart notes from appropriate specialists (e.g. rheumatologist, cardiologist, neurologist), in the absence of neurologic or cardiac manifestations, that have ruled out underlying conditions that may have the similar symptoms as Lyme disease.

F. Treatment with IV antibiotics is supported by medical guidelines or peer reviewed literature and meets MVP Clinical Coverage Criteria for medical necessity.

**Medicaid Variation:** Medications that are a pharmacy benefit are covered and billed to New York State Fee-For-Service (FFS) program. They are defined as medications that go through a retail or specialty pharmacy, including self-administered injectable products. Pharmacy medications are subject to FFS's clinical criteria including (but not limited to) coverage, quantity limit, step therapy, and prior authorization. Pharmacy benefit information can be found here: https://www.emedny.org/info/fullform.pdf

## Exclusions

- Additional or prolonged courses of antibiotic therapy have not been demonstrated to benefit individuals and may expose them to significant risk from adverse effects of the medications.
- Indication, age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling
- Intravenous antibiotic therapy in excess of 28 days.
- Members with a positive ELISA test but unconfirmed by striped type immunoblot tests approved by the FDA and currently recommended by CDC

- Treatment of post-Lyme disease or post-Lyme disease syndrome (symptomatic therapy is recommended)
- Additional therapy after recommended treatment for members with persistent or recurring nonspecific symptoms (i.e. fatigue, pain or cognitive impairment) who lack objective evidence of reinfection or treatment failure
- Prophylaxis of Lyme disease in the absence of clinical symptoms.
- Treatment with IV antibiotics for non-specific symptoms (fatigue, headache, etc.)

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**MVP Health Care Medical Policy**

**Mail Order**

| | |
|---|---|
| **Type of Policy:** | **Drug Therapy** |
| **Prior Approval Date:** | **02/01/2024** |
| **Approval Date:** | **02/01/2025** |
| **Effective Date:** | **04/01/2025** |

**Related Policies:** **N/A**

Refer to the MVP Medicare website for the Medicare Part D Formulary and Part D policies for drugs that may be covered under the Part D benefit.

## Overview

Maintenance drugs, as identified on the MVP Formularies, are available to members through the mail order benefit. No other drugs will be eligible for mail order copay structure. For determination of coverage for this policy, a maintenance drug is defined as "any drug, taken regularly, used to treat or prevent a chronic health condition such as, but not limited to high blood pressure, diabetes, and asthma". MVP reserves the right to determine which drugs are considered mail order eligible. Exceptions listed in this policy are not all inclusive. Please refer to the Formulary lists for current information.

## Indications/Criteria

Covered when below criteria are met:

- Drug(s) must be prescribed by a participating provider for a 90-day supply.
- The member must send appropriate paperwork plus the prescription(s) to the mail order vendor with at least a 14 day lead time for processing.
- Member copayments will depend on mail order benefit purchased. Member will be able to obtain a 90-day supply of medication, at a reduced copayment.
- Some Plans may allow a 90-day supply of medications at a retail pharmacy. Only medications in the categories below are eligible and are subject to the applicable 90-day copayments.

- If a drug is not considered a maintenance medication by Medi-Span, CVS mail service will only dispense a 30-day supply of medication if stocked.

The following drug categories are available through mail order. Please refer to the Formulary lists for current information:

**Anti-infectives**

Antimycobacterials

**Autonomic & CNS Drugs, Neurology & Psychotherapies**

Antiparkinson Agents (except Apokyn)
Alzheimers Agents
Anticonvulsants
Antidepressants
Antipsychotics
Lithium Carbonate
Anxiolytics
CNS Stimulants (ADHD)

**Cardiovascular Therapy**

Antiarrythmic agents
Cardiac Glycosides
Nitrates
Coagulation Therapy:
    Anticoagulants (oral dosage forms only)
    Antiplatelet Drugs
Thiazide & Related Diuretics
Beta Blockers
Calcium Channel Blockers
Ace Inhibitors
Ace II Antagonists
Adrenergic Antagonists & Related Drugs (excluding Yohimbine)
Vasodilators (except Remodulin and Flolan)
Combination Antihypertensive Agents
Lipid/Cholesterol Lowering Agents

**Endocrine Therapy**

Antithyroid Agents
Thyroid Hormones
Adrenal Hormones

**Diabetes Therapy**

Insulins
Oral Hypoglycemics
Diabetic Supplies (including lancets, test strips)
Insulin Syringes/Needles

**Musculoskeletal & Rheumatology**

Non-steroidal Anti-inflammatory Drugs (NSAIDs)
Cox II Inhibitors
Salicylates (except Fiorinal type products)
Gout Therapy
Rheumatological Agents (except Enbrel, Humira, Kineret, Remicade, Simponi, Cimzia, Actemra, Xeljanz, Otezla and Orencia)
Osteoporosis Therapy (except Forteo, Boniva IV, Prolia and Reclast)

**Obstetric & Gynecology**

Progestins (except Depo-Provera)
Estrogens
Estrogen/progestin combination products
Oral Contraceptives (except emergency contraceptives i.e.: Plan B)
Intravaginal Contraceptives
Transdermal Contraceptives

**Ophthalmology**

Glaucoma Therapy
- Beta Blockers
- Cholinase Inhibitor Miotics
- Direct Acting Miotics
- Oral Glaucoma Therapy
- Sympathomimetics

Other Glaucoma Drugs

**Respiratory and Allergy Therapy - Nasal Steroids**

Non-sedating Antihistamines (except decongestant combinations)

Asthma Medications
- Xanthines
- Bronchodilators, oral and inhalation (long-acting)
- Inhaled Corticosteroids
- Leukotriene Receptor Antagonists
- Nedocromil Sodium
- Misc. Pulmonary Agents (except Revatio, Tracleer, Opsumit, Orenitram XR, Xolair, Ventavis, Pulmozyme, Letairis, Adcirca, Cayston and Tyvaso)

**Electrolytes**
Potassium Replacements

**Genitourinary**
Antispasmotics
Acidifiers
Alkalinizers

**Antineoplastics** (oral dosage forms only)
- Alkylating Agents
- Antimetabolites
- Androgens
- Estrogens
- Progestins
- Antiestrogens
- Antiandrogens

**Immunosuppressant Drugs**

**Gastroenterology**
H2 Antagonists
Prostaglandins
Other Ulcer Therapy
Digestive Enzymes
Inflammatory Bowel . Agents (except Amitiza, Giazo, Lialda, Linzess and Lotronex, Uceris)
Sulfasalazine
Bile Acids
PPIs
BPH Agents

**Vitamins** (federal legend only)

## Exclusions

- Those drugs limited exclusively to specialty pharmacy or special distribution programs.
- Injectable drugs that are not routinely self-administered are not considered eligible for mail order.
- Drugs not suitable for mail delivery, medications indicated for short term use or requiring frequent physician evaluation and/or dose adjustments are not considered eligible for mail order.
- Drugs that are not listed in the Mail Order Drug Categories, have not been prior authorized if required, or are not covered by contract will not be available through the mail order vendor.
- Medicare beneficiaries and select ASO Plans are not limited to the maintenance listing above.
- Drugs which are subject to quantity limits, prior authorization, and/or specialized dispensing requirements may be limited to retail channels only.
- Members must have a mail order benefit to obtain medications by mail.
- Exceptions apply to both brand drugs listed above and generic products if available.
- Non-A/B rated generics are not available through the mail.

## References

Not applicable

**MVP Health Care Medical Policy**

**Male Hypogonadism**

| | |
|---|---|
| **Type of Policy:** | **Drug Therapy** |
| **Prior Approval Date:** | **02/01/2024** |
| **Approval Date:** | **02/01/2025** |
| **Effective Date:** | **04/01/2025** |
| **Related Policies:** | **N/A** |

Refer to the MVP website for the Medicare Part D formulary for drugs that may covered under the Part D benefit.

## Medicaid Variation

- Testopel pellets and Aveed require a trial of self-administered testosterone products and member must meet the diagnostic criteria in the policy below.
- Use in sexual dysfunction and/or erectile dysfunction is excluded from coverage.
- Medications that are a pharmacy benefit are covered and billed to New York State Fee-For-Service (FFS) program. They are defined as medications that go through a retail or specialty pharmacy, including self-administered injectable products. Pharmacy medications are subject to FFS's clinical criteria including (but not limited to) coverage, quantity limit, step therapy, and prior authorization. Pharmacy benefit information can be found here: https://www.emedny.org/info/fullform.pdf

## Codes Requiring Prior Authorization (covered under the medical benefit). (See Medicaid and Medicare Variation)

J3145 Aveed (Testosterone undecanoate 750mg/3ml)

## Codes Requiring Prior Authorization (covered under the medical benefit) when quantity limits are exceeded. (See Medicaid and Medicare Variation)

J3490 Testopel (Testosterone pellet, 75 mg)

S0189 Testopel (Testosterone pellet, 75 mg non-Medicare)

**Drugs Requiring Prior Authorization (covered under the pharmacy benefit)-all products when the quantities below are exceeded. Non-preferred products require prior authorization regardless of quantity. (See Medicaid variation)**

| **Brand Name** | **Chemical Name** | **Quantity Limit every 30 days (applies to both brand name and to generic products)** | **Prior Authorization Required (regardless of quantity)** |
|---|---|---|---|
| Androderm Patches<br>*2mg/24 HR*<br>*4mg/24 HR* | testosterone | 30 patches | Yes |
| Androgel 1% Topical Gel Packets<br>*25mg testosterone in 2.5g gel*<br>*50mg testosterone 5g gel* | testosterone | 150 grams | No |
| Androgel 1.62% Topical Gel/Packets | testosterone | 150 grams | No |
| Aveed Injection | testosterone undecanoate | 3 mL | Yes |
| *Depo-Testosterone Injection<br>*100mg/mL*<br>*200mg/mL* | testosterone cypionate | 10 mL | Yes (brand name only) |
| Fortesta Gel<br>*10mg/act* | testosterone | 60 grams | Yes (brand name only) |
| Kyzatrex Capsules<br>100mg<br>150mg<br>200mg | Testosterone undecanoate | 120 capsules | Yes |
| Jatenzo Capsules<br>*158mg*<br>*198mg* | testosterone undecanoate | 120 capsules | Yes |

| | | | |
|---|---|---|---|
| *237mg* | | | |
| ^Methitest Tablets *10mg* | methyltestosterone | 30 tablets | Yes |
| ^Methyltestosterone Capsules | methyltestosterone | 30 capsules | Yes |
| Natesto Nasal Gel *5.5mg* | testosterone | Three tubes | Yes |
| Striant Buccal Tablets *30mg* | testosterone | 60 buccal tablets | Yes |
| Testim Gel/Packets (One tube = 50mg testosterone) | testosterone | 150 grams | No |
| Testopel | testosterone pellets | 10 pellets | No |
| Testosterone Topical Solution/Pump *30mg/act* | testosterone | 90 mL | No |
| *Testosterone IM Injection *200mg/mL* | testosterone enanthate | One 5 mL vial | No |
| Vogelxo 1% Gel Pump *(One tube or packet provides 50mg testosterone in 5g of gel) (One pump actuation delivers 12.5mg testosterone in 1.25g of gel. 4 actuations = 50mg testosterone)* | testosterone | 150 grams | Yes (brand name only) |
| Xyosted Injection *50mg/0.5mL 75mg/0.5mL 100mg/0.5mL* | testosterone enanthate | 5 mL (10 pens) | Yes |

| | | | |
|---|---|---|---|
| | | | |

**QL applies when adjudicated through the pharmacy benefit manager*

*^Modified testosterone 17a-methyltestosterone, is not recommended as a therapy for treatment of hypogonadism per the Endocrine Society Guidelines due to its hepatoxic side effects*

Anabolic Steroids:

| **Drug Name** | **chemical name** | **Quantity per 30 days[#] without PA** | **Prior authorization required regardless of quantity** |
|---|---|---|---|
| Anadrol | oxymetholone | 30 tablets | Yes |
| Oxandrin | oxandrolone | 60 tablets | Yes (brand name only) |

[#] 90 days supplies are available if the benefit allows.

## Overview

Endogenous androgens such as testosterone, are responsible for the normal growth and development of the male sex organs and for maintenance of secondary sex characteristics. Male hypogonadism results from insufficient secretion of testosterone and is characterized by low serum testosterone concentrations (normal range of serum total testosterone is 300-1000 ng/dL). Signs and symptoms associated with male hypogonadism include erectile dysfunction and decreased sexual desire, fatigue and loss of energy, mood depression, regression of secondary sexual characteristics and osteoporosis. Individuals with HIV and on high dose glucocorticoids may experience hypogonadism and may benefit from testosterone therapy. Anabolic steroids are synthetic derivatives of testosterone.

## Indications/Criteria

The following criteria must be met for coverage:

- Biologically male; **AND**
- Early morning serum testosterone level below the lower limit of normal range for healthy young men established in the laboratory (200 to 400 ng/dL) prior

to start of therapy. The target of therapy should be the mid-normal range of serum total testosterone; **AND**

- Confirmation of early morning serum total testosterone level **on a separate occasion** OR if the patient is suspected to have alterations in sex hormone-binding globulin (SHBG) measurement below the lower limit of normal established in the laboratory of early morning free testosterone (=50 pg/mL measured by equilibrium dialysis or =65 pg/mL for calculated) or bioavailable testosterone using an accurate and reliable assay. Conditions associated with alterations in SHBG concentration include moderate obesity, nephritic syndrome, hypothyroidism, acromegaly, diabetes mellitus, aging, hepatic cirrhosis and hepatitis, hyperthyroidism, HIV disease, polymorphisms in the SHBG gene, or use of glucocorticoids, progestins, and androgenic steroids, anticonvulsants, and estrogens; **AND**
- Consistent (daily) signs and symptoms of testosterone deficiency**.** Specific symptoms must be provided with each request. (i.e. incomplete or delayed sexual development, eunuchoidism, loss of body (axillary and pubic) hair significant muscle loss or fatigue interfering with activities of daily living, breast discomfort, gynecomastia, very small testes (especially 6mL), low trauma fracture, low bone mineral density); **AND**
- Documentation of:
    - Baseline hematocrit below 48%. For reauthorization of coverage repeat annually.
    - Baseline PSA level prior to initiation of testosterone therapy in men 40 years of age or older. For reauthorization of coverage repeat PSA level at 3-12 months, and then in accordance with prostate cancer screening guidelines; **AND**
- Prior Authorization is required for all non-preferred agents (tier 3) products and documented trial and failure or contraindication to Androgel and Testim is required.
- All agents require prior authorization for quantities exceeding the quantity limit for 30 days stated above.

**Initial approval** for **6 months**.

**Extension of therapy up to 12 months** will be provided if documentation identifies continued benefit including improvement in symptoms and an increase in serum testosterone levels to within normal limits (if used for testosterone deficiency).

**Exclusions**

- Indication, age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling. Enhancement of athletic ability or for bodybuilding beyond what is required for activities of daily living
- Hematocrit >48% (>50% for men living at high altitude)
- Metastatic prostate cancer
- Breast cancer
- PSA > 4 ng/ml (>3 ng/ml in individuals at high risk for prostate cancer, such as African Americans or men with first-degree relatives who have prostate cancer)
- Uncontrolled or poorly controlled congestive heart failure
- Untreated severe obstructive sleep apnea
- Severe lower urinary tract symptoms associated with benign prostatic hypertrophy as indicated by AUA/IPSS score > 19
- Myocardial infarction or stroke within the last six months
- Thrombophilia
- Unevaluated prostate nodule or induration
- Desire for fertility in the near term
- Requests for therapy to increase serum total testosterone level above mid-normal range
- First-Testosterone cream/ointment are excluded from coverage
- Testosterone implant pellets 87.5mg, 100mg, 200mg are excluded from coverage
- Jatenzo
    - Use in men with hypogonadal conditions not associated with structural or genetic etiologies
- Age-related hypogonadism

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15. Testim (testosterone gel) package insert. St-Laurent, Quebec; Paladin Labs, Inc. ; 2017 Feb.
16. Testopel (testosterone pellets) package insert. Malvern, PA: Endo Pharmaceuticals Inc.; 2024 Mar.
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19. Bhasin S, Brito JP, Cunningham GR, et al. Testosterone therapy in men with hypogonadism: an endocrine society clinical practice guideline. J Clin Endocrinol Metab. 2018 May;103(5):1715-1744.
20. Xyosted (testosterone enanthate) package insert. Ewing, NJ. Antares Pharma, Inc. 2019 November.
21. Vogelxo (testosterone) package insert. Maple Grove, MN. Upsher-Smith Laboratories, LLC.; 2019 May.
22. Androxy (fluoxymesterone) package insert. Maple Grove, MN. Upsher-Smith Laboratories, LLC.; 2017 Sep.
23. Aveed (testosterone undecanoate) package insert. Malvern, PA. Endo Pharmaceuticals Inc.; 2021 Aug.

24. Methyltestosterone Capsules package insert. Bridgewater, NJ. Amneal Pharmaceuticals LLC; 2019 May.
25. Jatenzo package insert. Northbrook, IL. Clarus Therapeutics, Inc.; 2019 Mar.

| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Complete Wellness | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D |
| USA Care PPO | Refer to the MVP website for the Medicare Part B and Part D |
| 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 | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

**Medicare Part B: Male Hypogonadism**

| | |
|---|---|
| **Type of Policy:** | **Medical Therapy** |
| **Prior Approval Date:** | **N/A** |
| **Approval Date:** | **02/01/2025** |
| **Effective Date:** | **04/01/2025** |
| **Related Policies:** | **Medicare Part B Drug Therapy** |

Refer to the MVP website for the Medicare Part D formulary for drugs that may covered under the Part D benefit.

- **Please refer to relevant CMS LCDs/NCDs/Policy Articles for most up to date Medicare Part B guidance if available.**

**Codes Requiring Prior Authorization (covered under the medical benefit).**

J3145 Aveed (Testosterone undecanoate 750mg/3ml)

**Codes Requiring Prior Authorization (covered under the medical benefit) when quantity limits are exceeded. Quantities greater than 10 pellets.**

J3490 Testopel (Testosterone pellet, 75 mg)

## Overview

Endogenous androgens such as testosterone, are responsible for the normal growth and development of the male sex organs and for maintenance of secondary sex characteristics. Male hypogonadism results from insufficient secretion of testosterone and is characterized by low serum testosterone concentrations (normal range of serum total testosterone is 300-1000 ng/dL). Signs and symptoms associated with male hypogonadism include erectile dysfunction and decreased sexual desire, fatigue and loss of energy, mood depression, regression of secondary sexual characteristics and osteoporosis. Individuals with HIV and on high dose glucocorticoids may experience hypogonadism and may benefit from testosterone therapy.

## Indications/Criteria

The following criteria must be met for coverage of **Aveed**:

- Member has coverage under Medicare Part B and meets the criteria for a not usually self-administered, physician administered Medicare Part B covered drug **AND**
- Biologically Male; **AND**
- Early morning serum testosterone level below the lower limit of normal range for healthy young men established in the laboratory (200 to 400 ng/dL) prior to start of therapy. The target of therapy should be the mid-normal range of serum total testosterone; **AND**
- Confirmation of early morning serum total testosterone level **on a separate occasion** OR if the patient is suspected to have alterations in sex hormone-binding globulin (SHBG) measurement below the lower limit of normal established in the laboratory of early morning free testosterone (=50 pg/mL measured by equilibrium dialysis or =65 pg/mL for calculated) or bioavailable testosterone using an accurate and reliable assay. Conditions associated with alterations in SHBG concentration include moderate obesity, nephritic syndrome, hypothyroidism, acromegaly, diabetes mellitus, aging, hepatic cirrhosis and hepatitis, hyperthyroidism, HIV disease, polymorphisms in the SHBG gene, or use of glucocorticoids, progestins, and androgenic steroids, anticonvulsants, and estrogens; **AND**
- Consistent (daily) signs and symptoms of testosterone deficiency**.** Specific symptoms must be provided with each request. (i.e. incomplete or delayed sexual development, eunuchoidism, loss of body (axillary and pubic) hair significant muscle loss or fatigue interfering with activities of daily living, breast discomfort, gynecomastia, very small testes (especially 6mL), low trauma fracture, low bone mineral density); **AND**
- Documentation of:
    - Baseline hematocrit below 48%. For reauthorization of coverage repeat annually.
    - Baseline PSA level prior to initiation of testosterone therapy in men 40 years of age or older. For reauthorization of coverage repeat PSA level at 3-12 months, and then in accordance with prostate cancer screening guidelines; **AND**

**Initial approval** will be for **12 months**.

**Extension of therapy** will be for **12 months** will be provided if documentation identifies continued benefit including improvement in symptoms and an increase in serum testosterone levels to within normal limits (if used for testosterone deficiency).

## Exclusions

- Indication, age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling.
- Enhancement of athletic ability or for bodybuilding beyond what is required for activities of daily living
- Hematocrit >48% (>50% for men living at high altitude)
- Metastatic prostate cancer
- Breast cancer
- PSA > 4 ng/ml (>3 ng/ml in individuals at high risk for prostate cancer, such as African Americans or men with first-degree relatives who have prostate cancer)
- Uncontrolled or poorly controlled congestive heart failure
- Untreated severe obstructive sleep apnea
- Severe lower urinary tract symptoms associated with benign prostatic hypertrophy as indicated by AUA/IPSS score > 19
- Myocardial infarction or stroke within the last six months
- Thrombophilia
- Unevaluated prostate nodule or induration
- Desire for fertility in the near term
- Requests for therapy to increase serum total testosterone level above mid-normal range
- Testosterone implant pellets 87.5mg, 100mg, 200mg are excluded from coverage
- Age-related hypogonadism

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## References

1. AACE Hypogonadism Task Force. American Association of Clinical Endocrinologists medical guidelines for clinical practice for the evaluation and treatment of hypogonadism in adult male patients. Endocrine Practice Vol 8 No. 6 November/December 2002.
2. Bhasin S, Cunningham GR, Hayes FJ, et al. Testosterone therapy in adult men with androgen deficiency syndromes: an endocrine society clinical practice guideline. J Clin Endocrinol Metab. 2010 Jun;95(6):2536-59.

3. Bhasin S, Brito JP, Cunningham GR, et al. Testosterone therapy in men with hypogonadism: An endocrine society clinical practice guideline. J Clin Endocrinol Metab. 2018 May;103(5):1715-1744.
4. Testopel (testosterone pellets) package insert. Malvern, PA: Endo Pharmaceuticals Inc.; 2024 Mar.
5. Aveed (testosterone undecanoate) package insert. Malvern, PA. Endo Pharmaceuticals Inc.; 2021 Aug.

**MVP Health Care Medical Policy**

**Medicare Part B Drug Therapy**

| | |
|---|---|
| **Type of Policy:** | **Drug/Medical Therapy** |
| **Prior Approval Date:** | **01/01/2024** |
| **Approval Date:** | **11/01/2024** |
| **Effective Date:** | **01/01/2025** |
| **Related Policies:** | **Pharmacy Programs Administration** |
| | **Medicare Part B vs. Part D Determination** |
| | **Medicare Part B Step Therapy** |

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies for drugs that may be covered under the Part D benefit.

## Overview

Medical outpatient medications are covered under the Medicare Part B benefit, in accordance with Medicare coverage criteria when furnished incident to a physician service for drugs that are not usually self-administered. MVP Medicare Part B medical policies are put in place to implement prior authorization requirements for prescription drugs that are administered by a healthcare professional or medical facility.

Coverage is limited to drugs or biologicals administered by infusion or injection. However, if the injection is generally self-administered, it is not covered under Part B. Despite this general limitation on coverage for outpatient drugs under Part B, some self-administered drugs may also be covered under Part B. Refer to the MVP Policy Medicare Part B vs Part D Coverage Determination Policy for coverage criteria of these drugs.

## Criteria

Members already established on therapy
A member cannot be required to change drug therapy if they are currently established on the therapy as determined by provider documentation and/or a paid claim for the drug within the past 365 days. Refer to the MVP Policy Medicare Part B Step Therapy.

A minimum 90-day transition period will be provided when a member who is currently undergoing treatment switches to a new Medicare plan or is new to Medicare.

CMS National and Local Coverage Determinations
Certain medical drugs covered under Part B follow Medicare National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs) and therefore, some drugs are not included in the MVP Medicare Part B medical policies.

**MVP Medicare Part B medical policies are supplements to Medicare NCDs or LCDs and do not supersede CMS criteria outlined within an applicable NCD, LCD, or policy article. Refer to www.cms.gov for the most up to date coverage criteria and billing guidance for specific medical drugs.** MVP Medicare Part B policy criteria has been developed based upon review of clinical treatment guidelines, and clinical literature and evidence (ie. clinical trials). The following factors are considered during the development of clinical criteria: multiple drugs or treatments available to treat the same condition(s), routes of administration, sites of administration, place in therapy, comparative efficacy and safety considerations.

## Coverage Duration

Initial therapy will be up to 6 months in duration and continuation of coverage will be up to 12 months unless otherwise specified within the policy or as indicated by provider's recommended dosing regimen.

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## References

1. Medicare Benefit Policy Manual. Chapter 15. Covered Medical and Other Health Services. Revised 06/13/2024. Available: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf
2. Medicare Claims Processing Manual. Chapter 17- Drugs and Biologicals. Revised 02/15/2024. Available: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c17.pdf

3. Medicare Prescription Drug Benefit Manual, Chapter 6. Available at https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/part-d-benefits-manual-chapter-6.pdf
4. Medicare Coverage Database. https://cms.gov/medicare-coverage-database/search.aspx

**Medical Drug List**

**Revised:** **08/01/2025**

## Overview

**On label use** of medical drugs are covered under the member's medical benefit and are subject to retro-review only.

**Off label use** is subject to prior authorization and must meet MVP's clinical coverage criteria for Experimental or Investigational Procedures Experimental or Investigational Procedures, Behavioral Health Services, Drugs and Treatments, Off-Label use of FDA Approved Drugs, and Clinical Trials Policy.

**New to Market Drugs**: This List also includes new drugs that have recently been introduced to the market (notated in the "Notes" column). It is MVP's policy not to cover newly introduced drugs until they have been reviewed by MVP's Pharmacy and Therapeutics (P&T) or Medical Management (AMMC) Committee. The designated committee will evaluate the merits of adding the new drug to those accepted for reimbursement. If it is determined that a new drug has significant clinical and therapeutic advantage over drugs currently accepted by MVP, the drug will be added to the formulary.

**J3490, J9999** and **J3590** are miscellaneous codes which requires prior authorization.

**Excluded** medical drugs are not covered on the formularies. Providers may request a coverage determination or prior authorization.

**Optum Cancer Guidance Program:** Effective 01/01/2024, medical oncology medications will be reviewed by a delegated vendor Optum. Impacted codes are listed below under the "Optum Cancer Guidance Program Review". These codes may also appear in the "Medical Drug List" and their Optum status will be listed in the Notes column.

The Medical Drug List and the Optum Cancer Guidance Program list are not an all-inclusive.

# Medical Drug List

**Unless indicated in the "Notes" column, the medical drugs below do not require prior authorization for **on label use**

| Medication | Billing Code(s) | Notes |
|---|---|---|
| Abilify Asimtufii (injection, aripiprazole, extended release) | J0402 | |
| Abilify-Maintena (Injection, aripiprazole, extended release, 1 mg) | J0401 | |
| Actemra tocilizumab, 1mg injection (Actemra injection) | J3262 | Subject to Tocilizumab policy and may be subject to Site of Care |
| Adakveo Injection, crizanlizumab-tmca, 5mg | J0791 | Subject to Adakveo policy and may be subject to Site of Care |
| Adcetris (Injection, brentuximab vedotin, 1 mg) | J9042 | See Optum List if treatment is being used for a cancer diagnosis |
| Adstiladrin (inj, nadofaragene firadenovec-vncg) | J9029 | See Optum List if treatment is being used for a cancer diagnosis |
| Adzynma (ADAMTS13, Recombinant) | J7171 | Prior Authorization per Orphan Drug(s) and Biologicals Policy |
| Akynzeo (Injection, fosnetupitant 235 mg and palonosetron 0.25 mg) | J1454 | See Optum List if treatment is being used for a cancer diagnosis |
| Aldurazyme (Inj, laronidase, 0.1 mg) | J1931 | Subject to Orphan Drug(s) and Biologicals policy and may be subject to Site of Care |
| Aliqopa (Injection, copanlisib, 1 mg) | J9057 | See Optum List if treatment is being used for a cancer diagnosis |
| Aloxi Injection (Injection, palonosetron HCl, 25) mcg) | J2469 | See Optum List if treatment is being used for a cancer diagnosis |
| Alymsys (Injection, bevacizumab) | Q5126 | See Optum List if treatment is being used for a cancer diagnosis |
| Amvuttra (Injection, vutrisiran, 1 mg) | J0225 | Subject to Transthyretin-Mediated Amyloidosis Therapy policy and may be subject to Site of Care |
| Andexxa | J7169 | |

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|---|---|---|
| (Injection, coagulation factor Xa (recombinant), inactivated (andexxa), 10 mg) | | |
| Anktiva (nogapendekin alfa inbakicept, intravesical)) | J9028 | See Optum List if treatment is being used for a cancer diagnosis |
| Aphexda (motixafortide) | J2277 | |
| Aponvie (aprepitant,fosaprepitant) | J3490 | |
| Apretude (Injection, cabotegravir) | J0739 | |
| Aralast-NP (Injection, alpha 1-proteinase inhibitor, human, 10 mg, not otherwise specified) | J0256 | |
| Aranesp Injection, darbepoetin alfa, (for non-esrd use) | J0881 | See Optum List if treatment is being used for a cancer diagnosis |
| Aristada (Injection, aripiprazole lauroxil, (aristada initio), 1 mg) | J1943, J1944 | |
| Asparlas (calaspargase pegol-mknl) injection for intravenous use | J9118 | See Optum List if treatment is being used for a cancer diagnosis |
| Aucatzyl (obecabtagene Autoleucel) | J9999 | Subject to 6-month new drug. Prior authorization required. |
| Aurlumyn (Injection, iloprost, 0.1 mcg) | J1749 | |
| Avastin (bevacizumab) | C9257, J9035 | See Optum List if treatment is being used for a cancer diagnosis |
| Avsola (Infliximab, 10mg) | Q5121 | Subject to Infliximab policy and may be subject to Site of Care |
| Azmiro (testosterone) | J1072 | Subject to 6-month new drug. Prior authorization required. |
| BabyBIG (Botulism Immune Globulin) | 90288 | Note: This is supplied, billed and obtained directly though the California Department of Public Health |
| Balfaxar (prothrombin complex concentrate, human) | J7165 | |
| Barhemsys | J0184 | See Optum List if treatment is being used for a cancer diagnosis |

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|---|---|---|
| (amisulpride, injection for intravenous use) | | |
| Bavencio (Injection, avelumab) | J9023 | See Optum List if treatment is being used for a cancer diagnosis |
| Beleodaq (Injection, belinostat) | J9032 | See Optum List if treatment is being used for a cancer diagnosis |
| Bendeka (Injection, bendamustine) | J9034 | See Optum List if treatment is being used for a cancer diagnosis |
| Benlysta (Injection, belimumab) | J0490 | |
| Beovu (brolucizumab-dbll) injection for intravitreal injection | J0179 | |
| Berinert (Injection, C1 esterase inhibitor (human), 10 units) | J0597 | Subject to Hereditary Angioedema policy and may be subject to Site of Care |
| Besponsa (Injection, inotuzumab ozogamicin) | J9229 | See Optum List if treatment is being used for a cancer diagnosis |
| Bizengri (zenocutuzumab) | J9382 | See Optum List if treatment is being used for a cancer diagnosis. |
| Bkemv (eculizumab-aeeb,biosimilar) | Q5152 | Subject to Eculizumab policy and may be subject to Site of Care |
| Blincyto (Injection, blinatumomab) | J9039 | See Optum List if treatment is being used for a cancer diagnosis |
| Boniva IV (Injection, ibandronate) | J1740 | |
| Boruzu (Injection, bortezomib (boruzu), 0.1 mg) | J9054 | See Optum List if treatment is being used for a cancer diagnosis |
| Botox (Injection, onabotulinumtoxinA, 1 unit) | J0585 | Prior authorization is not required for **on label** use and off label compendia supported use. Off label compendia supported use must meet the requirements of the Experimental and Investigational policy. Cosmetic use and formulations are not covered per Cosmetic Drug Agents policy |
| Briumvi (Ublituximab) | J2329 | Subject to the Multiple Sclerosis policy and Site of Care |
| Brixadi (buprenorphine) | J0576, J0577, J0578 | |

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|---|---|---|
| Byooviz<br>(ranibizumab-nuna) | Q5124 | |
| Cabenuva<br>(cabtegravir, rilpivirine) | J0741 | |
| Caldolor<br>(ibuprofen, inj) | J1741 | |
| Camcevi<br>(Leuoprolide inj 1mg) | J1952 | See Optum List if treatment is being used for a cancer diagnosis |
| Caspofungin<br>(Injection, caspofungin acetate) | J0637 | |
| Ceftriaxone, per 250mg | J0696 | Prior authorization required when used for the treatment of Lyme Disease. See "Lyme Disease/IV Antibiotic Treatment". |
| Cerezyme<br>(imiglucerase, 10 units) | J1786 | Subject to Gaucher Disease Type 1 Treatment policy and may be subject to Site of Care |
| Cimerli<br>(ramibizumab) | Q5128 | |
| Cinryze<br>(Injection, C1 esterase inhibitor (human), 10 units) | J0598 | Subject to Hereditary Angioedema policy and may be subject to Site of Care |
| Cinvanti<br>(aprepitant) | J0185 | See Optum List if treatment is being used for a cancer diagnosis |
| Columvi<br>(glofitamab) | J9286 | See Optum List if treatment is being used for a cancer diagnosis |
| Cosela<br>(Trilaciclib) | J1448 | See Optum List if treatment is being used for a cancer diagnosis |
| Crysvita<br>(inj, burosumab-twza 1 mg) | J0584 | Subject to Orphan Drug(s) and Biologicals policy and may be subject to Site of Care |
| Cyramza<br>(Injection, ramucirumab) | J9308 | See Optum List if treatment is being used for a cancer diagnosis |
| Dalvance<br>(Injection, dalbavancin) | J0875 | |
| Danyelza<br>(injection, naxitamab) | J9348 | Prior Authorization per Orphan Drug and Biologicals Policy. See Optum List if treatment is being used for a cancer diagnosis |
| Darzalex<br>(Injection, daratumumab) | J9145 | See Optum List if treatment is being used for a cancer diagnosis |
| Darzalex Faspro | J9144 | |

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|---|---|---|
| (subcutaneous inj, daratumumab and hyaluronidase-fihj) | | |
| Datroway (datopotamab deruxtecan) | J9999 | Subject to 6-month new drug. Prior authorization required |
| Daxxify (injection, daxibotulinumtoxina-lanm) | J0589 | Prior authorization is not required for **on label** use and off label compendia supported use. Off label compendia supported use must meet the requirements of the Experimental and Investigational policy. Cosmetic use and formulations are not covered per Cosmetic Drug Agents policy |
| Defitelio (injection, defibrotide) | J3490 | |
| Diphenhydramine (Injection, diphenhydramine HCl, up to 50 mg) | J1200 | |
| Dsuvia (sufentanil tablets) | J8499 | Excluded |
| Durysta (bimatoprost implant) | J7351 | |
| Dysport (Injection, abobotulinumtoxinA, 5 units) | J0586 | Prior authorization is not required for **on label** use and off label compendia supported use. Off label compendia supported use must meet the requirements of the Experimental and Investigational policy. Cosmetic use and formulations are not covered per Cosmetic Drug Agents policy |
| Elahere (mirvetuximab soravtansine injection) | J9063 | See Optum List if treatment is being used for a cancer diagnosis |
| Elaprase (Inj, idursulfase) | J1743 | Subject to Orphan Drug(s) and Biologicals policy and may be subject to Site of Care |
| Elelyso (Injection, taliglucerase alfa, 10 units) | J3060 | Subject to Gaucher Disease Type 1 Treatment policy and may be subject to Site of Care |
| Elfabrio (pegunigalsidase alfa), solution for injection | J2508 | |
| Eligard | J9217 | See Optum List if treatment is being used for a cancer diagnosis |

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|---|---|---|
| (Leuprolide acetate (for depot suspension) | | |
| Elrexfio (elranatamab, injection) | J1323 | See Optum List if treatment is being used for a cancer diagnosis |
| Emblaveo (aztreonam and avibactam) | J3490 | Subject to 6-month new drug. Prior authorization required |
| Emend injection (injection, fosaprepitant) | J1453 | See Optum List if treatment is being used for a cancer diagnosis |
| Empliciti (Injection, elotuzumab) | J9176 | See Optum List if treatment is being used for a cancer diagnosis |
| Emrelis (telisotuzumab vedotin) | J9999 | Subject to 6-month new drug. Prior authorization required |
| Encelto (Revakinagene Taroretcel) | J3590 | Subject to 6-month new drug. Prior authorization required |
| Enflonsia (Respiratory syncytial virus, monoclonal antibody, seasonal dose, 0.7 mL, for intramuscular use) | J3590 | Subject to 6-month new drug. Prior authorization required |
| Enjaymo (sutimlimab-jome) | J1302 | Prior Authorization per the Orphan Drug Policy |
| Entyvio (vedolizumab, injection 1mg) | J3380 | Subject to Entyvio policy and may be subject to Site of Care |
| Epogen/Procrit Injection, epoetin alfa, (for non-esrd use) | J0885 | See Optum List if treatment is being used for a cancer diagnosis |
| Epysqli (eculizumab) | Q5151 | Subject to Eculizumab policy and may be subject to Site of Care |
| Epkinly (epcoritamab) solution for injection | J9321 | See Optum List if treatment is being used for a cancer diagnosis |
| Erwinaze (Injection, asparaginase) | J9019 | |
| Erzofri (paliperidone) | J2428 | |
| Evenity (Injection, romosozumab-aqqg) | J3111 | |
| Evomela (Injection, melphalan hydrochloride) | J9245 | See Optum List if treatment is being used for a cancer diagnosis |
| Exparel (injection, bupivacaine) | J0666 | Excluded |
| Eylea HD | J0177 | |

| | | |
|---|---|---|
| (aflibercept) | | |
| Eylea<br>(aflibercept) | J0178 | |
| Fabrazyme<br>(Injection, agalsidase beta) | J0180 | |
| Famotidine<br>(Injection, famotidine, 0.25 mg) | J1308 | |
| Feraheme<br>(Injection, ferumoxytol) | Q0138, Q0139 | |
| Ferrlecit<br>(Injection, sodium ferric gluconate complex in sucrose injection) | J2916 | |
| Fetroja<br>(cefiderocol, IV) | J0693 | |
| Firmagon<br>(Injection, degarelix) | J9155 | See Optum List if treatment is being used for a cancer diagnosis |
| Focinvez<br>(fosasprepitant) | J1434 | See Optum List if treatment is being used for a cancer diagnosis |
| Furoscix<br>(furosemide controlled release on body infuser) | J1941 | |
| Fyarro<br>(Injection, nanoparticle albumin-bound sirolimus) | J9331 | See Optum List if treatment is being used for a cancer diagnosis |
| Gazyva<br>(Injection, obinutuzumab) | J9301 | See Optum List if treatment is being used for a cancer diagnosis |
| Glassia<br>(Injection, alpha 1 proteinase inhibitor (human)) | J0257 | |
| Gleolan | J8499 | |
| Grafapex<br>(treosulfan) | J9999 | Subject to 6-month new drug. Prior authorization required. |
| Granix<br>(Injection, tbo-filgrastim) | J1447 | See Optum List if treatment is being used for a cancer diagnosis |
| Herceptin<br>(trastuzumab) | J9355 | See Optum List if treatment is being used for a cancer diagnosis |
| Herceptin Hylecta<br>(trastuzumab) | J9356 | See Optum List if treatment is being used for a cancer diagnosis |
| Hercessi | Q5146 | See Optum List if treatment is being used for a cancer diagnosis |

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| (trastuzumab-strf (hercessi), biosimilar, 10 mg) | | |
| Halaven<br>(Injection, eribulin mesylate) | J9179 | See Optum List if treatment is being used for a cancer diagnosis |
| Herzuma<br>(Injection, traztuzumab-pkrb) | Q5113 | See Optum List if treatment is being used for a cancer diagnosis |
| Hyaluronic Acid Derivatives | J7318<br>J7320<br>J7321<br>J7322<br>J7323<br>J7324<br>J7325<br>J7326<br>J7327<br>J7328<br>J7329<br>J7331<br>J7332 | Not covered for MVP Medicaid Managed Care Products when billed with diagnosis codes for osteoarthritis of the knee as Listed in the Viscosupplementation of the knee: Non-Coverage for Medicaid Managed Care Plans Payment Policy |
| IDose TR<br>(travoprost implant) | J7355 | Excluded |
| Iheezo gel<br>(chloroprocaine) | J2403 | |
| Ilumya<br>(Injection, tildrakizumab, 1mg) | J3245 | Excluded |
| Imaavy<br>(Nipocalimab, solution for injection) | J3590 | Subject to 6-month new drug. Prior authorization required. |
| Imdelltra<br>(tarlatamab, injection) | J9026 | See Optum List if treatment is being used for a cancer diagnosis |
| Imfinzi<br>(Injection, durvalumab) | J9173 | See Optum List if treatment is being used for a cancer diagnosis |
| Imjudo<br>(Injection, tremelimumab) | J9347 | See Optum List if treatment is being used for a cancer diagnosis |
| Imlygic<br>(Injection, talimogene laherparepvec) | J9325 | See Optum List if treatment is being used for a cancer diagnosis |
| Inflectra<br>(Injection, infliximab, 10mg) | Q5103 | Subject to Infliximab policy and may be subject to Site of Care |
| Injectafer<br>(Injection, ferric carboxymaltose) | J1439 | |

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| Invega Hafyera (paliperidone palmitate extended release) | J2426 | |
| Invega- Sustenna (Injection, paliperidone palmitate extended release) | J2426 | |
| Invega- Trinza (paliperidone) | J2427 | |
| Ixempra (Injection, ixabepilone) | J9207 | See Optum List if treatment is being used for a cancer diagnosis |
| Jelmyto (mitomycin) | J9281 | |
| Jemperli (Dostarlimab, solution for injection) | J9272 | See Optum List if treatment is being used for a cancer diagnosis |
| Jetrea (Injection, ocriplasmin) | J7316 | |
| Jevtana (Injection, cabazitaxel) | J9043 | See Optum List if treatment is being used for a cancer diagnosis |
| Jubbonti (Injection, denosumab-bbdz biosimilar, 1 mg) | Q5136 | See Optum List if treatment is being used for a cancer diagnosis |
| Kadcyla (Injection, ado-trastuzumab emtansine) | J9354 | See Optum List if treatment is being used for a cancer diagnosis |
| Kanjinti (trastuzumab) | Q5117 | See Optum List if treatment is being used for a cancer diagnosis |
| Kebilidi (eladocagene exuparvovec-tneq) | J3590 | Subject to 6-month new drug. Prior authorization required. |
| Kepivance (Injection, palifermin, 50 micrograms) | J2425 | |
| Keytruda (pembrolizumab) | J9271 | See Optum List if treatment is being used for a cancer diagnosis |
| Kimmtrak (tebentafusp-tebn) | J9274 | See Optum List if treatment is being used for a cancer diagnosis |
| Kimyrsa (oritavancin inj) | J2406 | |
| Korsuva (difelikefalin, 0.1mcg) | J0879 | |
| Kyleena | J7296 | |

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| (Levonorgestrel-releasing intrauterine contraceptive system) | | |
| Kyprolis (carfilzomib) | J9047 | See Optum List if treatment is being used for a cancer diagnosis |
| Lamzede (velmanase alfa, injection) | J0127 | Prior Authorization per Orphan Drugs and Biologicals policy |
| Lartruvo (olaratumab) | J9285 | See Optum List if treatment is being used for a cancer diagnosis |
| Leqvio (injection, inclisiran, 1mg) | J1306 | Excluded |
| Libtayo (cemiplimab-rwlc) | J9119 | See Optum List if treatment is being used for a cancer diagnosis |
| Liletta (Levonorgestrel-releasing intrauterine contraceptive system) | J7297 | |
| Loqtorzi (toripalimab) | J3263 | See Optum List if treatment is being used for a cancer diagnosis |
| Lucentis (ranibizumab) | J2778 | |
| Lumizyme (Inj, alglucosidase alfa) | J0221 | Subject to Orphan Drug(s) and Biologicals policy and may be subject to Site of Care |
| Lunsumio (mosunetuzumab) | J9350 | See Optum List if treatment is being used for a cancer diagnosis |
| Lupron Depot (Leuprolide acetate (for depot suspension)) | J9217, J1950 | See Optum List if treatment is being used for a cancer diagnosis |
| Lymphir (Injection, denileukin diftitox-cxdl) | J9161 | See Optum List if treatment is being used for a cancer diagnosis |
| Lynozyfic (linvoseltamab) | J3490 | Subject to 6-month new drug. Prior authorization required. |
| Macrilen (macimorelin) | C9399 | |
| Makena (Injection, hydroxyprogesterone caproate) | J1726 | |
| Margenza (margetuximab-cmkb) | J9353 | See Optum List if treatment is being used for a cancer diagnosis |
| Marqibo (Injection, vincristine sulfate liposome) | J9371 | |

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| Mirena<br>(Levonorgestrel-releasing intrauterine contraceptive system) | J7298 | |
| Monoferric<br>(injection, ferric derisomaltose, 10mg) | J1437 | |
| Monjuvi<br>(tafasitamab) | J9349 | See Optum List if treatment is being used for a cancer diagnosis |
| Mvasi<br>(bevacizumab) | Q5107 | See Optum List if treatment is being used for a cancer diagnosis; |
| Mylotarg<br>(Injection, gemtuzumab ozogamicin) | J9203 | See Optum List if treatment is being used for a cancer diagnosis |
| Myobloc<br>(Injection, rimabotulinumtoxinB, 100 units) | J0587 | Prior authorization is not required for **on label** use and off label compendia supported use. Off label compendia supported use must meet the requirements of the Experimental and Investigational policy. Cosmetic use and formulations are not covered per Cosmetic Drug Agents policy |
| Myxredlin<br>(insulin human in sodium chloride injection), for intravenous use | J3590 | |
| Naglazyme<br>(Inj, galsulfase, 1 mg) | J1458 | Subject to Orphan Drug(s) and Biologicals policy and may be subject to Site of Care |
| Nexobrid<br>(anacaulase) | J7353 | |
| Nexplanon<br>(Etonogestrel (contraceptive) implant system) | J7307 | |
| Niktimvo<br>(axatilimab-csfr) | J9038 | Subject to 6-month new drug. Prior authorization required. |
| Nivestym IV<br>(Injection, filgrastim-aafi) | Q5110 | See Optum List if treatment is being used for a cancer diagnosis |
| Nplate<br>(Injection, romiplostim) | J2796 | |

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| Nplate<br>(Injection, romiplostim) | J2802 | See Optum List if treatment is being used for a cancer diagnosis |
| Nulojix<br>(Injection, belatacept) | J0485 | |
| Nuzyra IV<br>(Injection, omadacycline) | J0121 | |
| Nypozi<br>(Injection, filgrastim-txid (nypozi), biosimilar) | Q5148 | Subject to 6-month new drug. Prior authorization required. See Optum List if treatment is being used for a cancer diagnosis |
| Ocrevus<br>(Injection, ocrelizumab) | J2350 | May be subject to Site of Care |
| Ocrevus Zunovo<br>(Injection, ocrelizumab) | J2351 | May be subject to Site of Care |
| Ogivri<br>(Trastuzumab) | Q5114 | See Optum List if treatment is being used for a cancer diagnosis |
| Olinvyk<br>(oliceridine) | J3490 | |
| Omegaven<br>(10 grams lipids) | B4187 | Excluded |
| Omvoh<br>(mirikizumab, solution for injection, IV) | J2267 | Exclude |
| Ondansetron<br>(Injection, ondansetron hydrochloride, per 1 mg) | J2405 | |
| Onivyde<br>(Injection, irinotecan liposome) | J9205 | See Optum List if treatment is being used for a cancer diagnosis |
| Onpattro<br>(patisiran), injection 0.1 mg | J0222 | Subject to Transthyretin-Mediated Amyloidosis Therapy policy and may be subject to Site of Care |
| Ontruzant<br>(Injection, trastuzumab-dttb) | Q5112 | See Optum List if treatment is being used for a cancer diagnosis |
| Opdivo<br>(Injection, nivolumab) | J9299 | See Optum List if treatment is being used for a cancer diagnosis |
| Opdivo Qvantig<br>(Nivolumab + hyaluronidase-nvhy) | J9289 | See Optum List if treatment is being used for a cancer diagnosis |
| Opdualag<br>(injection, nivolumab, relatlimab) | J9298 | See Optum List if treatment is being used for a cancer diagnosis |
| Opuviz | Q5153 | |

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| (Injection, aflibercept-yszy biosimilar, 1 mg) | | |
| Orbactiv<br>(Injection, oritavancin) | J2407 | |
| Orencia<br>(abatacept, 10mg (Orencia IV) | J0129 | Subject to Abatacept policy and may be subject to Site of Care |
| Osenvelt<br>(denosumab solution for injection ) | J3590 | |
| Otiprio<br>(Installation, ciprofloxacin otic suspension) | J7342 | |
| Ozurdex<br>(Injection, dexamethasone, intravitreal implant) | J7312 | |
| Padcev<br>(enfortumab vedotin-ejfv) for injection, for intravenous use | J9177 | |
| Paragard<br>(Intrauterine copper contraceptive) | J7300 | |
| Pavblu<br>(aflibercept) | Q5147 | |
| Pedmark<br>(sodium thiosulfate) | J0208 | |
| Pemfexy<br>(pemetrexed) | J9304 | See Optum List if treatment is being used for a cancer diagnosis |
| Perjeta<br>(Injection, pertuzumab) | J9306 | See Optum List if treatment is being used for a cancer diagnosis |
| Perseris<br>(Injection, risperidone) | J2798 | |
| Pemetrexed ditromethamine | J9305 | See Optum List if treatment is being used for a cancer diagnosis |
| Phesgo<br>(pertuzumab/trastuzumab hyaluronidase-zzxf) | J9316 | See Optum List if treatment is being used for a cancer diagnosis |
| Piasky<br>(Crovalimab solution for injection) | J1307 | Prior authorization required per Orphan Drug Policy |
| Portrazza<br>(Injection, necitumumab) | J9295 | See Optum List if treatment is being used for a cancer diagnosis |
| Praxbind<br>(idarucizumab) | J3590 | |
| Prevduo | J3490 | |

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| (neostigmine, glycopyrrolate, solution for injection) | | |
| Prevymis IV (letermovir, IV) | J3490 | Prior authorization required per Pharmacy Programs Administration Policy |
| Probuphine (Buprenorphine implant) | J0570 | |
| Prolastin-C (Injection, alpha 1-proteinase inhibitor, human) | J0256 | |
| Prolia (Injection, denosumab) | J0897 | See Optum List if treatment is being used for a cancer diagnosis |
| Propel Implant (Mometasone furoate sinus implant) | S1091 | Excluded per UM E/I List |
| Qutenza (Capsaicin 8% patch, per square centimeter) | J7336 | |
| Quzyttir (cetirizine, inj) | J1201 | Prior Authorization required as a non-Formulary drug for **Medicaid** only due to CMS rebate labeler requirement |
| Radicava (edaravone, 1mg) | J1301 | Subject to Radicava policy and may be subject to Site of Care |
| Rapiblyk (Landiolol) | J3490 | Subject to 6-month new drug. Prior authorization required. |
| Rapivab (Injection, peramivir) | J2547 | |
| Reclast (Injection, zoledronic acid) | J3489 | |
| Remicade (Injection, infliximab, 10mg) | J1745 | Subject to Infliximab policy and may be subject to Site of Care |
| Renflexis (Injection, infliximab, 10mg) | Q5104 | Subject to Infliximab policy and may be subject to Site of Care |
| Retacrit (Injection, epoetin alfa, biosimilar,(for non-esrd use) | Q5106 | See Optum List if treatment is being used for a cancer diagnosis |
| Rezzayo (Rezafungin) | J0349 | |
| Risperdal-Consta (Injection, risperidone) | J2794 | |
| Rituxan (Injection, rituximab) | J9312 | See Optum List if treatment is being used for a cancer diagnosis |
| Rituxan Hycela (Injection, rituximab) | J9311 | See Optum List if treatment is being used for a cancer diagnosis |

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| Rivfloza<br>(nedosiran, vials) | J3490 | Prior authorization required per Orphan Drug Policy |
| Rolvedon<br>(eflapegrastim) | J1449 | See Optum List if treatment is being used for a cancer diagnosis |
| Ruxience<br>(Injection, rituximab-pvvr, biosimilar, (ruxience), 10 mg) | Q5119 | See Optum List if treatment is being used for a cancer diagnosis |
| Rybrevant<br>(amivantamab) | J9061 | See Optum List if treatment is being used for a cancer diagnosis |
| Rykindo<br>(risperidone, injection) | J2801 | |
| Rylaze<br>(asparaginase erwinia chrysanthemi [recombinant]-rywn) | J9021 | See Optum List if treatment is being used for a cancer diagnosis |
| Rytelo<br>(Imetelstat) | J0870 | |
| Ryznueta<br>(efbemalenograstim alfa-vuxw) | J9361 | Subject to 6-month new drug. Prior authorization required. |
| Sandostatin LAR<br>(Injection, octreotide) | J2353 | See Optum List if treatment is being used for a cancer diagnosis |
| Saphnelo<br>(anifrolumab) | J0491 | |
| Sarclisa<br>(intravenuous, isatuximab-irfc) | J9227 | See Optum List if treatment is being used for a cancer diagnosis |
| Sezaby<br>(phenobarbital, injection) | J2561 | |
| Signifor LAR<br>(Injection, pasireotide long acting) | J2502 | |
| Simponi Aria<br>(injection, golimumab) | J1602 | Subject to Golimumab policy and may be subject to Site of Care |
| Skyla<br>(Levonorgestrel-releasing intrauterine contraceptive system) | J7301 | |
| Soliris<br>(Injection, eculizumab 300 mg/30 mL solution for injection) | J1300 | Subject to Eculizumab policy and may be subject to Site of Care |
| Stoboclo<br>Denosumab solution for injection | J3590 | |

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| Sublocade<br>(Injection, buprenorphine extended-release) | Q9991, Q9992 | |
| Sunlenca<br>(lenacapavir, injection) | J1961 | |
| Supprelin-LA<br>(Histrelin implant) | J9226 | |
| Sustol<br>(Injection, granisetron, extended-release) | J1627 | See Optum List if treatment is being used for a cancer diagnosis |
| Synribo<br>(Injection, omacetaxine mepesuccinate) | J9262 | See Optum List if treatment is being used for a cancer diagnosis |
| Talvey<br>(injection, talquetamab-tgvs) | J3055 | See Optum List if treatment is being used for a cancer diagnosis |
| Tecentriq<br>(Injection, atezolizumab) | J9022 | See Optum List if treatment is being used for a cancer diagnosis |
| Tecentriq Hybreza<br>(Injection, atezolizumab) | J9024 | See Optum List if treatment is being used for a cancer diagnosis |
| Tecvayli<br>(Injection, tecListamab) | J9380 | See Optum List if treatment is being used for a cancer diagnosis |
| Teflaro<br>(Injection, ceftaroline fosamil) | J0712 | |
| Temodar IV<br>(Injection, temozolomide) | J9328 | See Optum List if treatment is being used for a cancer diagnosis |
| Tepezza<br>(teprotumumab-trbw, injection, 500 mg powder vials for solution) | J3241 | Subject to Tepezza (teprotumumab-trbw) policy and may be subject to Site of Care |
| Tepylute<br>(Thiotepa) | J9341 | Subject to 6-month new drug. Prior authorization required. See Optum List if treatment is being used for a cancer diagnosis |
| Terlivaz<br>(Injection, terlipressin) | J3490 | |
| Tevimbra<br>(tislelizumab-jsgr) | J9329 | See Optum List if treatment is being used for a cancer diagnosis |
| Tezspire<br>(Injection, Tezepelumab) | J2356 | Excluded |
| Tivdak<br>(tisotumab vedotin) | J9273 | See Optum List if treatment is being used for a cancer diagnosis |
| Tofidence<br>(tocilizumab, inj) | Q5133 | Subject to 6-month new drug. Prior authorization required. See Optum List if |

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| | | treatment is being used for a cancer diagnosis |
| Torisel<br>(Injection, temsirolimus) | J9330 | See Optum List if treatment is being used for a cancer diagnosis |
| Treanda<br>(Injection, bendamustine) | J9033 | See Optum List if treatment is being used for a cancer diagnosis |
| Trelstar<br>(Injection, triptorelin pamoate) | J3315 | See Optum List if treatment is being used for a cancer diagnosis |
| Triferic<br>(Injection, ferric pyrophosphate citrate solution) | J1443 | |
| Triptodur<br>(Injection, triptorelin) | J3316 | |
| Trodelvy<br>(intravenous, sacituzumab govitecan-hziy) | J9317 | See Optum List if treatment is being used for a cancer diagnosis |
| Trogarzo<br>(Injection, ibalizumab-uiyk) | J1746 | |
| Truxima<br>(Injection, rituximab-abbs) | Q5115 | See Optum List if treatment is being used for a cancer diagnosis |
| Tyenne<br>(tocilizumab) | Q5135 | Subject to 6-month new drug. Prior authorization required |
| Ultomiris<br>(Injection, rivulizumab) | J1303 | Subject to Ultomiris (rivulizumab-cwvz) policy and may be subject to Site of Care |
| Uplizna<br>(10mg/ml solution inebilizumab-cdon, 1mg) | J1823 | Prior authorization required per Orphan Drug Policy |
| Uzedy<br>(risperidone) suspension for injection | J2799 | Exclude |
| Vabysmo<br>(faricimab-svoa) | J2777 | |
| Vantas<br>(Histrelin implant) | J9225 | |
| Varubi<br>(rolapitant) | J2797 | |
| Vegzelma<br>(injection, bevacizumab-adcd, biosimilar, 10mg) | Q5129 | See Optum List if treatment is being used for a cancer diagnosis |
| Venofer<br>(Injection, iron sucrose, 1 mg) | J1756 | |

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| Vibativ<br>(Injection, telavancin) | J3095 | |
| Vivitrol<br>(Injection, naltrexone) | J2315 | |
| Voraxaze<br>(Injection, glucarpidase) | J3590 | |
| Vyjuvek<br>(beremagene geperpavec) | J3401 | Prior Authorization per the Orphan Drug Policy |
| Vyloy<br>(zolbetuximab) | J1326 | See Optum List if treatment is being used for a cancer diagnosis |
| Vyxeos<br>(Injection, liposomal, 1 mg daunorubicin and 2.27 mg cytarabine) | J9153 | See Optum List if treatment is being used for a cancer diagnosis |
| Wyost<br>(Injection, denosumab-bbdz, biosimilar, 1 mg) | Q5136 | See Optum List if treatment is being used for a cancer diagnosis |
| Xacduro<br>(inj, sulbactum, durlobactum) | J3490 | |
| Xenpozyme<br>(olipudase alfa) | J0218 | Prior Authorization per the Orphan Drug Policy and may be subject to Site of Care |
| Xeomin<br>(Injection, incobotulinumtoxinA, 1 unit) | J0588 | Prior authorization is not required for **on label** use and off label compendia supported use. Off label compendia supported use must meet the requirements of the Experimental and Investigational policy. Cosmetic use and formulations are not covered per Cosmetic Drug Agents policy |
| Xerava<br>(Injection, eravacycline) | J0122 | |
| Xgeva<br>(Injection, denosumab) | J0897 | See Optum List if treatment is being used for a cancer diagnosis |
| Xiaflex<br>(Injection, collagenase, clostridium histolyticum) | J0775 | Prior authorization for **Medicaid only**. Please see Prescription Drugs with Sexual Dysfunction/Erectile Dysfunction Indication (Medicaid and HARP) Internal. |
| Xifyrm<br>(meloxicam, solution for injection) | J3490 | Subject to 6-month new drug. Prior authorization required. |
| Xipere | J3299 | Excluded |

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| (triamcinolone acetonide injection) | | |
| Xofigo<br>(Radium Ra-223 dichloride) | A9606 | |
| Yervoy<br>(Injection, ipilimumab) | J9228 | See Optum List if treatment is being used for a cancer diagnosis |
| Yondelis<br>(Injection, trabectedin) | J9352 | See Optum List if treatment is being used for a cancer diagnosis |
| Yutiq<br>(Injection, fluocinolone acetonide, intravitreal implant) | J7314 | |
| Zaltrap<br>(Injection, ziv-aflibercept) | J9400 | See Optum List if treatment is being used for a cancer diagnosis |
| Zemaira<br>(Injection, alpha 1-proteinase inhibitor) | J0256 | |
| Zemdri<br>(Injection, plazomicin) | J0291 | |
| Zepzelca<br>(lurbinectedin) | J9223 | See Optum List if treatment is being used for a cancer diagnosis |
| Zerbaxa<br>(Injection, ceftolozane) | J0695 | |
| Zevaskyn<br>(prademagene zamikeracel cellular sheets) | J3590 | Subject to 6-month new drug. Prior authorization required. |
| Zevtera<br>(ceftobiprole, powder for injection) | J3490 | Subject to 6-month new drug. Prior authorization required. |
| Ziihera<br>(zanidatamab) | J9276 | See Optum List if treatment is being used for a cancer diagnosis |
| Zilretta<br>(Injection, triamcinolone acetonide, preservative-free, extended-release,) | J3304 | |
| Zirabev<br>(bevacizumab-bvzr, IV) | Q5118 | See Optum List if treatment is being used for a cancer diagnosis |
| Zoladex<br>(Goserelin acetate implant) | J9202 | Zoladex requires a prior authorization for **Medicaid** effective 05/14/2022;<br>**See Optum List if treatment is being used for a cancer diagnosis** |
| Zoledronic acid | J3489 | |

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| Zusduri (mitomycin) | J9999 | Subject to 6-month new drug. Prior authorization required. |
| Zynlonta (Loncastuximab tesirine, solution for injection) | J9359 | Prior Authorization per the Orphan Drug Policy. |
| Zynyz (Retifanlimab, solution for injection) | J9345 | See Optum List if treatment is being used for a cancer diagnosis |
| Zyprexa- Relprevv (Injection, olanzapine) | J2358 | |
| Zyvox injection (Injection, linezolid) | J2020 | Prior authorization required per Pharmacy Programs Administration Policy |

Investigational/Experimental use not covered per member contract.
Unless otherwise specified, does not apply to inpatient use.
Drugs pending committee review may be submitted for consideration on a case-by-case basis.

## Optum Cancer Guidance Program Review

Effective 01/01/2024, medical oncology medications will be reviewed by a delegated vendor Optum.

| Brand Name | Generic Name | Full HCPC NDC Crosswalk HCPC |
|---|---|---|
| Cinvanti | Aprepitant | J0185 |
| Pedmark | sodium thiosulfate | J0208 |
| Busulfex | Busulfan | J0594 |
| Wellcovorin | Leucovorin Calcium | J0640 |
| Fusilev | Levoleucovorin | J0641 |
| Khapzory | Levoleucovorin | J0642 |
| Aranesp | Darbepoetin alfa | J0881 |
| Epogen/Procrit | Epoetin Alfa | J0885 |
| Decitabine (sun pharma) | Decitabine | J0893 |
| Dacogen | Decitabine | J0894 |
| Reblozyl | Luspatercept-aamt | J0896 |
| Prolia/Xgeva | Denosumab | J0897 |
| Zinecard | Dexrazoxane | J1190 |
| Neupogen | Filgrastim | J1442 |
| Granix | Tbo-filgrastim | J1447 |
| Cosela | Trilaciclib | J1448 |
| Rolvedon | Eflapegrastim-xnst | J1449 |
| Emend | Fosaprepitant | J1453 |
| Akynzeo | Fosnetupitant/Palonosetron | J1454 |

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| Fosaprepitant(teva) | Fosaprepitant (teva), not therapeutically equivalent to J1453 | J1456 |
| Sustol | Granisetron | J1627 |
| Somtuline Depot | Lanreotide Depot | J1930 |
| Lanreotide (Cipla) | Lanreotide Depot | J1932 |
| Lupron Depot | Leuprolide Acetate | J1950 |
| Camcevi | Leuprolide | J1952 |
| Lutrate | Leuprolide acetate depot | J1954 |
| Sandostatin LAR Depot | Octreotide Depot | J2353 |
| Sandostatin | Octreotide non-depot, inj, 25 mcg | J2354 |
| Neumega | Oprelvekin | J2355 |
| Xolair | Omalizumab | J2357 |
| Aloxi | Palonosetron | J2469 |
| Neulasta | Pegfilgrastim | J2506 |
| Mozobil | Plerixafor | J2562 |
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| Leukine | Sargramostim | J2820 |
| Sylvant | Siltuximab | J2860 |
| Actemra IV | Tocilizumab | J3262 |
| Trelstar | Triptorelin | J3315 |
| N/A | Unclassified drugs | J3490 |
| N/A | Unclassified biologics | J3590 |
| Atgam | Antithymocyte globulin, equine, inj, 250 mg | J7504 |
| Myleran | Busulfan, oral, 2 mg | J8510 |
| Adriamycin | Doxorubicin inj | J9000 |
| Proleukin | Aldesleukin | J9015 |
| Trisenox | Arsenic trioxide | J9017 |
| Rylaze | Asparaginase, recombinant | J9021 |
| Tecentriq | Atezolizumab | J9022 |
| Bavencio | Avelumab | J9023 |
| Vidaza | Azacitidine | J9025 |
| Clolar | Clofarabine | J9027 |
| Adstiladrin | Nadofaragene firadenovec-vncg | J9029 |
| BCG | BCG live intravesical | J9030 |
| Beleodaq | Belinostat | J9032 |
| Treanda | Bendamustine | J9033 |
| Bendeka | Bendamustine | J9034 |
| Avastin | Bevacizumab | J9035 |

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|---|---|---|
| Belrapzo | Bendamustine | J9036 |
| Blincyto | Blinatumomab | J9039 |
| Blenoxane | Bleomycin Sulfate | J9040 |
| Velcade | Bortezomib | J9041 |
| Bortezomib | Bortezomib | J9051 |
| Adcetris | Brentuximab Vedotin | J9042 |
| Jevtana | Cabazitaxel | J9043 |
| Cabazitaxel | Cabazitaxel | J9064 |
| Paraplatin | Carboplatin | J9045 |
| Bortezomib, Dr. Reddy's | Bortezomib | J9046 |
| Kyprolis | Carfilzomib | J9047 |
| Bortezomib (Fresenius Kabi) | Bortezomib | J9048 |
| Bortezomib (Hospira) | Bortezomib | J9049 |
| BICNU | Carmustine | J9050 |
| Erbitux | Cetuximab | J9055 |
| Bendamustine (Vivimusta) | Bendamustine | J9056 |
| Aliqopa | Copanlisib | J9057 |
| Platinol | Cisplatin | J9060 |
| Rybrevant | Amivantamab-vmjw | J9061 |
| Elahere | mirvetuximab soravtansine-gynx | J9063 |
| Cladribine | Cladribine, inj, 1 mg | J9065 |
| Cyclophosphamide (AuroMedics) | Cyclophosphamide (AuroMedics) | J9071 |
| DepoCyt | Cytarabine Liposomal | J9098 |
| Ara-C | Cytarabine | J9100 |
| Asparlas | Calaspargase pegol | J9118 |
| Libtayo | Cemiplimab-rwlc | J9119 |
| Cosmegen | Dactinomycin | J9120 |
| DTIC | Dacarbazine | J9130 |
| Darzalex Faspro™ | Daratumumab hyaluronidase-fihj | J9144 |
| Darzalex | Daratumumab | J9145 |
| Cerubidine | Daunorubicin Hcl | J9150 |
| Vyxeos | Daunorubicin and Cytarabine liposomal | J9153 |
| Firmagon | Degarelix | J9155 |
| Taxotere | Docetaxel | J9171 |
| Imfinzi | Durvalumab | J9173 |
| Elliotts' B Solution | | J9175 |

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|---|---|---|
| Empliciti | Elotuzumab | J9176 |
| Padcev | Enfortumab Vedotin-ejfv | J9177 |
| Ellence | Epirubicin | J9178 |
| Halaven | Eribulin Mesylate | J9179 |
| Toposar | Etoposide Inj | J9181 |
| Fludara | Fludarabine Phosphate | J9185 |
| Adrucil | Fluorouracil Inj | J9190 |
| Gemcitabine (Accord) | gemcitabine (accord), not therapeutically equivalent to J9201 | J9196 |
| Infugem™ | Gemcitabine Hydrochloride | J9198 |
| FUDR | Floxuridine | J9200 |
| Gemzar | Gemcitabine Hydrochloride | J9201 |
| Zoladex | Goserelin | J9202 |
| Mylotarg | Gemtuzumab ozogamicin | J9203 |
| Poteligeo | Mogamulizumab-kpkc | J9204 |
| Onivyde | Irinotecan Liposome | J9205 |
| Camptosar | Irinotecan | J9206 |
| Ixempra | Ixabepilone | J9207 |
| Ifex | Ifosfamide | J9208 |
| Mesnex | Mesna | J9209 |
| Idamycin | Idarubicin | J9211 |
| Alferon | Interferon, alfa-n3, (human leukocyte derived) | J9215 |
| Actimmune | Interferon Gamma-1b | J9216 |
| Eligard | Leuprolide acetate | J9217 |
| Zepzelca™ | Lurbinectedin | J9223 |
| Sarclisa | Isatuximab-irfc | J9227 |
| Yervoy | Ipilimumab | J9228 |
| Besponsa | Inotuzumab Ozogamicin | J9229 |
| Mechlorethamine | Mechlorethamine | J9230 |
| Alkeran | Melphalan | J9245 |
| Evomela | Melphalan(evomela) | J9246 |
| | | |
| Methotrexate | Methotrexate | J9260 |
| Arranon | Nelarabine | J9261 |
| Synribo | Oxmacetaxine mepesuccinate, inj, 0.01 mg | J9262 |
| Eloxatin | Oxaliplatin | J9263 |
| Abraxane | Paclitaxel Protein-Bound | J9264 |

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|---|---|---|
| Oncaspar | Pegaspargase | J9266 |
| Taxol® | Paclitaxel | J9267 |
| Nipent | Pentostatin | J9268 |
| Elzonris | Tagraxofusp-erzs | J9269 |
| Keytruda | Pembrolizumab | J9271 |
| Jemperli | Dostarlimab-gxly | J9272 |
| Tivdak | Tisotumab vedotin-tftv | J9273 |
| Kimmtrak | Tebentafusp-tebn | J9274 |
| Mutamycin | Mitomycin | J9280 |
| Jelmyto™ | Mitomycin pyelocalyceal instillation | J9281 |
| Lartruvo | Olaratumab | J9285 |
| Novantrone | Mitoxantrone | J9293 |
| Pemetrexed (Hospira) | pemetrexed (hospira), not therapeutically equivalent to J9305 | J9294 |
| Portrazza | Necitumumab | J9295 |
| Pemetrexed (Accord) | pemetrexed (accord), not therapeutically equivalent to J9305 | J9296 |
| Pemetrexed (Sandoz) | pemetrexed (sandoz), not therapeutically equivalent to J9305 | J9297 |
| Opdualag™ | Nivolumab and Relatimab-rmbw, [3mg/1mg] per mL | J9298 |
| Opdivo | Nivolumab | J9299 |
| Gazyva | Obinutuzumab | J9301 |
| Arzerra | Ofatumumab | J9302 |
| Vectibix | Panitumumab | J9303 |
| Pemfexy | Pemetrexed | J9304 |
| Alimta | Pemetrexed | J9305 |
| Perjeta | Pertuzumab | J9306 |
| Folotyn | Pralatrexate | J9307 |
| Cyramza | Ramucirumab | J9308 |
| Polivy | Polatuzumab vedotin | J9309 |
| Rituxan Hycela | Rituximab and Hyaluronidase | J9311 |
| Rituxan | Rituximab | J9312 |
| Lumoxiti | Moxetumomab Pasudotox | J9313 |
| Pemetrexed (Teva) | Pemetrexed | J9314 |
| Pemetrexed (Avyxa) | Pemetrexed | J9292 |
| Phesgo™ | Pertuzumab, trastuzumab, and hyaluronidase-zzxf | J9316 |
| Trodelvy | Sacituzumab govitecan-hziy | J9317 |

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|---|---|---|
| Istodax | romidepsin, non-lyophilized, inj, 0.1 mg | J9318 |
| Istodax | romidepsin, lyophilized, inj, 0.1 mg | J9319 |
| Zanosar | Streptozocin | J9320 |
| Pemetrexed (BluePoint) | Pemetrexed (BluePoint), not therapeutically equivalent to J9305 | J9322 |
| Pemetrexed | Pemetrexed ditromethamine | J9323 |
| Imlygic | Talimogene laherparepvec | J9325 |
| Temodar | Temozolomide , inj, 1 mg | J9328 |
| Torisel | Temsirolimus | J9330 |
| Fyarro | sirolimus protein-bound particles, 1 mg | J9331 |
| Thiotepa | Thiotepa | J9342 |
| Imjudo | tremelimumab-actl | J9347 |
| Danyelza | Naxitamab-gqgk | J9348 |
| Monjuvi | Tafasitamab-cxix | J9349 |
| Lunsumio | Mosunetuzumab-axgb | J9350 |
| Hycamtin | Topotecan | J9351 |
| Yondelis | Trabectedin | J9352 |
| Margenza | Margetuximab-cmkb | J9353 |
| Kadcyla | Ado-Trastuzumab Emtansine | J9354 |
| Herceptin | Trastuzumab | J9355 |
| Herceptin Hylecta | Trastuzumab and Hyaluronidase | J9356 |
| Valstar | Valrubicin | J9357 |
| Enhertu | Fam-trastuzumab Deruxtecan-nxki | J9358 |
| Zynlonta | Loncastuximab tesirine-lpyl | J9359 |
| Velban | Vinblastine | J9360 |
| Oncovin | Vincristine | J9370 |
| Tecvayli | TecListamab-cqyv | J9380 |
| Navelbine | Vinorelbine | J9390 |
| Fulvestrant (teva) | Fulvestrant | J9393 |
| Fulvestrant (fresenius kabi) | Fulvestrant | J9394 |
| Faslodex | Fulvestrant | J9395 |
| Zaltrap | Ziv-Aflibercept | J9400 |
| Photofrin | Porfimer sodium | J9600 |
| Epkinly | Epcoritamab-bysp | J9321 |
| Vumon | Teniposide | Q2017 |
| Provenge | Sipuleucel-T | Q2043 |
| Doxil | Doxorubicin liposomal | Q2050 |

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|---|---|---|
| Zarxio | Filgrastim-sndz | Q5101 |
| Retacrit | Epoetin alfa-epbx | Q5106 |
| Mvasi™ | Bevacizumab-awwb | Q5107 |
| Fulphila | Pegfilgrastim-jmdb | Q5108 |
| Nivestym | Filgrastim-aafi | Q5110 |
| Udenyca | Pegfilgrastim-cbqv | Q5111 |
| Ontruzant | Trastuzumab-dttb | Q5112 |
| Herzuma | Trastuzumab-pkrb | Q5113 |
| Ogivri | Trastuzumab-dkst | Q5114 |
| Truxima | Rituximab-abbs | Q5115 |
| Trazimera | Trastuzumab-qyyp | Q5116 |
| Kanjinti | Trastuzumab-Anns | Q5117 |
| Zirabev™ | Bevacizumab-bvzr | Q5118 |
| Ruxience | Rituximab-pvvr | Q5119 |
| Ziextenzo | Pegfilgrastim-bmez | Q5120 |
| Nyvepria | Pegfilgrastim-apgf | Q5122 |
| Riabni™ | Rituximab-arrx | Q5123 |
| Releuko | Filgrastim-ayow | Q5125 |
| Alymsys | Bevacizumab-maly | Q5126 |
| Stimufend | pegfilgrastim-fpgk | Q5127 |
| Vegzelma | Bevacizumab-adcd, biosimilar | Q5129 |
| Zynyz | Retifanlimab-dlwr | J9345 |
| Carmustine | Carmustine | J9052 |
| Cyclophoshamide | Cyclophoshamide | J9072 |
| Docetaxel | Docetaxel | J9172 |
| Methotrexate | Methotrexate | J9255 |
| Columvi | Glofitamab | J9286 |
| Pemrydi rtu | pemetrexed | J9324 |
| Fylnetra | Pegfilgrastim-pbbk | Q5130 |
| Sodium Thiosulfate (Hope) | Sodium Thiosulfate (Hope) | J0209 |
| Cyclophosphamide | Cyclophosphamide | J9075 |
| Cyclophosphamide | Cyclophosphamide (Baxter) | J9076 |
| Cyclophosphamide | Cyclophosphamide(ingenus) | J9073 |
| Cyclophosphamide | Cyclophosphamide | J9074 |
| Melphalan (apotex) | Melphalan (apotex) | J9249 |
| Focinvez | fosaprepitant | J1434 |
| Elfrexio | elranatamab-bcmm | J1323 |
| Talvey | talquetamab-tgvs | J3055 |
| Tofidence | tocilizumab-bavi, biosimilar | Q5133 |

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|---|---|---|
| Loqtorzi | Toripalimab-tpz | J3263 |
| Palonosetron hcl | Palonosetron hcl (Avyxa) | J2468 |
| Tevimbra | Tislelizumab-jsgr | J9329 |
| Hepzato kit | Melphalan | J9248 |
| Hercessi | trastuzumab-strf (hercessi), biosimilar, 10 mg | Q5146 |
| Anktiva | nogapendekin alfa inbakicept-pmln | J9028 |
| Imdelltra | Tarlatamab-dlle | J9026 |
| Nplate | romiplostim | J2802 |
| Nypozi | Injection, filgrastim-txid (nypozi), biosimilar | Q5148 |
| Lymphir | Injection, denileukin diftitox-cxdl | J9161 |
| Tecentriq Hybreza | Injection, atezolizumab, 5 mg and hyaluronidase-tqjs | J9024 |
| Boruzu | Injection, bortezomib (boruzu) | J9054 |
| Jubbonti/Wyost | Injection, denosumab-bbdz (jubbonti/wyost), biosimilar, 1 mg | Q5136 |
| Vyloy | Zolbetuximab0clzb | J1326 |
| Ziihera | Zanidatamab-hrii | J9276 |
| Beizray | docetaxel | J9174 |
| Bizengri | Zenocutuzumab-zbco | J9382 |
| Opdivo Qvantig | Nivolumab + hyaluronidase-nvhy | J9289 |
| Tepylute | Thiotepa | J9341 |
| Unloxcyt | cosibelimab-ipdl | J9275 |

**MVP Health Care Medical Policy**

**Medicare Part B Step Therapy**

**Type of Policy:** **Administrative**
**Prior Approval Date:** **11/01/2024**
**Approval Date:** **06/01/2025**
**Effective Date:** **04/01/2025**

**Related Policies:**

Pharmacy Programs Administration

Pharmacy Management Programs

Medicare Part B vs. Part D Determination

Medical Drug List

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies.

Refer to the MVP website for the Medicare Part B policies for coverage criteria of drugs covered under the medical benefit.

**Codes Requiring Prior Authorization:** N/A

## Overview

Step therapy requires one or more preferred drugs to be trialed to treat a medical condition prior to using a non-preferred/non-covered drug.

The list of drugs that require step therapy may change throughout the plan year. Refer to the MVP Medical Drug List for a complete list of preferred medical drugs.

Part D drugs MAY be preferred over non-preferred Part B drugs in some instances. For a full list of covered drugs, refer to the MVP Medicare website for the Medicare Part D Formulary and Part D policies.

## Indications/Criteria

Medicare Part B Step Therapy will be required for the medications listed in this policy, provided the following criteria are met:

- **National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and/or related Policy Articles may exist and compliance with these policies is required where applicable**
- The requested medication meets the definition of a Part B drug
- Step therapy applies to new starts ONLY, as defined by no use in the last 365 days:
    - Members currently established on a non-preferred drug are not required to switch to a preferred drug
    - Supporting documentation must be submitted by the provider stating that the member is currently established on therapy OR there is a paid claim for the non-preferred drug in the past 365 days
- The requested non-preferred drug must be used for a medically accepted indication under Medicare rules.
- Members and/or providers may request an exception to step therapy.
- Documentation of medical necessity must be provided by the prescriber.
- This list includes common uses for which the drug is prescribed. For specific criteria for drug coverage, please refer to the corresponding clinical policy associated with the drug if applicable.

**Part B Step Therapy Drug List (non-Oncology)**

| Drug Category | Preferred Drug(s) | Non-Preferred Drug(s)* |
|---|---|---|
| **Asthma Agents** | Cinqair, Fasenra, Nucala | Tezspire |
| **Central Nervous System** | Abilify Asimtufii, Abilify Maintena, Aristada, Invega Hayfera, Invega Sustenna, Invega Trinza, Perseris, Risperdal Consta, Zyprexa Relprevv | Uzedy |
| **Erythropoietic Agents** | Retacrit, Procrit | N/A |
| **Multiple Sclerosis Agents** | Ocrevus | Lemtrada, Tysabri, Briumvi |

***Not an all-inclusive list and is subject to change at any time***

## Oncology Medical Drug List

| Preferred Oncology Product | Non-Preferred Oncology Product |
|---|---|
| Zirabev<br>Mvasi | Avastin<br>Alymsys<br>Vegzelma |
| Herceptin<br>Trazimera<br>Herceptin Hylecta | Kanjinti<br>Ogivri<br>Ontruzant<br>Herzuma<br>Hercessi |
| Neulasta<br>Udenyca | Fulphila<br>Ziextenzo<br>Fylnetra<br>Rolvedon<br>Stimufend<br>Nyvepria |
| Nivestym<br>Releuko | Zarxio<br>Neupogen<br>Granix |
| Ruxience<br>Rituxan<br>Rituxan Hycela | Truxima<br>Riabni |
| Gemcitabine | Infugem |
| leucovorin | levoleucovorin |
| Aranesp<br>Retacrit<br>Procrit/Epogen | N/A |
| Aloxi<br>Emend<br>Fosaprepitant | Akynzeo<br>Cinvanti<br>Sustol |

## References

1. Centers for Medicare and Medicaid Services, Health Plan Management System (HPMS), MA_Step_Therapy_HPMS_Memo_8_7_18
2. Centers for Medicare and Medicaid Services, Medicare Benefit Policy Manual, CMS Pub. 100-02, Chapter 15, Sec. 50. Revised 06/13/2024. Available at:

https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/bp102c15.pdf
3. Local Coverage Determination (LCD). Centers for Medicare & Medicare Services. http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx.
4. National Coverage Determination (NCD). Centers for Medicare & Medicare Services. http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx.
5. Medicare Advantage (MA) and step therapy for Part B drugs. Code of Federal Regulations 422.136. Updated 4/15/2025. Available at: eCFR :: 42 CFR 422.136 -- Medicare Advantage (MA) and step therapy for Part B drugs.

**MVP Health Care Medical Policy**

**Medicare Part B vs. Part D Determination**

| | |
|---|---|
| **Type of Policy:** | **Drug/Medical Therapy** |
| **Prior Approval Date:** | **12/01/2023** |
| **Approval Date:** | **11/01/2024** |
| **Effective Date:** | **01/01/2025** |
| **Related Policies:** | **Pharmacy Programs Administration** |
| | **Medicare B vs D (Part D policy)** |
| | **Medicare Part B Drug Therapy** |

## Codes Requiring Prior Authorization

Various

Refer to the Medicare Part D formulary for drugs that may be covered under the Part D benefit.

## Overview

Traditional Medicare Part A or B does not cover most outpatient prescription drugs. However, the law does authorize coverage under Medicare Part B of some medications if certain criteria are met. Those agents which may be prescribed for conditions that are allowable under Part B coverage as well as Part D coverage will be prior authorized to determine the appropriate coverage benefit and copayment.

## Indications/Criteria

The drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug (such as how the drug is being obtained and where the drug is being administered) to make the determination.

The medication will be covered under the Medicare Part D benefit if:

- the information provided identifies that conditions of use **do not meet** the criteria for use under the Part B benefit; **and**
- the drug (and indication) meets the definition of a Part D drug; **and**
- the member is currently enrolled in Medicare Part D with MVP

The medication will be covered under the Medicare Part B benefit if:

- the information provided identifies that conditions of use **meet** the criteria for use under the Part B benefit; **and**
- the drug (and indication) meets the definition of a Part B drug; **and**
- the member is currently enrolled in Medicare Part B with MVP

**Please refer to relevant CMS LCDs/NCDs/Policy Articles for most up to date Medicare Part B guidance if available**

**Outpatient Drugs**-are covered under Part B when furnished "incident to" a physician service for drugs that are not usually self-administered by the member. Coverage is usually limited to drugs administered by infusion or injection

- Certain drugs may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and administration setting of the drug, or how the drug is being obtained (buy and bill by office, shipped to office by specialty pharmacy for administration, or obtained by member from a pharmacy) to make the determination.
- Drugs that are usually self-administered are a Part D benefit

**Inhalation Drugs**-The following drugs would be covered under Part B when **used in the home and administered using a nebulizer:**

- Albuterol, arformoterol (Brovana), budesonide, cromolyn, formoterol, ipratropium, levalbuterol, metaproterenol, and revefenacin for the management of obstructive pulmonary disease
- Dornase alpha for the management of cystic fibrosis
- Tobramycin for the management of cystic fibrosis or bronchiectasis
- Pentamidine for the management of HIV, pneumocystosis, or complications of organ transplants
- Acetylcysteine for the management of persistent thick or tenacious pulmonary secretions
- Treprostinil inhalation solution and iloprost for the treatment of pulmonary arterial hypertension

For a member in a SNF or hospital who does not have Part A coverage, the Part A coverage has run out, or whose stay is non-covered, these medications would be covered under Part D as the Part B DME coverage is limited to items that are furnished for use in the member's home
Refer to LCD for Nebulizers (L33370) and Policy Article for Nebulizers (A52466) for coverage details.

**Infusion Pump Medications**-The following would be covered under Part B if administered in the home using an infusion pump

- Antiviral/antifungal drugs acyclovir, foscarnet, amphotericin B, ganciclovir
- Administration of the anticancer chemotherapy drugs cladribine, fluorouracil, cytarabine, bleomycin, floxuridine, doxorubicin (non-liposomal), vincristine (non-liposomal) or vinblastine by continuous infusion over at least 8 hours when the regimen is proven or generally accepted to have significant advantages over intermittent administration regimens
- Blinatumomab
- Deferoxamine for the treatment of chronic iron overload
- Insulin (used with pump)
- Morphine for the treatment of intractable pain
- Narcotic analgesics (except meperidine) for the treatment of severe intractable pain of malignant or nonmalignant origin that has not responded to an adequate oral/transdermal therapeutic regimen or cannot tolerate oral/transdermal narcotic analgesics
- Administration of parenteral inotropic therapy with dobutamine, milrinone, or dopamine
- Levodopa-Carbidopa enteral suspension for the treatment of motor fluctuations in Parkinson's disease
- Epoprostenol or treprostinil for the treatment pulmonary hypertension
- Gallium nitrate for the treatment of symptomatic cancer-related hypercalcemia
- Subcutaneous immune globulin for the treatment of primary immune deficiency
- Ziconotide (intrathecal) for severe chronic pain
- The drug is reasonable and necessary for the individual member, it is medically necessary that the drug be administered through an implanted infusion pump, and the drug has FDA approved labeling indicating use for the pump

Refer to NCD for Infusion Pumps (280.14) for coverage details, LCD for External Infusion Pumps (L33794), Article for Implantable Infusion Pumps (A56695), and Article for External Infusion Pumps (A52507)

**Immunosuppressive drugs**- covered under Part B if meet the following:

- Must be FDA approved for immunosuppression or identified in the label for use in conjunction with immunosuppressive drug therapy
- Member must have received an organ transplant while enrolled in Medicare Part A (a Medicare covered transplant) and the immunosuppressive therapy is appropriate for the transplant.

**Hemophilia clotting factors**-are covered under Part B for hemophilia members competent to use such factors to control bleeding without medical supervision.

**Erythropoietin (EPO)**-is covered for the treatment of anemia for members with chronic renal failure who are on dialysis.

- Refer to Chapter 15 Section 50.5.2 of the Medicare Benefit Policy Manual for coverage details

**Oral anti-cancer drugs**-certain drugs where there is an infusible version of the drug are covered under Part B

- Must be used for the same indication of the infusible version of the drug
- Drug has no other medically accepted indication besides cancer treatment
- The following oral drugs may be covered under Part B
    - busulfan, capecitabine, cyclophosphamide, etoposide, fludarabine phosphate, melphalan, methotrexate, temozolomide, topotecan
- Refer to LCD for Oral Anticancer Drugs (L33826) and the accompanying Policy Article (A52479) for coverage guidance.

**Oral anti-emetic drugs**- covered under Part B if meet the following:

- Must be used as full therapeutic replacement for intravenous drugs as part of a cancer chemotherapeutic regimen
- Must be approved by the FDA for use as an anti-emetic
- Must be administered within 48 hours of the administration of the chemotherapy agent
- Maximum of 48 hours of therapy is covered
- Refer to NCD 110.18 Aprepitant for Chemotherapy-Induced Emesis for coverage guidance for oral aprepitant.
- Refer to LCD for Oral Antiemetic Drugs (Replacement for Intravenous Antiemetics) (L33827) and the accompanying Policy Article (A52480) for coverage guidance.

**Immunizations**-covered under Part B

- Hepatitis B vaccine- when administered to member who is at high or intermediate risk of contracting hepatitis B

    - 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, persons diagnosed with diabetes mellitus.
    - 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 vaccine
- Tetanus-when administered directly related to the treatment of an injury
- Influenza vaccine

**Parenteral nutrition**- covered under Part B if meet the following:

- Covered under the prosthetic devices benefit when criteria are met (The LCD for Enteral Nutrition (LCD L38955) accompanying Policy Article (A58833), and Medicare Part B Enteral Nutrition Policy)
- Intraperitoneal Nutrition is considered a Part B compound
- If therapy was being provided because of a non-functioning digestive tract

**Parsabiv (etelcalcetide)**

- CMS considers Parsabiv to be included in the ESRD PPS (Prospective Payment System) bundled payment, therefore prior authorization is not required. Providers must follow the CMS PPS payment methodology.

**Intravenous immune globulin (IVIG**)-covered under Part B in the home if meet the following:

- Used for the treatment of primary immune deficiency and administered with an infusion pump
- IVIG is defined as approved pooled plasma derivative for the treatment of primary immune deficiency disease
- See Immunoglobulin Therapy policy and applicable LCDs, NCDs, and policy articles for coverage criteria which may include LCD- Off-Label Use of Intravenous Immune Globulin (IVIG) (L39314), and Policy Article-Billing and Coding: Off-Label Use of Intravenous Immune Globulin (IVIG) (A59105)

**Preexposure Prophylaxis (PrEP) Using Antiretroviral Therapy to Prevent Human Immunodeficiency Virus (HIV) Infection** (Apretude, Descovy, Truvada, and generic):

- Coverage of PrEP to prevent HIV is covered under Medicare Part B

- Prior authorization requirements on PrEP drugs that are on their formularies may NOT be imposed
- Apretude is always covered under Part B
- May use information available, such as a diagnosis code presented on a claim, to determine whether the claim should process under the Part B or Part D benefit
- If there is insufficient information to determine a use for PrEP, coverage will be with the Part D benefit

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**Exclusions**

Not meeting the definition of a Part D drug or covered under the Part B benefit.

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1. Medicare Claims Processing Manual. Chapter 17- Drugs and Biologicals. Revised 02/15/2024. Available: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c17.pdf
2. Medicare Benefit Policy Manual. Chapter 15. Covered Medical and Other Health Services. Revised 06/13/2024. Available: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf
3. Medicare Benefit Policy Manual. Chapter 2. Medicare Marketing Guidelines. Revised 06/28/2013.
4. Department of Health & Human Services (DHHS). Centers for Medicare & Medicaid Services (CMS). Pub 100-04 Medicare Claims Processing. Revisions to the End Stage Renal Disease (ESRD) Medicare Benefit Policy Manual to Reflect the Implementation of the ESRD Prospective Payment System (PPS). 11/14/2011.
5. Local Coverage Determination for Nebulizers- LCD (L33370), Original Effective Date 10/01/2015. Revision Effective Date: 01/01/2024
6. Centers of Medicare & Medicaid Services. National Coverage Determination for Infusion Pumps (280.14). Effective Date 12/17/2004.
7. Medicare Prescription Drug Benefit Manual, Chapter 6. Revised 01/19/2016.
8. Intravenous Immune Globulin- Policy Article- (A52509)- Original Effective Date: 10/01/2015. Revision Effective Date: 01/01/2024.
9. Medicare Local Coverage Determination for Enteral Nutrition (L38955). Original Effective Date: 09/05/2021. Revision Effective Date: 01/01/2024.
10. Medicare Local Coverage Determination for Oral Anticancer Drugs (L33826). Original Effective Date: 10/01/20215. Revision Effective Date: 01/01/2024.
11. Medicare Local Coverage Article Oral Anticancer Drugs – Policy Article (A52479). Original Effective Date: 10/01/2015. Revision Effective Date: 10/01/2023.

12. External Infusion Pumps - Policy Article (A52507)- Original Effective Date: 10/01/2015. Revision Effective Date: 01/01/2024.
13. Local Coverage Determination for External Infusion Pumps (L33794). Original Effective Date: 10/01/2015. Revision Effective Date: 07/01/2024
14. Implantable Infusion Pumps - Policy Article (A56695)- Original Effective Date: 07/11/2019. Revision Effective Date: 10/01/2024.
15. Preexposure Prophylaxis (PrEP) Using Antiretroviral Therapy to Prevent Human Immunodeficiency Virus (HIV) Infection. Effective Date 9/30/2024
16. PrEP for HIV & Related Preventive Services. CMS.gov. Page Last Modified 10/01/2024
17. Medicare Benefit Policy. Chapter 11. End Stage Renal Disease (ESRD). Last Revised 03/01/2019.

**MVP Health Care Medical Policy**

**Metformin ER**

**Type of Policy:** **Drug Therapy**
**Prior Approval Date:** **02/01/2024**
**Approval Date:** **02/01/2025**
**Effective Date:** **04/01/2025**

**Related Policies:** N/A

**Drugs Requiring Prior Authorization under the pharmacy benefit**
Glumetza (Metformin SR 24hr modified release, 500 mg and 1000 mg extended release tablets)

Metformin SR 24hr modified release, 500mg and 1000mg extended release tablets

Metformin SR 24hr osmotic, 500mg and 1000mg extend release tablets (generic Fortamet)

Refer to the Medicare Part D formulary for drugs that may be covered under the Part D benefit.

**Overview**
Glumetza is a brand name version, for which generics are available, of metformin, a biguanide used to help control hyperglycemia in patients with type 2 diabetes mellitus. Clinical data suggests that patients receiving extended release formulations of metformin experience less gastrointestinal upset than those receiving immediate release formulations. Through increased glucose control, patients may experience an improvement in hemoglobin A1c, as well as modest weight loss.

**Indications/Criteria**

Generic Fortamet and Glumetza are indicated as an adjunct to diet and exercise to improve glycemic control to improve control in adults with type 2 diabetes mellitus

All requests require the following:

- Current HbA1c must be provided with request
- Member has a diagnosis of type 2 diabetes mellitus

Generic Fortamet will be considered for coverage when all of the following criteria are met:

- Chart notes documenting contraindication or intolerable adverse reaction causing discontinuation of therapy after appropriate dose titration and administration to **ALL** of the following products, with immediate-release (IR) trialed prior to extended-release (ER) formulations:
    - Metformin IR (generic Glucophage IR)
    - Metformin ER (generic Glucophage XR)

Glumetza (and generic Glumetza) will be considered for coverage when all of the following criteria are met:

- Chart notes documenting contraindication or intolerable adverse reaction causing discontinuation of therapy after appropriate dose titration and administration to **ALL** of the following products, with immediate-release (IR) trialed prior to extended-release (ER) formulations, and ER trialed prior to osmotic-release (SR)
    - Metformin IR (generic Glucophage IR)
    - Metformin ER (generic Glucophage XR)
    - Metformin SR 24hr osmotic release (generic Fortamet)
- If approved generic Glumetza must be used and failed prior to approval for brand Glumetza

**Initial approval** will be for up to one year.

**Extension requests** will be approved for up to one year when accompanied by current chart notes identifying continued benefit and current HbA1c. Prescription history must show compliance, as defined by a medication possession ratio of at least 80%.

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**Exclusions**

Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling **References**

1. Bailey CJ, Turner RC. Metformin. N Engl J Med. 1996; 334: 574-579.
2. Glumetza (metformin ER) tablets. Prescribing Information. Raleigh (NC): Salix Pharmaceuticals.
3. Ali S, Fonseca V. Overview of metformin: special focus on metformin extended release. Expert Opin Pharmacother. 2012; 13(12): 1797-1805.

| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Complete Wellness | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| USA Care PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

**Methotrexate autoinjector**

| | |
|---|---|
| **Type of Policy:** | **Drug Therapy** |
| **Prior Approval Date:** | **08/01/2023** |
| **Approval Date:** | **08/01/2024** |
| **Effective Date:** | **10/01/2024** |
| **Related Policies:** | **Rheumatoid Arthritis Drug Therapy** |
| | **Inflammatory Biologic Drug Therapy** |
| | **Experimental or Investigational Policy** |

## Drug Requiring Prior Authorization

Otrexup® (methotrexate autoinjector) 10, 12.5, 15,17.5, 20, 22.5, 25 mg for subcutaneous injection

Rasuvo® (methotrexate autoinjector) 7.5, 10, 12.5, 15, 17.5, 20, 22.5, 25, 30mg for subcutaneous injection

Refer to the MVP website for the Medicare Part D formulary for drugs that may be covered under the Part D benefit.

## Overview

Otrexup and Rasuvo, the subcutaneous autoinjector formulations of methotrexate, are indicated for severe, active Rheumatoid Arthritis (RA), Polyarticular Juvenile Idiopathic Arthritis (pJIA), and severe, recalcitrant, disabling psoriasis.[3,6] These autoinjector formulations are not FDA approved for psoriatic arthritis. Otrexup and Rasuvo are both for once weekly, subcutaneous use only; other methotrexate formulations allow for intramuscular, intravenous, intra-arterial, and intrathecal dosing. Each injector is one-time use, and the pre-filled dose to be administered cannot be changed on the device.

## Indications/Criteria

Otrexup® and Rasuvo® (methotrexate for subcutaneous auto injection) may be considered medically necessary when the following criteria are met:

**For Rheumatoid Arthritis (RA):**

- Prescriber must be a rheumatologist/immunologist
- Failure/intolerance of oral methotrexate
- Failure/intolerance of generically available injectable methotrexate ('vial & syringe')

**For Polyarticular Juvenile Idiopathic Arthritis (pJIA):**

- Prescriber must be a rheumatologist
- Failure of oral methotrexate
- Failure/intolerance of generically available injectable methotrexate ('vial & syringe')

**For Psoriasis:**

- Prescriber must be a dermatologist
- Failure of oral methotrexate
- Failure/intolerance of generically available injectable methotrexate ('vial & syringe')

Initial authorizations and continuations, if approved, will be for a period of one year.

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## Exclusions

- Hypersensitivity reaction to methotrexate
- Pregnancy
- Nursing mothers
- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling Creatinine clearance ≤ 30 mL/min[5]
- Active alcoholism
- Liver disease
- Immunodeficiency syndromes
- Active infection
- Blood dyscrasias like bone marrow hypoplasia, leukopenia, thrombocytopenia, or significant anemia
- Concomitant cytotoxic drugs

- Concomitant radiation therapy

## References


1. Lehman, TJ. Polyarticular onset juvenile idiopathic arthritis: Management. In: UpToDate, Klein-Gitelman, M (Ed), UpToDate, Waltham, MA; Feb 2013 [cited July 7 2014].
2. Foell D, Wulffraat N, Wedderburn LR, et al. Methotrexate withdrawal at 6 vs 12 months in juvenile idiopathic arthritis in remission: a randomized clinical trial. JAMA. 2010;303(13):1266-73.
3. Otrexup® (Methotrexate) injection, for subcutaneous use. Prescribing Information. Ewing, NJ: Antares Pharma; April 2014. Revised December 2019.
4. Aletaha D, Neogi T, Silman AJ, et al. 2010 rheumatoid arthritis classification criteria: an American College of Rheumatology/European League Against Rheumatism collaborative initiative. [Table 3] Ann Rheum Dis. 2010;69(9):1580-8. Kintzel PE, Dorr RT. Anticancer drug renal toxicity and elimination: dosing guidelines for altered renal function. Cancer Treat Rev. 1995;21(1):33-64Rasuvo (methotrexate) injection, for subcutaneous use. Prescribing Information. Chiacago, IL: Medac Pharma Inc; July 2014. Revised March 2020.


| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Medicare Gold Giveback | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |

| | |
|---|---|
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D |
| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

# Monoclonal Antibodies for Alzheimer's Disease

**Type of Policy:** Drug Therapy
**Prior Approval Date:** 11/01/2023
**Approval Date:** 11/01/2024
**Effective Date:** 01/01/2025

**Related Policies:** N/A

Refer to the MVP website for the Medicare Part B policies for coverage criteria of drugs covered under the medical benefit.

## Drugs Requiring Prior Authorization (covered under the medical benefit)

J0172 Aduhelm (aducanumab-avwa)

J0174 Leqembi (lecanemab-irmb)

J0175 Kisunla (donanemab-azbt)

## Overview

Aduhelm, Kisunlaand Leqembi are amyloid beta-directed antibody indicated for the treatment of Alzheimer's disease. Aduhelm was approved under Accelerated Approval based on reduction in amyloid beta plaques observed in patients. Continued approval for this indication may be contingent upon verification of clinical benefit in confirmatory trials.

Aduhelm, Kisunla and Leqembi can cause amyloid related imaging abnormalities-edema (ARIA-E), which can be observed on MRI as brain edema or sulcal effusions, and amyloid related imaging abnormalities hemosiderin deposition (ARIA-H), which includes microhemorrhage and superficial siderosis.

## Clinical Criteria

## Medicaid Variation

Before initiating aducanumab-avwa (Aduhelm®), prescribers must attest that the patient has been diagnosed with mild cognitive impairment due to Alzheimer's disease or mild Alzheimer's dementia by meeting one of the following scores:

- Clinical Dementia Rating (CDR)-Global Score of 0.5 to 1
- Mini-Mental Status Exam (MMSE) score between 24 and 30
- Montreal Cognitive Assessment (MoCA) score of at least 18

Before initiating aducanumab-avwa (Aduhelm®), prescribers must provide medical records for the following pre-treatment testing:

- genetic testing to assess apolipoprotein E ε4 carrier status, **and**
- positron emission tomography (PET) scan or cerebrospinal fluid (CSF) analysis to confirm the presence of amyloid beta deposits.

Before initiating aducanumab-avwa (Aduhelm®), prescribers must attest that the patient does not have evidence of any medical or neurological condition other than Alzheimer's disease that could be contributing to the patient's cognitive impairment.

Before initiating aducanumab-avwa (Aduhelm®), prescribers must attest that the patient does not have a history of a clotting disorder and is not taking any form of antiplatelet or anticoagulant medications other than aspirin ≤325 mg/day.

Requests for Leqembi must meet the criteria above

**Initial authorization** for 6 months

**For continuation of therapy**, providers must attest that the patient's score remained stable or improved, utilizing the same baseline assessment tool as outlined for initiation of therapy.

## Commercial (NY & VT), Exchange (NY & VT), ASO, CHP, Essential Plan Variation

Aduhelm, Kisunla and Leqembi may be considered for coverage when ALL the following criteria is met:

1. Documented clinical diagnosis of mild cognitive impairment (MCI) due to Alzheimer's Disease (AD) or mild AD dementia consistent with Stage 3 and Stage 4 Alzheimer's disease
2. Confirmed presence of amyloid beta pathology

3. Documentation of one of the following scores:
    a. Clinical Dementia Rating (CDR)-Global Score of 0.5 to 1
    b. Mini-Mental Status Exam (MMSE) score between 19 to 30
    c. Montreal Cognitive Assessment (MoCA) score of at least 18
4. Documentation of the following pre-treatment testing:
    a. Genetic testing to assess apolipoprotein E ε4 carrier status, **AND**
    b. Positron emission tomography (PET) scan or cerebrospinal fluid (CSF) analysis to confirm the presence of amyloid beta deposits.

**Initial authorization** for 6 months

**For continuation of therapy**, providers must attest that the member's score remained stable or improved, utilizing the same baseline assessment tool as outlined for initiation of therapy.

**Exclusions**

- Diagnosis, dosing, age, and/or frequency outside of the FDA approved package labeling
- Combination therapy of Aduhelm, Kisunla and Leqembi

**References**

1. FDA News Release: https://www.fda.gov/news-events/press-announcements/fda-grantsaccelerated-approval-alzheimers-drug.
2. Biogen Press Release (FDA Approval): https://investors.biogen.com/news-releases/news-releasedetails/fda-grants-accelerated-approval-aduhelmtm-first-and-only.
3. ICER Press Release: https://icer.org/news-insights/press-releases/icer-issues-statement-on-thefdas-approval-of-aducanumab-for-alzheimers-disease/.
4. Aduhelm Label: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761178s000lbl.pdf.
5. Medicare Coverage Policy for Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease. April 7, 2022. Medicare Coverage Policy for Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease | CMS. Accessed April 21, 2022.
6. Medicare National Coverage Analysis Decision Memo for Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease (CAG-00460N). Effective Date: 04/07/2022.

7. Updates to Medicaid Fee-For-Service Practitioner Administered Drug Policies and Billing Guidance: Aducanumab-avwa (Aduhelm). New York State Medicaid Update November 2022 Volume 38 Number 13 (ny.gov)
8. Medicare National Coverage Determination for Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease (AD) (NCD 200.3). Effective Date: 04/07/2022; Implementation Date: 12/12/2022. Available at: https://www.cms.gov.
9. Medicare Learning Network Article National Coverage Determination 200.3: Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease. MLN Matters: MM12950. Related Request (CR) Number: 12950. Initial article release date: 12/08/2022.CMS announces new details of plan to cover Alzheimer's drugs Fact Sheet. June 22, 2023. Available at: www.cms.gov/newsroom/fact-sheets/cms-announces-new-details-plan-cover-alzheimers-drugs.
10. Clinical Dementia Rating - an overview | ScienceDirect Topics
11. Prescribing-Information.pdf (leqembi.com). Revised 07/2023. Kisunla package insert

| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Complete Wellness | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D |
| USA Care 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 | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

**Medicare Part B: Monoclonal Antibodies for Alzheimer's Disease**

**Type of Policy:** **Drug Therapy**

**Prior Approval Date:** **11/01/2023**

**Approval Date:** **11/01/2024**

**Effective Date:** **01/01/2025**

**Related Policies:** **N/A**

## Drugs Requiring Prior Authorization (covered under the medical benefit)

J0172 Aduhelm (aducanumab-avwa)

J0174 Leqembi (lecanemab-irmb)

J0175 Kisunla (donanemab-azbt)

## Overview

Aduhelm, Kisunla and Leqembi are amyloid beta-directed antibody therapies indicated for the treatment of Alzheimer's disease. This indication is approved under Accelerated Approval based on reduction in amyloid beta plaques observed in members. Continued approval for this indication may be contingent upon verification of clinical benefit in confirmatory trials.

Aduhelm, Kisunlaand Leqembi can cause amyloid related imaging abnormalities-edema (ARIA-E), which can be observed on MRI as brain edema or sulcal effusions, and amyloid related imaging abnormalities hemosiderin deposition (ARIA-H), which includes microhemorrhage and superficial siderosis.

This policy may not list all available therapies for the treatment of Alzheimer's Disease (AD). If the Food and Drug Administration (FDA) grants traditional approval for a drug used to slow the progression of Alzheimer's disease, Medicare will cover the drug in accordance with the National Coverage Determination (NCD) for Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease (NCD 200.3).

## Clinical Criteria

Effective April 7, 2022, CMS covers FDA-approved monoclonal antibodies directed against amyloid for the treatment of Alzheimer's Disease (AD) under coverage with evidence development (CED) for members with a clinical diagnosis of mild cognitive impairment due to AD or mild AD dementia, both with confirmed presence of amyloid beta pathology consistent with AD, according to the coverage criteria outlined in the National Coverage Determination (NCD) for Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease (NCD 200.3). Please refer to this NCD for coverage guidance.

Before initiating treatment for monoclonal antibodies directed against amyloid for the treatment of Alzheimer's Disease (AD), the following criteria must be met (consistent with NCD 200.3):

- Clinical diagnosis of mild cognitive impairment (MCI) due to AD or mild AD dementia, both with confirmed presence of amyloid beta pathology consistent with AD
- The member must have a physician participating in a registry with an appropriate clinical team and follow-up care. Registries are listed at www.cms.gov. If the Food and Drug Administration (FDA) grants traditional approval for a drug used to slow the progression of Alzheimer's disease, Medicare will cover the drug in appropriate settings that also support the collection of real-world information to study the usefulness of these drugs for people with Medicare. Clinicians must participate in the Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease Registry available nationwide at www.cms.gov.

**Approval Duration:** (unless otherwise indicated in applicable NCD/LCD or CMS guidance if available)*

**Initial authorization** for 6 months

**For continuation of therapy**, providers must provide documentation necessary for approval based on current NCD/CMS guidance and will be for up to 6 months

**Exclusions**

- Indication, diagnosis, dosing, age, and/or frequency outside of the FDA approved package labeling
- Monoclonal antibodies directed against amyloid for the treatment of AD provided outside of an FDA-approved randomized controlled trial, CMS-approved studies, or studies supported by the NIH are nationally non-covered.

## References


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2. Biogen Press Release (FDA Approval): https://investors.biogen.com/news-releases/news-releasedetails/fda-grants-accelerated-approval-aduhelmtm-first-and-only.
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8. Medicare National Coverage Determination for Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease (AD) (NCD 200.3). Effective Date: 04/07/2022; Implementation Date: 12/12/2022. Available at: https://www.cms.gov.
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**MVP Health Care Medical Policy**

**Movement Disorders**

| | |
|---|---|
| **Type of Policy:** | **Drug Therapy** |
| **Prior Approval Date:** | **11/01/2023** |
| **Approval Date:** | **10/01/2024** |
| **Effective Date:** | **01/01/2025** |
| **Related Policies:** | **N/A** |

**Drug Requiring Prior Authorization (covered under the pharmacy benefit)**

Austedo (deutetrabenazine)

Austedo XR (deutetrabenazine) extended-release

Ingrezza (Valbenazine)

Xenazine (tetrabenazine)

Refer to the MVP website for the Medicare Part D formulary for drugs that may be covered under the Part D benefit.

**Overview**

Huntington's disease (HD) is an inherited autosomal dominant progressive neurodegenerative disorder. The disease is characterized by progressive motor, cognitive, and psychiatric symptoms. Symptomatic treatment and supportive care remain the only options for patients as there is no know disease-modifying therapy or cure. Chorea associated with Huntington's disease is an abnormal involuntary movement characterized by irregular, abrupt, brief, and unpredictable movements. Chorea can affect various body parts, and potentially interfere with swallowing, speech, gait, speech, and posture.

Tardive Dyskinesia (TD) is a movement disorder characterized by chorea, athetosis, dystonia, akathisia, and rarely tremor. Delayed onset of TD is caused by prolonged use of dopamine receptor blocking agents. Symptomatic improvement is often evaluated using the Abnormal Involuntary Movement Scale (AIMS), which assesses the severity of involuntary movements across body regions ranging for 0 (no dyskinesia) to 28 (maximum amplitude dyskinesia).

Tetrabenazine, valbenazine and deutetrabenazine are vesicular monoamine transporter 2 (VMAT) inhibitor. The precise mechanism by which it exerts its anti-chorea effects and treatment of tardive dyskinesia is unknown. Indirect treatment comparisons have demonstrated that for the treatment of HD chorea, deutetrabenzine has a favorable tolerability profile compared to tetrabenazine.

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**Indications/Criteria**

Huntington's disease

All of the following must be met for coverage of Xenazine (brand and generic), Austedo/XR and Ingrezza:

- Diagnosis of Huntington's disease including family history, clinical features (i.e., chorea, abnormal eye movement) and genetic testing
  Baseline Total Chorea Score from the Unified Huntington's Disease Rating Scale must be provided
- Approval for **brand** Xenazine will require contraindication or therapeutic failure of tetrabenazine (generic Xenazine).
- Approval for Austedo/XR will require contraindication or therapeutic failure of tetrabenazine **and** Ingrezza.

**Initial approval** will be for 12 weeks.

**Extension requests** will require a decrease in the Total Chorea Score of 2.5 units from baseline. Approval will be for 12 months.

Tardive Dyskinesia

All of the following must be met for coverage of Austedo/XR and Ingrezza:

- Diagnosis of moderate to severe tardive dyskinesia
- If clinically appropriate the offending dopamine receptor blocking agent must be discontinued. If offending agent cannot be discontinued documentation must be provided identifying that the lowest effective dose is being used
- If patient is on a first-generation antipsychotic a switch to a second-generation antipsychotic should be attempted unless clinically inappropriate
- Baseline Abnormal involuntary Movement Scale (AIMS)-items 1 to 8 scores must be provided
- Approval for Austedo/XR will require contraindication or therapeutic failure of Ingrezza.

**Initial approval** will be for 12 weeks.

**Extension requests** will require a decrease in the AIMS score of 3 points from baseline. Approval will be for 12 months

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## Exclusions

- Indication, age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling
- Members with untreated or inadequately treated depression or who are suicidal
- Members with long QT syndrome or arrhythmias associated with a prolong QT interval

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## References


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4. Nance M, Paulsen J, Rosenblatt A. A Physician's Guide to the Management of Huntington's Disease. Third Edition. Huntington's Disease Society of America. http://hdsas.org (Accessed on 1/3/2018)
5. Austedo (deutetrabenazine) tablets. Prescribing Information. North Wales, PA. Teva Pharmaceuticals. August 2017. Revised 07/2024.
6. Ingrezza (valbenazine) capsules. Prescribing Information. San Diego, CA. Neurocrine Biosciences, Inc. October 2017. Revised 04/2024.
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8. Claassen D, Carroll B, De Boer, et al. Indirect tolerability comparison of Deutetrabenazine and Tetrabenazine for Huntington disease. J Clin Mov Disord. 2017; 4:3
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| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Medicare Gold Giveback | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D |
| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

**Mulpleta/Doptelet**

**Type of Policy:** **Drug Therapy**
**Prior Approval Date:** **10/01/2023**
**Approval Date:** **12/01/2024**
**Effective Date:** **02/01/2025**
**Related Policies:** **NA**

**Drug(s) Requiring Prior Authorization (covered under the pharmacy benefit)**
Mulpleta™ (lusutrombopag), 3mg tablet
Doptelet™ (avatrombopag), 20mg tablet

Refer to the MVP website for the Medicare Part D formulary for drugs that may be covered under the Part D benefit.

**Indications**
Mulpleta and Doptelet are thrombopoietin receptor agonists indicated for the treatment of thrombocytopenia in adult members with chronic liver disease who are scheduled to undergo a procedure. Doptelet is also indicated for the treatment of thrombocytopenia in adult members with chronic immune thrombocytopenia who have had an insufficient response to a previous treatment.

**Policy Criteria**

**Treatment of thrombocytopenia in adult members with chronic liver disease who are scheduled to undergo a procedure:**

**Mulpleta** may be considered for coverage in adults when the following criteria are met:

- Documentation of thrombocytopenia with current platelet count provided.
- Member has a diagnosis of chronic liver disease
- Member is scheduled to undergo a medical or dental procedure within the next 30 days

- Prescribed by, or consult with, a gastroenterologist, hepatologist, or hematologist

**Doptelet** may be considered for coverage in adults when the following criteria are met:

- All the criteria listed above **AND**
- Documented history of failure, contraindication, or intolerance to Mulpleta

**Approvals for Mulpleta or Doptelet will be issued for 1 month.**

**Treatment of chronic immune thrombocytopenia who have had an insufficient response to a previous treatment:**

**Doptelet** will be considered medically necessary in adults who meet the following criteria:

- Documentation of thrombocytopenia with current platelet count provided
- Prescribed by, or consult with, a hematologist
- Documentation of a failure, contraindication, or intolerance to first line agents:
    - Corticosteroids (i.e., prednisone, methylprednisolone, dexamethasone)
- Documented use of the lowest possible dose to maintain platelet counts of 50,000$mm^3$ or more
- Appropriate monitoring of platelet counts is performed
- Dosing adjustments is taken into consideration due to drug-drug interactions with CYP2C9 and CYP3A4 Inhibitors or Inducers

**Initial approvals for Doptelet will be issued for 3 months.**

**Continuation of therapy up to 6 months will be considered based on the criteria below:**

- If platelets do not increase to 50,000/$mm^3$ or more after 4 weeks of the maximum dose or if the platelet count is more than 400,000/$mm^3$ after 2 weeks of the lowest dose, discontinue avatrombopag.
- Subsequent approvals for this indication can be for 6 months provided that the platelet response continues to improve.

**Exclusions**

- Mulpleta or Doptelet should not be administered to members with chronic liver disease to normalize platelet counts

- Doptelet dosing exceeding 40mg per day when treating thrombocytopenia in adult members with chronic immune thrombocytopenia who have had an insufficient response to a previous treatment
- Indication, age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling

## References

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2. Doptelet [package insert]. Durham, NC: AkaRx, Inc.; Revised July 2021.

| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Complete Wellness | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| USA Care PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

**Multiple Sclerosis Agents**

**Type of Policy:** **Drug and Medical Therapy**
**Prior Approval Date:** **02/01/2025**
**Approval Date:** **08/01/2025**
**Effective Date:** **08/01/2025**
**Related Policies:** **Acthar**

Refer to the MVP Medicare website for the Medicare Part D Formulary and Part D policies for drugs that may be covered under the Part D benefit.

Refer to the MVP website for the Medicare Part B policies for coverage criteria of drugs covered under the medical benefit.

**Codes Requiring Prior Authorization (covered under the medical benefit)**

J0202 Lemtrada (alemtuzmab injection, 1mg)

J2323 Tysabri (natalizumab injection, 1 mg)

J2329 Briumvi (ublituximab, 150mg/6mL solution for infusion)

**Codes Requiring Prior Authorization when obtained from non-preferred vendor (covered under the medical benefit)**

J2350 Ocrevus (ocrelizumab injection, 1mg)

J3590 Ocrevus Zunovo (ocrelizumab, subcutaneous infusion)

**Drugs Requiring Prior Authorization (covered under the pharmacy benefit)**

Extavia (Interferon Beta 1 B)
Zinbryta (daclizumab)
Mavenclad (cladribine)
Zeposia (ozanimod)
Kesimpta (ofatumumab)
Ponvory (ponesimod)
Aubagio (brand only)

**Drugs Not Requiring Prior Authorization (covered under the pharmacy benefit)**

Teriflunomide
Avonex (Interferon Beta 1A)
Betaseron (Interferon Beta 1B)
Copaxone (Glatiramer Acetate)
Gilenya (fingolimod)
Dimethyl Fumarate
Plegridy (peginterferon beta-1a)
Rebif (interferon Beta-1a)
Mayzent (Siponimod)
Bafiertam (monomethyl fumarate)
Vumerity (diroximel fumarate)

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**Overview**

Multiple sclerosis (MS) is a chronic central nervous system disease that is an autoimmune disease. The body's own defense system attacks the myelin sheath which protects the nerve fibers in the central nervous system (CNS). Damage to the myelin sheath and nerve fibers may cause disruption to nerve impulses between the brain and spinal cord which can cause a variety of symptoms. The severity of symptoms and progression of disease is variable between individuals. FDA-approved drugs approved for multiple sclerosis included in this policy are indicated for functional improvement or disease modification.

FDA Approved Indications for MS:

Ampyra:

- A potassium channel blocker indicated to improve walking in members with multiple sclerosis (MS).

Aubagio:

- Is a pyrimidine synthesis inhibitor indicated for the treatment of members with relapsing forms of multiple sclerosis.

Avonex:

- Indicated in relapsing forms of MS to slow the accumulation of physical disability and decrease the frequency of clinical exacerbations. Members with multiple sclerosis in whom efficacy has been demonstrated include members who have experienced a first clinical episode and have MRI features consistent with multiple

sclerosis. Efficacy in chronic progressive MS has not been established. Indicated for adult and pediatric members. (*Intramuscular)*

Bafiertam

- Indicated for the treatment of relapsing forms of multiple sclerosis, including clinically isolated syndrome, relapsing-remitting disease and active secondary progressive disease.

Betaseron:

- Is indicated for the treatment of relapsing forms of multiple sclerosis to reduce the frequency of clinical exacerbations. Members with multiple sclerosis in whom efficacy has been demonstrated include members who have experienced a first clinical episode and have MRI features consistent with multiple sclerosis.

Briumvi:

- Briumvi is a CD20-directed cytolytic antibody indicated for the treatment of relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

Copaxone:

- Reduction of the frequency of relapses in members with Relapsing-Remitting Multiple Sclerosis (RRMS), including members who have experienced a first clinical episode and have MRI features consistent with multiple sclerosis. *(Subcutaneous)*

Extavia:

- Extavia is an interferon beta indicated for the treatment of relapsing forms of multiple sclerosis to reduce the frequency of clinical exacerbations, Members with multiple sclerosis in whom efficacy has been demonstrated include members who have experienced a first clinical episode and have MRI features consistent with multiple sclerosis.

Gilenya:

- is a sphingosine 1-phosphate receptor modulator indicated for the treatment of members with relapsing forms of multiple sclerosis to reduce the frequency of clinical exacerbations and to delay the accumulation of physical disability.

Kesimpta

- Kesimpta is a human monoclonal antibody that binds specifically to the CD20 molecule expressed on normal B lymphocytes. Kesimpta is approved for the treatment of relapsing forms of multiple sclerosis, including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease.

Lemtrada:

- is a CD52-directed cytolytic monoclonal antibody indicated for the treatment of members with relapsing forms of multiple sclerosis. Because of its safety profile, the use of Lemtrada should generally be reserved for members who have had an inadequate response to two or more drugs indicated for the treatment of MS.

Mavenclad

- is a synthetic purine nucleoside antimetabolite indicated for the treatment of relapsing forms of multiple sclerosis, including relapsing remitting disease and active secondary progressive disease. It is not indicated for members with clinically isolated syndrome.

Mayzent

is an oral sphingosine 1-phosphate receptor modulator indicated for relapsing forms of multiple sclerosis (including clinical isolated syndrome, relapsing-remitting disease and active secondary progressive disease. Due to heart rate decrease or atrioventricular conduction delays, a baseline electrocardiogram is recommended prior to the start of treatment and first dose monitoring is recommended for members with preexisting cardiac conditions. Members also must be tested for CYP2C9 variants to determine their CYP2C9 genotype prior to the start of therapy.

Ocrevus:

- Is a CD20-directed cytolytic antibody indicated for the treatment of members with relapsing or primary progressive forms of MS
    - See exclusions

Plegridy:

- is an interferon beta indicated for the treatment of members with relapsing forms of multiple sclerosis

Ponvory:

- is a oral sphingosine 1-phosphate receptor modulator indicated for the treatment of relapsing forms of multiple sclerosis in adults, to include clinically isolated syndrome, relapsing-remitting disease and active secondary progressive disease.

Rebif:

- For the treatment of relapsing forms of Multiple Sclerosis to decrease the frequency of clinical exacerbations and delay the accumulation of physical disability. Efficacy in chronic progressive MS has not been established.
  The results of multicenter, randomized trials demonstrate that initiation of an

interferon (IFN)-b1-a delays the development of clinically defined MS (CDMS) in members at high risk for this outcome. These studies do not, however, provide evidence that the ultimate development of CDMS is prevented by such treatment nor that early treatment affects long term disability outcome.

Tecfidera:

- is indicated for the treatment of members with relapsing forms of multiple sclerosis.

Tysabri:

- As monotherapy for the treatment of members with relapsing forms of multiple sclerosis to delay the accumulation of physical disability and reduce the frequency of clinical exacerbations. TYSABRI is generally recommended for members who have had an inadequate response to, or are unable to tolerate, an alternate MS therapy.

Vumerity

- Vumerity is an oral fumarate (like dimethyl fumarate) and it is indicated for the treatment of relapsing forms of multiple sclerosis, including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease.

Zeposia

- Is and oral sphingosine 1-phosphate receptor modulator which is indicated for the treatment of relapsing forms of multiple sclerosis in adults, including clinically isolated syndrome, relapsing- remitting disease and active secondary progressive disease.

Zinbryta:

- Is an interleukin-2 receptor blocking antibody indicated for the treatment of relapsing forms of MS in members that have had inadequate response to two or more drugs indicated for the treatment of MS.

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**Indications/Criteria**

**Agents for Disease Modification**

Treatment will be considered for coverage for the treatment of the FDA approved indications for multiple sclerosis:

**Preferred Agents:**

Teriflunomide, Avonex (Interferon Beta 1A), Betaseron (Interferon Beta 1B), Copaxone (Glatiramer Acetate), Gilenya (fingolimod), Ocrevus (ocrelizumab), Ocrevus Zunovo Plegridy (peginterferon beta-1a), Rebif (interferon beta 1-a) Dimethyl Fumarate, Mayzent (siponimod), Vumerity (Diroximal fumarate) and Bafiertam (Monomethyl Fumarate).

- Do not require prior authorization however must meet criteria below on retro review.

**Non-Preferred Agents (prior authorization required):**

Aubagio (brand), Tysabri (natalizumab), Briumvi (ublituximab), Extavia (Interferon Beta 1 B), Mavenclad (cladribine), Zeposia (ozanimod), Kesimpta (ofatumumab), Ponvory (ponesimod) and Zinbryta (daclizumab)

- See Medicaid Variation for Tysabri and Lemtrada coverage

Non-Preferred Agents will be considered for coverage for the treatment of FDA approved indications for multiple sclerosis when all of the following are met:

- Prescribed by a neurologist.
- Greater than or equal to 18 years old.
- Monitoring and REMS requirements per the prescribing information are met.
- Neurology chart notes for the past 2 years, including all radiologic reports substantiate MS diagnosis consistent with prescribing information and detail previous treatment, if any.
- Documented failure or significant adverse effects to all preferred agents
    - Documented failure defined as:
        - At least 2 relapses within the past 12 months, AND
        - MRI identifying lesion progression.
- **Tysabri** (natalizumab) coverage will be limited to monotherapy for those members meeting all the above criteria and have had an inadequate response to, or are unable to tolerate, both preferred and non-preferred MS therapies described above AND
    1. A baseline MRI scan must be obtained prior to natalizumab
    2. Members must be evaluated at 3 and 6 months after the first infusion and every 6 months thereafter.

3. Alternative treatment criteria for members currently with high disease activity, as defined by a high number of relapses while on treatment and the progression of gadolinium-positive lesions on MRI, will be reviewed on a case-by-case basis

- **Lemtrada** (alemtuzumab)-Must have inadequate response to all preferred MS therapies AND not have Human Immunodeficiency Virus (HIV)

- **Briumvi** (ublituximab) coverage will be considered for those members meeting all the above criteria for non-preferred agents and have had an inadequate response to, or are unable to tolerate ALL preferred MS therapies described above AND
    - Hepatitis B virus screening and quantitative serum immunoglobulin screening required prior to first dose
    - Member must be assessed for active infection prior to every infusion; if member has active infection, infusion must be delayed until infection is resolved.
    - Pregnancy test results prior to each infusion for females of reproductive potential
    - Member must not have received live vaccines within 4 weeks and non-live vaccines within 2 weeks of treatment with Briumvi.
    - Per the MVP Health Care Pharmacy Management Programs policy, Briumvi is subject to Site of Care requirements and must be obtained through a preferred home infusion vendor or contracted provider office. Prior Authorization and medical justification is required for Briumvi obtained and administered in a non-preferred site of care (i.e. outpatient hospital setting).
        - MVP will allow 60 days after prior authorization approval for members to transfer to a preferred infusion site.
        - This requirement does not apply to MVP Medicare, CHP and Medicaid members

**Initial approval** for up to 6 months for self-administered agents and up to 3 infusions in 3 months for Tysabri. Extension requests will be approved up to 6 months if the member has a continued benefit to therapy (decrease in number of relapses).

Lemtrada (alemtuzumab)

- **Initial approval** will be for 12mg/day on 5 consecutive days.
- **Second approval** will be 12 months after initial approval for 12mg/day on three consecutive days if documentation identifies benefit from initial treatment and no adverse reactions

- Briumvi
  - **Initial approval** for Briumvi will be 2 infusions within one month (150mg initially, followed by 450mg infusion 2 weeks later)
  - **Continuation of therapy** will be 1 infusion every 24 weeks for subsequent infusions if documentation identifies benefit from initial treatment and no adverse reactions

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**Ocrevus and Ocrevus Zunovo**

- Per the MVP Health Care Pharmacy Management Programs policy, Ocrevus is subject to Site of Care requirements and must be obtained through a preferred home infusion vendor or contracted provider office. Prior Authorization and medical justification is required for Ocrevus obtained and administered in a non-preferred site of care (i.e. outpatient hospital setting)..
- MVP will allow 60 days after prior authorization approval for members to transfer to a preferred infusion site.
- This requirement does not apply to MVP Medicare, CHP and Medicaid members

**Medicaid Variation**

- Medications that are a pharmacy benefit are covered and billed to New York State Fee-For-Service (FFS) program. They are defined as medications that go through a retail or specialty pharmacy, including self-administered injectable products. Pharmacy medications are subject to FFS's clinical criteria including (but not limited to) coverage, quantity limit, step therapy, and prior authorization. Pharmacy benefit information can be found here: https://www.emedny.org/info/formfile.aspx

- For Medical drugs requiring prior authorization (Lemtrada, Briumvi, and Tysabri) members must meet the above diagnostic criteria **AND** documentation of a trial of self-administered products must be provided. Covered products can be found in the NYS Reimbursable Drug List https://www.emedny.org/info/formfile.aspxand the NYS Preferred Drug Program https://newyork.fhsc.com/downloads/providers/NYRx_PDP_PDL.pdf

- If available self-administered products are contraindicated or medically inappropriate, the prescriber must provide documentation.

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**Exclusions**

Lemtrada
- Use beyond two years

Briumvi
- Active hepatitis B virus infection
- History of life-threatening infusion reaction to Briumvi

Ocrevus IV for the treatment of RMS (Relapsing Multiple Sclerosis)
- Doses above 600mg do not provide additional benefit and are not supported medical literature

Agents for Disease Modification exclusions:
- Combination use of disease modifying agents
- Doses exceeding prescribing information
- Members who have in the last 6 months experienced or may be expected to experience medical contraindications or are on concomitant therapy with an agent known to have a significant potential for adverse outcome when used in combination with the requested agent as noted in the prescribing literature.

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| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Complete Wellness | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| USA Care PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

**Medicare Part B: Multiple Sclerosis Agents**

| | |
|---|---|
| **Type of Policy:** | **Drug and Medical Therapy** |
| **Prior Approval Date:** | **11/01/2023** |
| **Approval Date:** | **11/01/2024** |
| **Effective Date:** | **01/01/2025** |
| **Related Policies:** | N/A |

Refer to the MVP Medicare website for the Medicare Part D Formulary and Part D policies for drugs that may be covered under the Part D benefit.

**Please refer to relevant CMS LCDs/NCDs/Policy Articles for most up to date Medicare Part B guidance if available**

**Codes Requiring Prior Authorization (covered under the medical benefit)**

J0202 Lemtrada (alemtuzmab injection, 1mg)

J2323 Tysabri (natalizumab injection, 1 mg)

J2329 Briumvi (ublituximab, 150mg/6mL solution for infusion)

**Codes Not Requiring Prior Authorization (covered under the medical benefit)**

J2350 Ocrevus (ocrelizumab injection, 1mg)

**Overview**

Multiple sclerosis (MS) is a chronic central nervous system disease that is an autoimmune disease. The body's own defense system attacks the myelin sheath which protects the nerve fibers in the central nervous system (CNS). Damage to the myelin sheath and nerve fibers may cause disruption to nerve impulses between the brain and spinal cord which can cause a variety of symptoms. The severity of symptoms and progression of disease is variable between individuals. FDA-approved drugs approved for multiple sclerosis included in this policy are indicated for functional improvement or disease modification.

FDA Approved Indications for MS:

Briumvi:

- Briumvi is a CD20-directed cytolytic antibody indicated for the treatment of relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

Lemtrada:

- is a CD52-directed cytolytic monoclonal antibody indicated for the treatment of patients with relapsing forms of multiple sclerosis. Because of its safety profile, the use of Lemtrada should generally be reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of MS.

Ocrevus:

- Is a CD20-directed cytolytic antibody indicated for the treatment of patient with relapsing or primary progressive forms of MS.

Tysabri:

- As monotherapy for the treatment of patients with relapsing forms of multiple sclerosis to delay the accumulation of physical disability and reduce the frequency of clinical exacerbations. TYSABRI is generally recommended for patients who have had an inadequate response to, or are unable to tolerate, an alternate MS therapy.

-

**Indications/Criteria**

**Agents for Disease Modification**

Treatment will be considered for coverage for the treatment of the FDA approved indications for multiple sclerosis:

**Preferred Agents:**

Ocrevus (ocrelizumab)

Refer to the Medicare Part D formulary for drugs that may be covered under the Part D benefit.

**Non-Preferred Agents (prior authorization required):**
Tysabri (natalizumab), Lemtrada (alemtuzumab), Briumvi (ublituximab),

Non-Preferred Agents will be considered for coverage for the treatment of FDA approved indications for multiple sclerosis when all of the following are met:

- Prescribed by a neurologist.
- Greater than or equal to 18 years old.
- Monitoring and REMS requirements per the prescribing information are met.
- Neurology chart notes for the past 2 years, including all radiologic reports substantiate MS diagnosis consistent with prescribing information and detail previous treatment, if any.
- Documented failure or significant adverse effects to all preferred agents
    - Documented failure defined as:
        - At least 2 relapses within the past 12 months, AND
        - MRI identifying lesion progression.
- **Tysabri** (natalizumab) coverage will be limited to monotherapy for those patients meeting all the above criteria and have had an inadequate response to, or are unable to tolerate, both preferred and non-preferred MS therapies described above AND
    1. A baseline MRI scan must be obtained prior to natalizumab
    2. Members must be evaluated at 3 and 6 months after the first infusion and every 6 months thereafter.
    3. Alternative treatment criteria for members currently with high disease activity, as defined by a high number of relapses while on treatment and the progression of gadolinium-positive lesions on MRI, will be reviewed on a case-by-case basis
- **Lemtrada** (alemtuzumab)-Must have inadequate response to all preferred MS therapies AND not have Human Immunodeficiency Virus (HIV)
- **Briumvi** (ublituximab) coverage will be considered for those patients meeting all the above criteria for non-preferred agents and have had an inadequate response to, or are unable to tolerate ALL preferred MS therapies described above AND
    - Hepatitis B virus screening and quantitative serum immunoglobulin screening required prior to first dose

  - Patient must be assessed for active infection prior to every infusion; if patient has active infection, infusion must be delayed until infection is resolved.
  - Pregnancy test results prior to each infusion for females of reproductive potential
  - Patient must not have received live vaccines within 4 weeks and non-live vaccines within 2 weeks of treatment with Briumvi.

Initial approval for up to 6 months for self-administered agents and up to 3 infusions in 3 months for Tysabri.

- For continuation of therapy for up to 6 months:
  - Continued benefit – decrease in number of relapses.
- Lemtrada (alemtuzumab)
  - Initial approval will be for 12mg/day on 5 consecutive days.
  - Second approval will be 12 months after initial approval for 12mg/day on three consecutive days if documentation identifies benefit from initial treatment and no adverse reactions
- Briumvi
  - Initial approval for Briumvi will be 2 infusions within one month (150mg initially, followed by 450mg infusion 2 weeks later)
  - Continuation of therapy will be 1 infusion every 24 weeks for subsequent infusions if documentation identifies benefit from initial treatment and no adverse reactions

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**Exclusions**

Lemtrada

- Use beyond two years

Briumvi

- Active hepatitis B virus infection
- History of life-threatening infusion reaction to Briumvi

Agents for Disease Modification exclusions:

- Combination use of disease modifying agents
- Doses exceeding prescribing information
- Members who have in the last 6 months experienced or may be expected to experience medical contraindications or are on concomitant therapy with an

agent known to have a significant potential for adverse outcome when used in combination with the requested agent as noted in the prescribing literature.

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9. ECRI Health Technology Assessment Information Service. Natalizumab (Tysabri) for the Treatment of Multiple Sclerosis available at: http://www.ta.ecri. 2006.
10. Goodin DS, Frohman EM, Garmany GP, et al. Disease modifying therapies in multiple sclerosis. Neurology 2002;58:169-78.

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18. Briumvi (ublituximab). Prescribing Information. Morrisville, NC. TG Therapeutics. Revised: December 2022

**MVP Health Care Medical Policy**

# Cancer Guidance Program-Oncology Medication Coverage and Review

**Type of Policy:** **Drug/Medical Therapy**
**Prior Approval Date:** **12/01/2024**
**Approval Date:** **02/01/2025**
**Effective Date:** **01/01/2025**

**Related Policies:**

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies.

## Overview

The purpose of this policy is to define the clinical criteria that will be utilized for prior authorization review in Optum Cancer Guidance Program (CGP) determining coverage for oncology medications under medical (including, but not limited to chemotherapy, immunotherapy, targeted therapies, oral oncolytics, leucovorin, gonadotropin releasing hormonal analogs, bone modifying agents, somotostatin analogs, white blood cell growth factors, red blood growth factors, other supportive drugs).

## Indications/Criteria

### Preferred Product Criteria

Treatment with a non-preferred product, specified below, will be considered medically necessary for oncology indications when one of the following criteria is met AND the provider attests that the same result is not expected to occur with the non-preferred product*:

- History of intolerance or contraindication one of the preferred products
- Previous documented failure with all of the preferred listed products for the same requested indication

If there is step therapy for bone modifying agents, criteria will be addressed in a separate policy.

| Preferred Oncology Product | Non-Preferred Oncology Product |
|---|---|
| Zirabev<br>Mvasi | Avastin<br>Alymsys<br>Vegzelma |
| Herceptin<br>Herceptin Hylecta<br>Trazimera | Kanjinti<br>Ogivri<br>Ontruzant<br>Herzuma<br>Hercessi |
| Neulasta<br>Udenyca | Fulphila<br>Ziextenzo<br>Fylnetra<br>Rolvedon<br>Stimufend<br>Nyvepria<br>Rolvedon |
| Nivestym<br>Releuko | Zarxio<br>Neupogen<br>Granix |
| Ruxience<br>Rituxan<br>Rituxan Hycela | Truxima<br>Riabni |
| Gemcitabine | Infugem |
| leucovorin | levoleucovorin |
| Aranesp<br>Retacrit<br>Procrit<br>Epogen | |
| Aloxi<br>Emend<br>Fosaprepitant | Akynzeo<br>Cinvanti<br>Sustol<br>Focinvez |

**Diagnosis Criteria**

In additional to the above Preferred Product Criteria, oncology medications are considered medically necessary if use is listed in the National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium or Guidelines with Categories of

Evidence of 1, 2A, and 2B. Category of Evidence of 3 uses are considered as unproven and not medically necessary. For new to market oncology drugs, coverage determination will be made if use is in accordance with FDA-approved indication(s).

Chemotherapy regimen associated incidence of FN will be based on the clinical trial(s) with the highest level of evidence. Chemotherapy regimens and associated incidence of FN based on the clinical trial(s) according to the grade based on Common Terminology Criteria for Adverse Events (CTCAE) by the National Cancer Institute (NCI) criteria.

All oncology medications, for patients under the age of 19, will be considered medically necessary for oncology indications without regard to NCCN recommendations.

For Medicare Advantage plans, the Optum Cancer Guidance Program will follow Medicare hierarchy in determining medical necessity for eligible members.

- Medicare Coverage Database: National Coverage Determinations (NCD)
- Medicare Coverage Database: Local Coverage Determination (LCD)
- Medicare Coverage Database: Local Coverage Articles
- Medicare Benefit Policy Manual*
- Optum Oncology Medication Policy
- National Comprehensive Cancer Network (NCCN) Compendium and Guidelines

*Medicare Benefit Policy Manual Chapter 15-50.4.1 allows for the approval of a drug if it is being used according to the FDA-approved labeling. Additionally, Chapter 15-50.4.5 allows for the off-label use anti-cancer drugs and biologicals if use is supported by either one for more of acceptable compendia or in peer-reviewed medical literature with clinically meaningful outcomes.

Compendia:

- American Hospital Formulary Service-Drug Information (AHFS-DI)
- National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium – Category 3 is not recognized as medically accepted
- Micromedex DrugDex – Class I, IIa, or IIb
- Clinical Pharmacology
- Lexi-Drugs – Evidence Level of A

Peer-Reviewed Medical Literature:

- American Journal of Medicine
- Annals of Internal Medicine
- Annals of Oncology
- Annals of Surgical Oncology
- Biology of Blood and Marrow Transplantation
- Blood

- Bone Marrow Transplantation
- British Journal of Cancer
- British Journal of Hematology
- British Medical Journal
- Cancer
- Clinical Cancer Research
- Drugs
- European Journal of Cancer (formerly the European Journal of Cancer and Clinical Oncology)
- Gynecologic Oncology
- International Journal of Radiation, Oncology, Biology, and Physics
- The Journal Of American Medical Association
- Journal of Clinical Oncology
- Journal of the National Cancer Institute
- Journal of the National Comprehensive Cancer Network (NCC)
- Journal of Urology
- Lancet
- Lancet Oncology
- Leukemia
- The New England Journal of Medicine
- Radiation Oncology

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| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP 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 | 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 | Prior Auth |
| USA Care 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 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

# Medicare Part B: Cancer Guidance Program-Oncology Medication Coverage and Review

**Type of Policy:** **Drug/Medical Therapy**
**Prior Approval Date:** **12/01/2024**
**Approval Date:** **06/01/2025**
**Effective Date:** **04/01/2025**

**Related Policies:** **Medicare Part B Step Therapy**

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies.

Refer to the MVP website for the Medicare Part B policies for coverage criteria of drugs covered under the medical benefit.

## Overview

The purpose of this policy is to define the clinical criteria that will be utilized for prior authorization review in Optum Cancer Guidance Program (CGP) determining coverage for oncology medications under medical (including, but not limited to chemotherapy, immunotherapy, targeted therapies, oral oncolytics, leucovorin, gonadotropin releasing hormonal analogs, bone modifying agents, somotostatin analogs, white blood cell growth factors, red blood growth factors, other supportive drugs).

## Indications/Criteria

### Preferred Product Criteria

Treatment with a non-preferred product, specified below, will be considered medically necessary for oncology indications when one of the following criteria is met AND the

provider attests that the same result is not expected to occur with the non-preferred product*:

- History of intolerance or contraindication one of the preferred products
- Previous documented failure with all of the preferred listed products for the same requested indication

If there is step therapy for bone modifying agents, criteria will be addressed in a separate policy.

| **Preferred Oncology Product** | **Non-Preferred Oncology Product** |
|---|---|
| Zirabev<br>Mvasi | Avastin<br>Alymsys<br>Vegzelma |
| Herceptin<br>Trazimera<br>Herceptin Hylecta | Kanjinti<br>Ogivri<br>Ontruzant<br>Herzuma<br>Hercessi |
| Neulasta<br>Udenyca | Fulphila<br>Ziextenzo<br>Fylnetra<br>Rolvedon<br>Stimufend<br>Nyvepria |
| Nivestym<br>Releuko | Zarxio<br>Neupogen<br>Granix |
| Ruxience<br>Rituxan<br>Rituxan Hycela | Truxima<br>Riabni |
| Gemcitabine | Infugem |
| leucovorin | levoleucovorin |
| Aranesp<br>Retacrit<br>Procrit/Epogen | N/A |
| Aloxi<br>Emend<br>Fosaprepitant | Akynzeo<br>Cinvanti<br>Sustol<br>Focinvez |

**Diagnosis Criteria**

In additional to the above Preferred Product Criteria, oncology medications are considered medically necessary if use is listed in the National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium or Guidelines with Categories of Evidence of 1, 2A, and 2B. Category of Evidence of 3 uses are considered as unproven and not medically necessary. For new to market oncology drugs, coverage determination will be made if use is in accordance with FDA-approved indication(s).

Chemotherapy regimen associated incidence of FN will be based on the clinical trial(s) with the highest level of evidence. Chemotherapy regimens and associated incidence of FN based on the clinical trial(s) according to the grade based on Common Terminology Criteria for Adverse Events (CTCAE) by the National Cancer Institute (NCI) criteria.

All oncology medications, for patients under the age of 19, will be considered medically necessary for oncology indications without regard to NCCN recommendations.

For Medicare Advantage plans, the Optum Cancer Guidance Program will follow Medicare hierarchy in determining medical necessity for eligible members.

- Medicare Coverage Database: National Coverage Determinations (NCD)
- Medicare Coverage Database: Local Coverage Determination (LCD)
- Medicare Coverage Database: Local Coverage Articles
- Medicare Benefit Policy Manual*
- Optum Oncology Medication Policy
- National Comprehensive Cancer Network (NCCN) Compendium and Guidelines

*Medicare Benefit Policy Manual Chapter 15-50.4.1 allows for the approval of a drug if it is being used according to the FDA-approved labeling. Additionally, Chapter 15-50.4.5 allows for the off-label use anti-cancer drugs and biologicals if use is supported by either one for more of acceptable compendia or in peer-reviewed medical literature with clinically meaningful outcomes.

Compendia:

- American Hospital Formulary Service-Drug Information (AHFS-DI)
- National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium – Category 3 is not recognized as medically accepted
- Micromedex DrugDex – Class I, IIa, or IIb
- Clinical Pharmacology
- Lexi-Drugs – Evidence Level of A

Peer-Reviewed Medical Literature:

- American Journal of Medicine
- Annals of Internal Medicine

- Annals of Oncology
- Annals of Surgical Oncology
- Biology of Blood and Marrow Transplantation
- Blood
- Bone Marrow Transplantation
- British Journal of Cancer
- British Journal of Hematology
- British Medical Journal
- Cancer
- Clinical Cancer Research
- Drugs
- European Journal of Cancer (formerly the European Journal of Cancer and Clinical Oncology)
- Gynecologic Oncology
- International Journal of Radiation, Oncology, Biology, and Physics
- The Journal Of American Medical Association
- Journal of Clinical Oncology
- Journal of the National Cancer Institute
- Journal of the National Comprehensive Cancer Network (NCC)
- Journal of Urology
- Lancet
- Lancet Oncology
- Leukemia
- The New England Journal of Medicine
- Radiation Oncology

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**Exclusions:** N/A

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**References**

1. The NCCN Drugs and Biologics Compendium (NCCN Compendium®) https://www.nccn.org/compendia-templates/compendia/drugs-and-biologics-compendia. Accessed June 6,2023.

2. The NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) https://www.nccn.org/guidelines/category_1. Accessed June 6, 2023.

3. U.S. Food & Drug Administration. Biosimilars. https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/biosimilars. Accessed June 6,2023.

4. Centers for Medicare & Medicaid Services. Medicare Benefit Policy Manual. Chapter 15-Covered Medical and Other Heath Services. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf. Accessed June 6,2023.

**MVP Health Care Medical Policy**

**Nuedexta**

**Type of Policy:** **Drug Therapy**
**Prior Approval Date:** **11/01/2023**
**Approval Date:** **11/01/2024**
**Effective Date:** **01/01/2025**

**Related Policies:** **N/A**

## Drug Requiring Prior Authorization (covered under the pharmacy benefit)

Nuedexta (Dextromethorphan; Quinidine)

Refer to the MVP website for the Medicare Part D formulary for drugs that may be covered under the Part D benefit.

## Overview

Pseudobulbar affect (PBA) occurs secondary to a variety of otherwise unrelated neurologic conditions, and is characterized by involuntary, sudden, and frequent episodes of laughing and/or crying. PBA episodes typically occur out of proportion or incongruent to the underlying emotional state. PBA is a specific condition, distinct from other types of emotional lability that may occur in patients with neurological disease or injury.

## Indications/Criteria

**ALL the following criteria must be met for coverage for Nuedexta:**

- Chart notes indicating a diagnosis of PBA
    - Laughing or crying spells caused by other diagnoses (i.e. depression, bipolar) must be ruled out
- Clinical chart notes documenting member's frequency of laughing and crying episodes for at least the past 3 months
- Chart notes identifying Center for Neurologic Studies Lability Scale (CNS-LS) score of 13 or greater

**Initial approval** will be for 3 months.
**Continuation** of Nuedexta will be for 12 months and will require current clinical

chart notes documenting improvement in frequency of laughing and crying episodes and improvement in CNS-LS score from baseline

## Exclusions

- Indication, age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling
    - Treatment of psychosis, delirium, or disruptive behavior
- Concomitant use with other drugs containing quinidine, quinine, or mefloquine
- A history of Nuedexta (dextromethorphan/quinidine), quinine, mefloquine or quinidine-induced thrombocytopenia, hepatitis, bone marrow depression or lupus-like syndrome
- Members taking monoamine oxidase inhibitors (MAOIs) or who have taken MAOIs within the preceding 14 days
- Members with a prolonged QT interval, congenital long QT syndrome, a history suggestive of torsades de pointes, in patients with heart failure, or in patients receiving drugs that both prolong QT interval and are metabolized by CYP2D6 (e.g., thioridazine and pimozide)
- Complete atrioventricular (AV) block without implanted pacemakers, or in patients who are at high risk of complete AV block

## References


1. NUEDEXTA (dextromethorphan hydrobromide and quinidine sulfate). Prescribing information. Aliso Viejo, CA: Avanir Pharmaceuticals, Inc. Approval 2010. Revised 12/2022
2. Jack J. Chen, PharmD, BCPS, BCGP. Pharmacotherapeutic Management of Pseudobulbar Affect. American Journal of Managed Care. Published 2017.
3. Fralick M, Sacks CA, Kesselheim AS. Assessment of Use of Combined Dextromethorphan and Quinidine in Patients With Dementia or Parkinson Disease After US Food and Drug Administration Approval for Pseudobulbar Affect. *JAMA Intern Med*. January 2019


| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Complete Wellness | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D |
| USA Care 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 | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| 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).** | |
| *© 2025 MVP Health Plan, Inc. All rights reserved. Descriptions contained within MVP's Medical Policies are not a guarantee of coverage. Each MVP Group or Subscriber Contract contains specific limitations, exclusions and requirements that may affect a Policy. If there is any discrepancy between your Group or Subscriber Contract and a Policy, your Group or Subscriber Contract shall in all cases govern.* | |

***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 |

**MVP Health Care Medical Policy**

**Onychomycosis**

| | |
|---|---|
| **Type of Policy:** | **Drug Therapy** |
| **Prior Approval Date:** | **04/01/2024** |
| **Approval Date:** | **04/01/2025** |
| **Effective Date:** | **06/01/2025** |
| **Related Policies:** | **N/A** |

## Drugs Requiring Prior Authorization under the Pharmacy Benefit

Jublia (efinaconazole)- brand and generic
Kerydin (tababorole)- brand and generic
Brand itraconazole products: Sporanox, Tolsura

## Drugs Requiring Prior Authorization under the Pharmacy Benefit when quantity limit is exceeded

Ciclopirox (Penlac®) if quantity is greater than 20ml per 365 days
Itraconazole (generic) if quantity is greater than 360 capsules per 365 days or 3600ml per 365 days
Terbinafine (Lamisil®) if quantity is greater than 168 units per 365 days.

Refer to the MVP website for the Medicare Part D formulary and policies for drugs that may covered under the Part D benefit.

## Overview

The use of antifungal agents to improve the appearance of discolored or thick nails is considered cosmetic unless the member meets the clinical criteria identified in this policy. Oral antifungal agents are prescribed for the treatment of onychomycosis (nail fungus) due to tinea unguium and other indications. Topical ciclopirox is indicated for onychomycosis due to trichophyton rubrum.

For the treatment of onychomycosis, oral therapy is the most effective treatment for any severity. They have a higher cure rate and shorter treatment duration compared to topical therapies. Terbinafine is first line therapy as it is the most effective oral agent due to a high cure rate. Topical therapies may be used as an alternative to first line treatments. Topical therapies have lower risks of adverse effects and less drug interactions.

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**Indications/Criteria**

**Terbinafine**

- Terbinafine does not require prior authorization for quantities less than 168 units per 365 days.

**Itraconazole**

- **Generic itraconazole** does not require prior authorization for quantities less than 360 capsules per 365 days or 3600ml per 365 days.
- **Brand itraconazole** products (e.g. Sporanox) for the use of onychomycosis may be covered with the presence of a positive KOH test from a nail scraping or a positive pathogenic fungal culture documenting the presence of hyphae consistent with a dermatophyte or candidal infection **AND** the following:
    - Member is immunocompromised (e.g., HIV/AIDS, undergoing chemotherapy, transplant recipient) or has a history of peripheral vascular disease (e.g., diabetes), **OR**
    - Activities of daily living (ADLs) are significantly compromised due to pain caused by the infection **AND**
    - If the member has a documented failure, lack of indication, or other contraindications to terbinafine **AND**Documentation indicating why generic itraconazole is not clinically appropriate for the member.
- Approval for onychomycosis will be for 6 months

**Itraconazole for Systemic Fungal Infections**

- Itraconazole, including Tolsura, for the treatment of systemic fungal infections is allowed for a longer duration of therapy when the following is met:

    - Chart notes are provided indicating the diagnosis being treated and confirmed by culture results
    - Prior use of terbinafine is **not** required for systemic fungal infections.
    - Prior use of generic itraconazole is **not** required for systemic fungal infections. Tolsura is not interchangeable with other itraconazole products.
- Approval will be for 12 months

**Brand name Lamisil or Penlac**

- The use of brand name Lamisil tablets or Penlac will require documentation of a severe adverse event from the generic product.
- Quantity limits still apply.
- Approval will be for 12 months

**Jublia**

The use of **Jublia** may be covered for onychomycosis of the toenail if the member has:

- Documentation of a positive KOH test from a nail scraping or a positive pathogenic fungal culture documenting the presence of hyphae consistent with a dermatophyte or candida infection **AND**
- Documentation of a failure or contraindication with itraconazole therapy **AND**
- Documentation of a failure of a 48-week trial of ciclopirox 8%
- Approval will be for 12 months

**Kerydin**

The use of **Kerydin** may be covered for onychomycosis of the toenail when

- The member meets ALL the above criteria for Jublia **AND**
- Documentation of a failure of a 48-week trial of Jublia
- Approval will be for 12 months

**Exclusions**

- Combination therapy with more than one agent identified in this policy.
- Age, dosing, frequency and/or duration of therapy outside of FDA approved package labeling

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**References**

1. Lamisil® (terbinafine) Tablets. Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; April 2012.

2. Sporanox® (itraconazole) Capsules/Oral Solution. Prescribing Information. Raritan, NJ: Ortho-McNeil-Janssen Pharmaceuticals, Inc.; April 2012.
3. Penlac® Nail Lacquer (ciclopirox) Topical Solution. Prescribing Information. Bridgewater, NJ: Sanofi Aventis US; July 2006.
4. Jublia® (efinaconazole) topical Solution, 10%. Prescribing Information. Bridgewater, NJ: Valeant Pharmaceuticals LLC, February 2015
5. Kerydin® (tavaborole) topical solution, 5%. Prescribing Information. Palo Alto, CA: Anacor Pharmaceuticals, Inc; February 2015
6. Tolsura (itraconazole capsules). Prescribing Information. Greenville, NC: Maybe Pharma; December 2018.
7. Jublia® (efinaconazole) topical Solution, 10%. Prescribing Information. Bridgewater, NJ: Valeant Pharmaceuticals LLC, July 2020.
8. Hainer, B. L. (2021). Onychomycosis: Current trends in diagnosis and treatment. *American Family Physician, 104*(7), 359-366. Retrieved from https://www.aafp.org/pubs/afp/issues/2021/1000/p359.html

| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Complete Wellness | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| USA Care PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

**Omidubicel**

| | |
|---|---|
| **Type of Policy:** | Medical Therapy (administered by the pharmacy department) |
| **Prior Approval Date:** | NA |
| **Approval Date:** | 02/01/2024 |
| **Effective Date:** | 02/01/2024 |
| **Related Policies:** | Donislecel<br><br>Experimental or Investigational Procedures, Behavioral Health Services, Drugs and Treatments, Off-Label use of FDA Approved Drugs, and Clinical Trials |

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies.

## Drugs Requiring Prior Authorization under the medical benefit

J3590 omidubicel (Omisirge), cell therapy suspension for infusion

## Overview

Omidubicel is approved for use in hematopoietic stem cell transplant following myeloablative conditioning in patients with hematologic malignancies to reduce the time to neutrophil recovery and incidence of infection. It has been designated an orphan drug for this indication. Omidubicel is a nicotinamide-modified allogeneic hematopoietic progenitor cell therapy derived from cord blood indicated for use in adults and pediatric patients 12 years and older with hematologic malignancies who are planned for umbilical cord blood transplantation following myeloablative conditioning to reduce the time to neutrophil recovery and the incidence of infection.

## Indications/Criteria

### Hematologic Malignancy

Omidubicel may be considered for coverage when all of the following criteria are met:

- Member is 12 years of age or older
- Member has a documented hematologic malignancy, and the medication is being used to reduce the time to neutrophil recovery and incidence of infection.
- Documentation that the member has not received a prior allogeneic hematopoietic stem cell transplant (allo-HSCT)
- Documentation of planned umbilical cord blood transplantation
- Documentation that member will receive myeloablative conditioning.
- Prescribed by or in consultation with a hematologist or oncologist
- Must be administered at a transplant center who is activated and able to administer omidubicel
    - Treatment centers that can administer are: OMISIRGE™ (omidubicel-onlv) | Allogeneic Hematopoietic Progenitor Cell Therapy
- Documentation that administration of omidubicel will be under the supervision of a physician experienced in treatment of hematologic malignancies,
- Documentation that the member does not have a known allergy or hypersensitivity to the following:
    - Dimethyl sulfoxide (DMSO)
    - Dextran 40
    - Gentamicin aminoglycoside albumin
    - Bovine protein hypersensitivity

If approved, coverage will be for one infusion of Omidubicel and will not be renewed. Requests for replacement due to lost or damaged product will not be covered. Coverage is contingent on eligibility at the time of infusion.

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## Exclusions

The use of Omidubicel will not be covered for the following situations:

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling.
- More than one infusion per lifetime

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## References


1. Omidubicel. Clinical Pharmacology. Revised May 2, 2023. Accessed December 6, 2023.

2. Prescribing Information. Omisirge. Gamida Cell, Inc. Boston, MA. Revised April 2023. Omisirge-final-PI.pdf (gamida-cell.com)


| 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 | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Authorization |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Medicare Gold Giveback | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

**Medicare Part B: Omidubicel**

| | |
|---|---|
| **Type of Policy:** | Medical Therapy (administered by the pharmacy department) |
| **Prior Approval Date:** | NA |
| **Approval Date:** | 02/01/2024 |
| **Effective Date:** | 02/01/2024 |
| **Related Policies:** | Donislecel<br><br>Experimental or Investigational Procedures, Behavioral Health Services, Drugs and Treatments, Off-Label use of FDA Approved Drugs, and Clinical Trials |

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies.

## Drugs Requiring Prior Authorization under the medical benefit

J3590 omidubicel, cell therapy suspension for infusion

## Overview/Summary of Evidence

Omidubicel is approved for use in hematopoietic stem cell transplant following myeloablative conditioning in patients with hematologic malignancies to reduce the time to neutrophil recovery and incidence of infection. It has been designated an orphan drug for this indication. Omidubicel is a nicotinamide-modified allogeneic hematopoietic progenitor cell therapy derived from cord blood indicated for use in adults and pediatric patients 12 years and older with hematologic malignancies who are planned for umbilical cord blood transplantation following myeloablative conditioning to reduce the time to neutrophil recovery and the incidence of infection.

## Indications/Criteria

### Hematologic Malignancy

Omidubicel may be considered for coverage when all of the following criteria are met:

- Member is 12 years of age or older
- Member has a documented hematologic malignancy, and the medication is being used to reduce the time to neutrophil recovery and incidence of infection.
- Documentation that the member has not received a prior allogeneic hematopoietic stem cell transplant (allo-HSCT)
- Documentation of planned umbilical cord blood transplantation
- Documentation that member will receive myeloablative conditioning.
- Prescribed by or in consultation with a hematologist or oncologist
- Must be administered at a transplant center who is activated and able to administer omidubicel
    - Treatment centers that can administer are: OMISIRGE™ (omidubicel-onlv) | Allogeneic Hematopoietic Progenitor Cell Therapy
- Documentation that administration of omidubicel will be under the supervision of a physician experienced in treatment of hematologic malignancies
- Documentation that the member does not have a known allergy or hypersensitivity to the following:
    - Dimethyl sulfoxide (DMSO)
    - Dextran 40
    - Gentamicin aminoglycoside albumin
    - Bovine protein hypersensitivity

If approved, coverage will be for one infusion of Omidubicel and will not be renewed. Requests for replacement due to lost or damaged product will not be covered. Coverage is contingent on eligibility at the time of infusion.

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## Exclusions

The use of Omidubicel will not be covered for the following situations:

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling.
- More than one infusion per lifetime

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## References

1. Omidubicel. Clinical Pharmacology. Revised May 2, 2023. Accessed December 6, 2023.

2. Prescribing Information. Omisirge. Gamida Cell, Inc. Boston, MA. Revised April 2023. Omisirge-final-PI.pdf (gamida-cell.com)

**MVP Health Care Medical Policy**

**Oral Allergen Immunotherapy Medications**

**Type of Policy:** **Drug Therapy**
**Prior Approval Date:** **11/01/2023**
**Approval Date:** **11/01/2024**
**Effective Date:** **01/01/2025**
**Related Policies:** **N/A**

## Drugs Requiring Prior Authorization

The following drugs listed are oral immunotherapy medications that may fall under prescription drug coverage.

| Brand Name | Chemical/Generic name |
|---|---|
| Grastek® | Timothy Grass Pollen Allergen Extract |
| Odactra® | House Dust Mite Allergen Extract |
| Oralair® | Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass Mixed Pollens Allergen Extract |
| Ragwitek® | Short Ragweed Pollen Allergen Extract |

Refer to the MVP website for the Medicare Part D formulary and policies for drugs that may covered under the Part D benefit.

## Overview

Allergen immunotherapy is typically provided as a subcutaneous injection given at the physician's office. Therapy consists of injecting a low dose of allergen extract that is escalated to a maintenance dose. Although the exact mechanism is not fully understood, it is believed this modulates and desensitizes the IgE response to the allergen, reducing IgE mediated symptoms. Treatment may continue to have a long-term effect after discontinuation, although this decision to discontinue therapy is generally individualized.

In the first half of 2014, the FDA approved its first allergen oral immunotherapy medications that can be taken at home. These medications are taken sublingually and are to be used for the treatment of grass pollen-induced allergic rhinitis with or without conjunctivitis. Therapy is typically started before the expected onset of each pollen season and is to be used throughout the season. Due to the safety concerns regarding the chance of causing an anaphylaxis reaction, these medications are to be given in the physician office for the first dose and are to be dispensed with an epinephrine auto-injector. Oral allergen immunotherapy medication's place in therapy relative to other methods has not yet been determined and the decision to initiate therapy is largely physician and member preference.

Cross-reactivity considerations are very important in the treatment of allergen immunotherapy, especially since the number of individual extracts available for commercial use is diminishing due to economic considerations. Many of these allergen extracts have allergy inducing epitopes that are similar between allergens in the same family or sub-family. Grastek® is the only drug that explicitly states that it can be used with cross-reactive grass pollens in its indication; however, it is reasonable to use the other oral allergen immunotherapy medications with their respective strongly cross-reactive representatives.
Even though treatment may have a long-term effect after discontinuation, Grastek® is the only drug that has proven to achieve a sustained effectiveness. If taken daily for 3 years sustained effectiveness for one grass pollen season can be achieved.

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## Indications/Criteria

Coverage of oral allergen immunotherapy medication for the treatment of grass pollen or house dust mite-induced allergic rhinitis with or without conjunctivitis will be considered when **ALL** of the following criteria are met:

1. Prescribed by a board-certified allergist or immunologist
2. Positive skin test or in vitro testing for pollen-specific IgE antibodies for the specific allergen extract included in the formation OR a strongly cross-reactive allergen (see chart below). Allergen must be identified as the cause of the major clinical symptoms
3. Member meets the age criteria approved for the oral allergen immunotherapy medication (see chart below)
4. Treatment is started before pollen season as specified below in chart
5. Member has failed at least three (3) of the following treatment options:

a. Intranasal corticosteroids
b. Oral or intranasal antihistamine
c. Oral leukotriene receptor antagonist OR
d. Intranasal cromolyn

**Cross-reactive allergen and approved age criteria:**

| Brand Name | Chemical/Generic name | Age Criteria | Strongly Cross-Reactive Allergen |
|---|---|---|---|
| Grastek® | Timothy Grass Pollen Allergen Extract | 5 through 65 years of age | Members of the pooideae sub family (includes but not limited to orchard, fescue, ryegrass, June, and sweet vernal) |
| Odactra® | House dust mite allergen extract | 12 through 65 years of age | (*Dermatophagoides farinae* and *Dermatophagoides pteronyssinus*) |
| Oralair® | Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass Mixed Pollens Allergen Extract | 5 through 65 years of age | Members of the pooideae sub family (includes but not limited to orchard, fescue, ryegrass, June, and sweet vernal) |
| Ragwitek® | Short Ragweed Pollen Allergen Extract | 5 through 65 years of age | Short, giant, western, and false ragweed |

**Initial start date criteria and initial approval duration:**

| Brand Name | Initiate Treatment | Initial Approval Duration |
|---|---|---|
| Grastek® | At least 12 weeks before expected pollen season (usually late April in Northeast). Therapy should be initiated in January/February in Northeast | 4 months |
| Odactra® | Not applicable | 3 months |
| Oralair® | At least 4 months before expected pollen season (usually late April in Northeast) Therapy should be initiated in January in Northeast | 5 months |
| Ragwitek® | At least 12 weeks before expected pollen season (usually mid-August in Northeast). Therapy should be initiated by April in Northeast | 4 months |
| *Expected pollen season should be based on geographical location | | |

**Continuation of treatment for all products require:**

- Chart notes documenting the benefits of treatment
- Medication compliance based on prescription claims review

**Extensions for Oralair and Ragwitek** will be through the end of pollen season, typically October in Northeast

**Extensions of daily therapy of Grastek after end of pollen season authorizations** will be for 6 months

- Members that were on active therapy daily for 3 consecutive years must wait at least 1 year until coverage may be reinitiated, unless members experience a documented severe increase in symptoms compared to the past 3 years

**Extensions of Odactra** will be up to 12 months

**Treatment for all products beyond three years requires**

- Chart notes documenting clinical rationale for continued treatment

**A presumption of failure can be made when**, after initial approval duration, a person does not experience a noticeable decrease of symptoms, an increase tolerance to grass pollen/house dust mite, and a reduction in medication usage

**Exclusions**

1. Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling
2. Non-FDA approved indications without documentation of supporting clinical studies and failure of preferred treatments
3. Caused by a non-IgE mediated allergy
4. No significant reduction in symptoms after 24 weeks of therapy
5. Severe unstable or uncontrolled asthma
6. History of eosinophilic esophagitis
7. History of any severe system allergic reaction or any severe local reaction to sublingual allergen immunotherapy
8. Receiving subcutaneous allergen immunotherapy

## References


1. Grastek® (Timothy Grass Pollen Allergen Extract). Prescribing Information. Whitehouse Station, NJ: Merck & Co., Inc.; September 2016. Revised March 2022.
2. Oralair® (Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass Mixed Pollens Allergen Extract). Prescribing Information. Antony, France: Stallergenes S.A.; 2014 Oct. Revised November 2018.
3. Ragwitek® (Short Ragweed Pollen Allergen Extract). Prescribing Information. Whitehouse Station, NJ: Merck & Co., Inc.; September 2016. Revised March 2022.
4. American Academy of Allergy, Asthma & Immunology/American College of Allergy, Asthma, & Immunology (AAAAI/ACAAI). Allergen immunotherapy: A practice parameter third update. J Allergy Clin Immunol. 2011 Jan;127(1 Suppl): S1-55.
5. Weber RW. Guidelines for using pollen cross-reactivity in formulating allergen immunotherapy. J Allergy Clin Immunol. 2008; 122:219-21.
6. Sur DK and Scandale S, Treatment of Allergic Rhinitis. Am Fam Physcian. 2010;81(12):1440-6.Seidman MD, Gurgel RK, Lin SY, et al. Clinical practice guideline: Allergic rhinitis. Otolaryngol Head Neck Surg. 2015;152(1 Suppl): S1-43.
7. Odactra ® Prescribing information. Whitehouse Station, NJ: Merck & Co., Inc. March 2017. Revised January 2023.
8. Nelson, Harold S. 2020 Updated Asthma Guidelines: Allergen immunotherapy. Journal of Allergy and Clinical Immunology, Volume 146, Issue 6, 1286 – 1287
9. Matthew Greenhawt, MD, MBA, MSc; John Oppenheimer, MD; Michael Nelson, MD, PhD; Sublingual immunotherapy, A focused allergen immunotherapy practice parameter update, Practice Parameter. Annals of Allergy, Asthma, & Immunology. 12/2016


| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Complete Wellness | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D |

| | |
|---|---|
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D |
| USA Care PPO | Refer to the MVP website for the Medicare Part B and Part D |
| 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 | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

**Orphan Drug(s) and Biologicals**

| | |
|---|---|
| **Type of Policy:** | **Drug/Medical Therapy** |
| **Prior Approval Date:** | **08/01/2023** |
| **Approval Date:** | **08/01/2024** |
| **Effective Date:** | **10/01/2024** |

**Related Policies:** **Experimental or Investigational Procedures, Behavioral Health Services, Drugs & Treatments, Off-Label use of FDA Approved Drugs, Clinical Trials**

***Codes Requiring Prior Authorization (covered under the medical benefit)**

Adagen® (J2504 Inj, pegademase bovine, 25 IU)
Aldurazyme® (J1931 Inj, laronidase, 0.1 mg)
Arikayce (J8499 amikacin liposome inhalation susp)
Brineura (J0567 cerliponase alfa inj. 1mg)
Cablivi (J3590, Inj Caplacizumab)
Ceprotin™ (J2724 Inj, protein C concentrate, IV 101U)
Clolar® (J9027 Inj, clofarabine, 1 mg)
Crysvita (J0584 inj, burosumab-twza 1 mg)
Elaprase® (J1743 Inj, idursulfase)
Elzonris (J9269 Inj, tagraxofusp-erzs)
Enjaymo™ (J1302 Inj, sutimlimab-jome)
Evkeeza™(J1305, evinacumab-dgnb)
Folotyn (J9307 Inj, pralatrexate, 1 mg)
Fusilev™ (J0641 Inj, levoleucovorin 0.5mg)
Gamifant (J9210, emapalumab-IZSG inj)
Ilaris® (J0638 Inj, canakinumab 1mg)
Kanuma (J2840 Inj, sebelipase alfa, 1mg)
Lamzede (J0217, velmanase alfa-tycv, 10mg)
Khapzory (J0642) levoleucovorin IV solution)
Lumizyme (J0221 Inj, alglucosidase alfa)Mepsevii (J3397 Inj. Vestronidase alfa)
Naglazyme® (J1458 Inj, galsulfase, 1 mg)

Nexviazyme® (J0219, avalglucosidase alfa-ngpt)
Nulibry® (C9399, J3490, fosdenopterin)
Oxlumo® (J0224, lumasiran)
Pombiliti (J1203, cipaglucosidase alfa, powder for injection)
Poteligeo (J9204) Inj. mogamulizumab-kpkc)
Reblozyl (J0896, luspatercept-aamt, SQ injection)
Retisert® (J7311 fluocinolone acetonide, intravitreal implant)
Rystiggo (J9333, Rozanolixizumab SQ infusion)
Scenesse (J7352, afamelanotide implant 16mg)
Soliris® (J1300 Inj, eculizumab, 10 mg)
Sylvant (J2860 Inj, siltuximab, 10mg)
Ultomiris™ (J1303, ravulizumab-cwvz IV, inj)
Uplizna® (J1823, inebilizumab-cdon)
Veopoz (J9376, pozelimab-bbfg, injection, 1mg)
Vimizim (J1322, Inj, elosulfase alfa, 1mg)
Vyjuvek (J3401, beremagene geperpavec)
Vyvgart™ (J9332 Inj, efgartigimod alfa-fcab)
Vyvgart Hytrulo (J9334 Injection, efgartigimod alfa; hyaluronidase)
Xenpozyme™ (J0218 Inj, olipudase alfa)
Zynlonta (J9359, loncastuximab tesirine-lpyl)
** This list is subject to change based on FDA approval of new drugs and/or new indications*

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***Drugs Requiring Prior Authorization (covered under the pharmacy benefit)**
Apokyn® (J0364 SQ Injection, apomorphine hydrochloride, 1 mg)
Arcalyst™ (J2793 SQ Injection, rilonacept, 1 mg)
Ayvakit (avapritinib tablets)
Benznidazole tab (J8499 12.5mg 100mg tabs)
Bylvay™ (odevixibat)
Calquence (C9399/J8999 acalabrutinib cap 100mg)
Camzyos™ (mavacamten)
Carbaglu® (carglumic acid)
Cholbam (cholic acid oral capsules)
Cometriq (cabozantinib oral capsules)

Cystaran (cysteamine ophthalmic solution)
Cystadrops (cysteamine ophthalmic solution
Danyelza® (J9348, naxitamab-gqgk)
Daurismo™ (glasdegib oral tablets)
Diacomit (Stiripentol)
Empaveli® (pegcetacoplan)
Enspryng® (satralizumab-mwge)
Exjade® (deferasirox oral tablet for suspension)
Fintepla® (fenfluramine)
Firdapse® (amifampridine oral tablets)
Galafold (migalastat, 123mg capsule)
Givlaari (givosiran,189mg/mL solution for subcutaneous injection)
Imcivree™ (setmelanotide)
Impavido® (miltefosine, oral capsule)
Inrebic (Fedratinib)
Jakafi (ruxolitinib oral tablet)
Joenja (leniolisib oral tablet)
Juxtapid (lomitapide oral capsules)
Korlym (mifepristone, oral tablets)
Koselugo (selumetinib capsules)
Kynamro (mipomersen injection)
Livmarli® (maralixibat)
Mifepristone (oral tablets)
Myalept (SQ Inj, metreleptin, 11.3mg)
Nityr (Nitisinone Tablets)
Ocaliva (obeticholic acid, oral tablet)
Ojjaara (momelotinib, oral tablet)
Opfolda (miglustat, oral capsule)
Onureg® (azacitidine)
Orfadin (nitisinone, oral capsules)
Oxbryta (voxelotor oral tablet)
Oxervate™ (ophthalmic solution)
Pemazyre (pemigatinib tablets)
Pheburane® (sodium phenylbutyrate)
Procysbi (cysteamine oral capsule)
Ravicti (glycerol phenylbotyrate oral liquid)

Relyvrio™ (sodium phenylbutyrate and taurusodiol)
Retevmo™ (selpercatinib)
Revcovi (elapegademase-lylr IM injection)
Rezurock® (belumosudil)
Rozlytrek® (entrectinib)
Ruzurgi (Amifampridine)
Signifor (SQ Injection pasireotide)
Skyclarys (omaveloxolone capsules)
Sohonos (palovarotene, oral capsules)
Strensiq (asfotase alfa injection)
Tabrecta® (capmatinib)
Tavalisse (fostamatinib oral tablets)
Tazverik (tazemetostat HBR tablets)
Tiglutik (riluzole oral suspension)
Tibsovo (ivosidenib oral tablets)
Turalio (Pexidartinib)
Ukoniq (Umbralisib)
Viktravi® (larotrectinib oral capsules, oral solution)
Vijoice® (alpelisib)
Vizimpro® (dacomitinib oral tablets) Xospata® (gilteritinib oral tablets)
Vonjo™ (pacritinib)
Xpovio (Selinexor)
Xuriden (uridine triacetate, oral granules)
Zokinvy (lonafarnib)
Zolinza® (vorinostat oral capsule)
** This list is subject to change based on FDA approval of new drugs and/or new indications*

Refer to the MVP website for the Medicare Part D formulary and policies for drugs that may covered under the Part D benefit.

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## Overview

An orphan drug is a drug used to treat a rare disease or condition which affects:

- less than 200,000 persons in the United States[1]; or

- more than 200,000 persons in the United States; and there is no reasonable expectation that the cost of developing and making a drug will be recovered from sales in the United States[1].

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**Indications/Criteria**

Orphan drugs or FDA approved drugs designated with an orphan drug indication may be covered on a case-by-case basis, with prior authorization, for the FDA approved indications only. Only drugs FDA approved for marketing as Orphan Drugs or Biologics will be considered for coverage under this policy.

The drug must be prescribed by a plan affiliated Specialist familiar with the treatment of the rare disease or condition.

Those drugs listed at https://www.accessdata.fda.gov/scripts/opdlisting/oopd/ have been designated by the FDA as Orphan Designated Products approved for marketing. The list is maintained by the FDA and is subject to change.

Physician and member must comply with all approved and/or limited distribution channels for the agent including specialty pharmacy vendors where applicable.

Drug and/or biological coverage is subject to the terms and conditions of the member's prescription drug rider and/or contract.

Documentation submitted must include baseline subjective/objective laboratory or test results (dependent on drug and diagnosis). If member started therapy while enrolled in a clinical trial, baseline laboratory or test results must be provided from prior to the start of the trial.

For continuation of therapy request documentation must show improvement in symptoms/condition from baseline.

**Site of Care**

- The following are subject to Site of Care: Aldurazyme, Crysvita, Elaprase, Lumizyme, Naglazyme and Xenpozyme
- Per the MVP Health Care Pharmacy Management Programs policy, Aldurazyme, Crysvita, Elaprase, Lumizyme, Naglazyme and Xenpozyme are subject to Site of Care requirements and must be obtained through a preferred home infusion vendor. Prior Authorization and medical justification is required for Aldurazyme, Crysvita, Elaprase, Lumizyme, Naglazyme and Xenpozyme obtained and administered in other outpatient settings such as a provider's office or hospital facility.
- MVP will allow 60 days after prior authorization approval for members to transfer to a preferred infusion site.

- This requirement does not apply to MVP Medicare and Medicaid members

**Medicaid Variation:** Medications that are a pharmacy benefit are covered and billed to New York State Fee-For-Service (FFS) program. They are defined as medications that go through a retail or specialty pharmacy, including self administered injectable products. Pharmacy medications are subject to FFS's clinical criteria including (but not limited to) coverage, quantity limit, step therapy, and prior authorization. Pharmacy benefit information can be found here: https://www.emedny.org/info/fullform.pdf

## Exclusions

The use of orphan drugs and biologics will not be considered medically necessary for the following situations:

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling Member has not failed all other standard therapies for the disease
- FDA warnings and contraindications for the use of the drug have not been addressed by the prescriber

## References

1. U.S. Food and Drug Administration (FDA). Orphan Drug Act Congressional Findings for the Orphan Drug Act. Available: http://www.fda.gov/regulatoryinformation/legislation/federalfooddrugandcosmeticactfdcact/significantamendmentstothefdcact/orphandrugact/default.htm
2. U.S. Food and Drug Administration (FDA). Developing Products for Rare Diseases & Conditions. Available: http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/default.htm
3. U.S. Food and Drug Administration (FDA). FDA Application. Search Orphan Drug Designations and Approvals [Database]. Available: http://www.accessdata.fda.gov/scripts/opdlisting/oopd/index.cfm.

| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Medicare Gold Giveback | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D |
| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

**Medicare Part B: Orphan Drug(s) and Biologicals**

| | |
|---|---|
| **Type of Policy:** | **Drug/Medical Therapy** |
| **Prior Approval Date:** | **11/01/2023** |
| **Approval Date:** | **08/01/2024** |
| **Effective Date:** | **10/01/2024** |

**Related Policies:** **Experimental or Investigational Procedures, Behavioral Health Services, Drugs & Treatments, Off-Label use of FDA Approved Drugs, Clinical Trials**

***Codes Requiring Prior Authorization (covered under the medical benefit)**

Adagen® (J2504 Inj, pegademase bovine, 25 IU)
Aldurazyme® (J1931 Inj, laronidase, 0.1 mg)
Arikayce (J8499 amikacin liposome inhalation susp)
Brineura (J0567 cerliponase alfa inj. 1mg)
Cablivi (J3590, Inj Caplacizumab)
Ceprotin™ (J2724 Inj, protein C concentrate, IV 101U)
Clolar® (J9027 Inj, clofarabine, 1 mg)
Crysvita (J0584 inj, burosumab-twza 1 mg)
Elaprase® (J1743 Inj, idursulfase)
Elzonris (J9269 Inj, tagraxofusp-erzs)
Enjaymo™ (J1302 Inj, sutimlimab-jome)
Evkeeza™(J1305, evinacumab-dgnb)
Folotyn (J9307 Inj, pralatrexate, 1 mg)
Fusilev™ (J0641 Inj, levoleucovorin 0.5mg)
Gamifant (J9210, emapalumab-IZSG inj)
Ilaris® (J0638 Inj, canakinumab 1mg)
Kanuma (J2840 Inj, sebelipase alfa, 1mg)
Khapzory (J0642) levoleucovorin IV solution)
Lamzede (J0217, velmanase alfa-tycv, 10mg)
Lumizyme (J0221 Inj, alglucosidase alfa)
Mepsevii (J3397 Inj. Vestronidase alfa)

Naglazyme® (J1458 Inj, galsulfase, 1 mg)
Nexviazyme® (J0219, avalglucosidase alfa-ngpt)
Nulibry® (C9399, J3490, fosdenopterin)
Oxlumo® (J0224, lumasiran)
Pombiliti (J1203, cipaglucosidase alfa, powder for injection)
Poteligeo (J9204) Inj. mogamulizumab-kpkc)
Reblozyl (J0896, luspatercept-aamt, SQ injection)
Retisert® (J7311 fluocinolone acetonide, intravitreal implant)
Rystiggo (J9333, Rozanolixizumab SQ infusion)
Scenesse (J7352, afamelanotide implant 16mg)
Soliris® (J1300 Inj, eculizumab, 10 mg)
Sylvant (J2860 Inj, siltuximab, 10mg)
Ultomiris™ (J1303, ravulizumab-cwvz IV, inj)
Uplizna® (J1823, inebilizumab-cdon)
Veopoz (J9376, pozelimab-bbfg, injection, 1mg)
Vimizim (J1322, Inj, elosulfase alfa, 1mg)
Vyjuvek (J3401, beremagene geperpavec)
Vyvgart™ (J9332 Inj, efgartigimod alfa-fcab)
Vyvgart Hytrulo (J9334 Injection, efgartigimod alfa; hyaluronidase)
Xenpozyme™ (J0218 Inj, olipudase alfa)
Zynlonta (J9359, loncastuximab tesirine-lpyl)* *This list is subject to change based on FDA approval of new drugs and/or new indications*

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Refer to the MVP website for the Medicare Part D formulary and policies for drugs that may covered under the Part D benefit.

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**Overview/Summary of Evidence**

An orphan drug is a drug used to treat a rare disease or condition which affects:

- less than 200,000 persons in the United States[1]; or
- more than 200,000 persons in the United States; and there is no reasonable expectation that the cost of developing and making a drug will be recovered from sales in the United States[1].

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**Indications/Criteria**

Orphan drugs or FDA approved drugs designated with an orphan drug indication may be covered on a case-by-case basis, with prior authorization, for the FDA approved indications only. Only drugs FDA approved for marketing as Orphan Drugs or Biologics will be considered for coverage under this policy.

The drug must be prescribed by a plan affiliated Specialist familiar with the treatment of the rare disease or condition.

Those drugs listed at https://www.accessdata.fda.gov/scripts/opdlisting/oopd/ have been designated by the FDA as Orphan Designated Products approved for marketing. The list is maintained by the FDA and is subject to change.

Physician and member must comply with all approved and/or limited distribution channels for the agent including specialty pharmacy vendors where applicable.

Drug and/or biological coverage is subject to the terms and conditions of the member's prescription drug rider and/or contract.

Documentation submitted must include baseline subjective/objective laboratory or test results (dependent on drug and diagnosis). If member started therapy while enrolled in a clinical trial, baseline laboratory or test results must be provided from prior to the start of the trial.

For continuation of therapy request documentation must show improvement in symptoms/condition from baseline.

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## Exclusions

The use of orphan drugs and biologics will not be considered medically necessary for the following situations:

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling Member has not failed all other standard therapies for the disease
- FDA warnings and contraindications for the use of the drug have not been addressed by the prescriber

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## References

1. U.S. Food and Drug Administration (FDA). Orphan Drug Act Congressional Findings for the Orphan Drug Act. Available: http://www.fda.gov/regulatoryinformation/legislation/federalfooddrugandcosmeticactfdcact/significantamendmentstothefdcact/orphandrugact/default.htm

2. U.S. Food and Drug Administration (FDA). Developing Products for Rare Diseases & Conditions. Available: http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/default.htm
3. U.S. Food and Drug Administration (FDA). FDA Application. Search Orphan Drug Designations and Approvals [Database]. Available: http://www.accessdata.fda.gov/scripts/opdlisting/oopd/index.cfm.

- more than 200,000 persons in the United States; and there is no reasonable expectation that the cost of developing and making a drug will be recovered from sales in the United States[1].

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The drug must be prescribed by a plan affiliated Specialist familiar with the treatment of the rare disease or condition.

Those drugs listed at https://www.accessdata.fda.gov/scripts/opdlisting/oopd/ have been designated by the FDA as Orphan Designated Products approved for marketing. The list is maintained by the FDA and is subject to change.

Physician and member must comply with all approved and/or limited distribution channels for the agent including specialty pharmacy vendors where applicable.

Drug and/or biological coverage is subject to the terms and conditions of the member's prescription drug rider and/or contract.

Documentation submitted must include baseline subjective/objective laboratory or test results (dependent on drug and diagnosis). If member started therapy while enrolled in a clinical trial, baseline laboratory or test results must be provided from prior to the start of the trial.

For continuation of therapy request documentation must show improvement in symptoms/condition from baseline.

**Medicaid Variation:** Medications that are a pharmacy benefit are covered and billed to New York State Fee-For-Service (FFS) program. They are defined as medications that go through a retail or specialty pharmacy, including self administered injectable products. Pharmacy medications are subject to FFS's clinical criteria including (but not limited to) coverage, quantity limit, step therapy, and prior authorization. Pharmacy benefit information can be found here: https://www.emedny.org/info/fullform.pdf

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**MVP Health Care Medical Policy**

# Ozanimod

**Type of Policy:** **Drug/Medical Therapy**
**Prior Approval Date:** **10/01/2023**

**Approval Date:** **11/01/2024**
**Effective Date:** **01/01/2025**

**Related Policies:** **Multiple Sclerosis Agents**

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies.

## Drugs Requiring Prior Authorization under the pharmacy benefit

Zeposia (ozanimod)

## Overview

Ozanimod is an oral sphingosine 1-phosphate receptor modulator. It is indicated for the treatment of relapsing forms of multiple sclerosis (MS) in adults, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease and the drug is additionally indicated for moderately to severely active ulcerative colitis (UC) in adult patients. Ozanimod must not be used with MAOI therapy as the metabolites of ozanimod may inhibit MAO which could lead to a hypertensive crisis. Prescribers should review for potential drug interactions prior to prescribing. Ozanimod has several cardiac contraindications, members should be evaluated for appropriate use.

## Indications/Criteria

### A. Multiple Sclerosis

- Please refer to the MVP Multiple Sclerosis Agents policy

**B. Ulcerative Colitis**

Ozanimod may be considered for coverage for ulcerative colitis when:

- A diagnosis of moderate to severe Ulcerative Colitis **AND**
- Ordered by a participating gastroenterologist or colorectal surgeon **AND**
- Documentation identifying inadequate response, intolerance, or contraindication to conventional therapy for maintenance of remission (i.e., anti-inflammatory aminosalicylates [e.g., mesalamine (5-ASA), sulfasalazine], 6-mercaptopurine, and azathioprine)
    - If conventional therapy is not considered medically appropriate, documentation must be provided

Documented failure, contraindication or ineffective response to all preferred/formulary therapies for the specific indication.
**Initial approval** will be for 6 months

**Extension requests** will be approved for up to 12 months if the member has a continued benefit to therapy. Extension requests where the ozanimod did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

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## Exclusions

The use of Ozanimod will not be covered for the following situations:

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling Ozanimod in combination with immunomodulators, biologic therapy, or targeted synthetic drugs.

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## References

1. Clinical Pharmacology

2. Zeposia (ozanimod). Prescribing Information. Summit, NJ. Celgene Corporation. May 2021.

3. ACG Clinical Guidline: Ulcerative Colitis in Adults. The American Journal of Gastroenterology: March 2019 - Volume 114 - Issue 3 - p 384-413 doi: 10.14309/ajg.0000000000000152. Accessed: ACG Clinical Guideline: Ulcerative

Colitis in Adults : Official journal of the American College of Gastroenterology | ACG (lww.com)

| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Complete Wellness | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D |
| USA Care 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 | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| 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).** | |
| *© 2025 MVP Health Plan, Inc. All rights reserved. Descriptions contained within MVP's Medical Policies are not a guarantee of coverage. Each MVP Group or Subscriber Contract contains specific limitations, exclusions and requirements that may affect a Policy. If there is any discrepancy between your Group or Subscriber Contract and a Policy, your Group or Subscriber Contract shall in all cases govern.* | |

***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 |

**MVP Health Care Medical Policy**

**Pain Medications**

**Type of Policy:** **Drug Therapy**
**Prior Approval Date:** **08/01/2023**
**Approval Date:** **08/01/2024**
**Effective Date:** **10/01/2024**
**Related Policies:** **Refer to the MVP Medicare website for the Medicare Part D formulary and policies for drugs covered under the Part D benefit.**

## Drugs Requiring Step Therapy and/or Prior Authorization

Additional quantities exceeding the amounts identified in the chart below will require prior authorization. The member is responsible for the applicable pharmacy copayment at each prescription fill/refill including any difference in cost between the generic and the brand name drug if a generic is available. Quantity limits apply to all brand and generic products.

| **Brand Name** | **Release Immediate (IR) Extended (ER)** | **Chemical/Generic Name** | **Requirement** | **Quantity Limit every 30 days except as noted** |
|---|---|---|---|---|
| +Actiq® | IR | fentanyl citrate | Prior authorization | 60 lozenges |
| Arymo | ER | morphine sulfate | Step edit | 90 tablets |
| Avinza® | ER | morphine sulfate | Step edit | 30 capsules |
| Belbuca | IR | buprenorphine buccal film | Quantity limit | 60 films |

| | | | | |
|---|---|---|---|---|
| Butrans® | ER | buprenorphine | Step edit | 4 patches/28 days |
| Conzip® | ER | tramadol | Quantity limit | 30 capsules |
| Duragesic Patch | ER | fentanyl | Step edit | 20 patches |
| Embeda® | ER | morphine/naltrexone | Step edit | 60 capsules |
| Exalgo™ | ER | hydromorphone | Step edit | 30 tablets |
| +Fentora® | IR | fentanyl citrate | Prior authorization | 60 tablets |
| Hysingla ER | ER | hydrocodone bitartrate | Step edit | 60 tablets |
| Kadian® | ER | morphine sulfate | Step edit | 90 capsules |
| +Lazanda® | IR | fentanyl citrate nasal | Prior Authorization | 7 bottles (56 doses) |
| Morphabond | ER | morphine sulfate | Step edit | 90 tablets |
| MS Contin® | ER | morphine sulfate | Step edit | 90 tablets |
| Nucynta ER | ER | tapentadol | Quantity limit | 60 tablets |
| Opana® ER | ER | oxymorphone HCL | Step edit | 90 tablets |
| Oxycontin® | ER | oxycodone HCL | Step edit | 90 tablets |
| Sprix™ | IR | ketorolac tromethamine | Prior authorization | 5 single-day spray bottles |
| +Subsys® | IR | fentanyl | Prior authorization | 60-unit dose sublingual spray |
| Ultram® ER | ER | tramadol | Quantity limit | 30 tablets |
| Xartemis XR | ER | oxycodone/acetaminophen | Step edit | 120 tablets |
| Xtampza | ER | oxycodone HCL | Step edit | 60 capsules |
| Zohydro™ER | ER | hydrocodone bitartrate | Step edit | 60 capsules |

+ Part of the single shared system REMS, the transmucosal immediate-release fentanyl (TIRF) REMS Access Program. This includes brand names and generics. Outpatients, prescribers who prescribe to outpatients, pharmacies, and distributors must enroll in the program. For inpatient administration (e.g. hospitals, hospices, and long-term care facilities that prescribe for inpatient use, patient and prescriber enrollment is not required

## Overview

Pain medications are FDA approved for use in mild to severe pain. They are available in many dosage forms including tablets, capsules, nasal sprays, topical patches and other forms.

The World Health Organization has issued the following guideline for the treatment of cancer pain. If pain occurs, there should be prompt oral administration of drugs in the following order: nonopioids (aspirin and paracetamol); then, as necessary, mild opioids (codeine); then strong opioids such as morphine, until the patient is free of pain. To calm fears and anxiety, additional drugs – "adjuvants" – should be used. To maintain freedom from pain, drugs should be given "by the clock", that is every 3-6 hours, rather than "on demand". This three-step approach of administering the right drug in the right dose at the right time is inexpensive and 80-90% effective. Surgical intervention on appropriate nerves may provide further pain relief if drugs are not wholly effective.[1]

The Centers for Disease Control and Prevention (CDC)'s Clinical Practice Guidelines for Prescribing Opioids for Pain includes recommendations to clinicians providing pain care to patients aged 18 years and older. The guidelines address naloxone has part of a patient's comprehensive pain management plan to mitigate opioid related harms. Naloxone is available through the pharmacy benefit without utilization management restrictions.

Ketorolac nasal spray (Sprix) is indicated for short term (up to 5 days) management of moderate to moderately severe pain.

Narcotic extended-release formulations are controlled release formulations indicated for the relief of moderate to severe pain requiring continuous, around-the-clock opioid therapy for an extended period of time. They are not indicated for treatment of acute pain (excluding Xartemis XR) or titration of opiate naive patients.

Fentanyl and buprenorphine transdermal formulations are indicated for the management of persistent, moderate to severe chronic pain that requires continuous, around-the-clock opioid administration for an extended period of time, and cannot be managed by other means such as non-steroidal analgesics, opioid combination products, or immediate-release opioids.

Fentanyl buccal (Fentora®), fentanyl oral transmucosal solid dosage forms, (Actiq® and generic), sublingual tablets (Abstral), Subsys sublingual spray and Lazanda nasal spray are indicated specifically for breakthrough cancer pain.

Tramadol ER and tapentadol are centrally acting synthetic opioid analgesics indicated for moderate to severe chronic pain in adults who require around-the-clock treatment for an extended period of time.

## Indications/Criteria

**A. Opioids for chronic use, greater than 3 months, will be considered if the ALL following is met in addition to other criteria:**

1. Must have current provider- patient opioid treatment agreement
2. Must have a documented pain management treatment plan that addresses taper
3. Must have documented verification of Prescription Monitoring Program Registry (if available)
4. Must have addressed opioid overdose risk management if MME >90
5. Documentation identifies at least one prescription for a chronic pain extended-release formulation in the preceding 90 days with immediate release formulations prescribed in quantities required for breakthrough pain

**B. Immediate Release Narcotic Formulations**

Fentanyl oral transmucosal, buccal, sublingual tablets, sublingual spray, and nasal spray dosage forms require prior authorization (for all quantities) and may be considered for coverage when all the following criteria are met:

1. Persistent breakthrough cancer pain and currently on an around-the-clock extended release narcotic formulation of any of the following: at least 60 mg of oral morphine/day, 25 mcg of transdermal fentanyl/hour, 30 mg of oxycodone/day, 8 mg oral hydromorphone/day, 25 mg oral oxymorphone/day or an equianalgesic dose of another opioid for at least seven days

2. Other formulary immediate release narcotic pain medications such as morphine and oxycodone have not provided adequate breakthrough pain relief or are contraindicated or not tolerated. After failure, contraindication, or intolerance to other formulary medications (e.g. morphine and oxycodone), fentanyl immediate release formulations must be tried in the following order:
    a. generic fentanyl
    b. brand name oral fentanyl dosage forms
    c. fentanyl sublingual spray
    d. fentanyl citrate nasal spray
3. Ordered by or pursuant to the consult of an oncologist or pain management specialist

4. Documentation identifies at least one prescription for a chronic pain extended release formulation such as a morphine derivative, fentanyl patch or an equianalgesic dose of another opioid along with an immediate-release (IR) medication within the preceding 90 days
5. If the request is for more than the quantity limit, documentation must demonstrate that the quantity is medically necessary. Documentation must support that the long-acting opioid is being titrated to maximize the around-the-clock dose and minimize the breakthrough pain (prn or "as needed") dosing for the fentanyl oral product

**Initial approval** will be for up to a maximum of 3 months and will be dose specific.

**Extensions of therapy** will be approved for a maximum of 6 months if documentation provided identifies continued benefit from therapy and "rescue" doses used in a 24-hour period and dosing of long-acting product has been evaluated and is appropriate. Increases in dose require a new request

**C. Extended Release Formulations**

Refer to chart for quantity limits that will be allowed per month by automated edit providing that the member's medication claim history has at least a seven-day supply for an immediate release opioid within the preceding 90 days. Medication history requirement does not apply to tramadol ER and tapentadol ER however criteria below will apply if quantity limit is exceeded

Requests for extended release dosage units in a quantity exceeding that available with the automated step edit described above may be considered medically necessary when all the following criteria are met:

1. Documentation identifies an inadequate response to or a contraindication to dosing at recommended intervals since the advantage of using long acting products is the extended dosing schedule
2. Documentation identifies persistent, moderate to severe pain that requires continuous, around-the-clock analgesia with a high potency opioid for an extended period of time (weeks to months) or longer
3. Documentation must identify that the strength of the long-acting product has been evaluated and the supplemental dose of the short-acting analgesic is appropriate. The number of "rescue" opioid doses during a

24-hour period can be a guide to determine whether the sustained release dose is appropriately dosed.

**Initial approval** will be up to 6 months

**Extension requests** will be approved up to 6 months if documentation provided identifies continued benefit from therapy and "rescue" doses used in a 24-hour period and dosing of long-acting product has been evaluated and is appropriate.

**D. Sprix** may be considered medically necessary in adults when all the following are met:

1. Moderate to severe pain post-surgery requiring analgesia at the opioid level
2. Not able to take oral medications including liquids, sublingual, etc
3. Approval will be for a maximum of 5 days per surgery
4. No evidence of peptic ulcer disease or history of GI bleed, suspected or confirmed cerebrovascular bleeding, bleeding tendency, incomplete hemostasis or at high risk of bleeding,
5. No evidence of advanced renal disease or risk for renal failure due to volume depletion

**Initial approval** will be for 5 days within 6 months

**E. <u>7 Day Opioid Rule</u>**

Initial prescriptions of immediate release opioids will be limited to a 7-day supply if the member has not filled the same opioid in the previous 60 days.

- Approval for greater than a 7-day supply will be granted when:
  - For new enrollees with no prescription history- if the provider submits documentation supporting previous use of the opioid during the previous 60 days
  - There is a change in dose of the same opioid product (i.e. morphine IR 15mg tablet to morphine IR 30mg tablet)
- This law will not apply to members with chronic pain due to cancer and sickle cell disease

**Approvals** will be one time only

**F. <u>4 Opioid Prescriptions in 30 Day Rule</u>**

- After 4 opioid prescriptions are filled in a 30-day period all additional opioid prescriptions will reject for the remainder of the 30 days.

- Approvals for greater than 4 opioid prescriptions will be allowed when:
    - The same opioid is being prescribed by providers in the same practice (i.e. multiple prescriptions for the same opioid during a 30-day period)
    - One immediate release product and one extended-release product are being prescribed by providers in the same practice
    - More than one opioid is being prescribed by providers in the same practice and rationale for multiple opioids or titration plan is provided
    - Members with a diagnosis of cancer or sickle cell or enrolled in hospice

  **Approval** will be for 3 months

- The following will **not** be approved:
    - Multiple providers not in the same practice prescribing opioids for member

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## Exclusions

1. Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling
2. Fentanyl oral transmucosal, buccal, sublingual tablets, sublingual spray, or nasal spray dosage forms used as monotherapy
3. Extended release narcotic formulations in opioid naive members or for short-term/acute use (excluding Xartemis XR).
4. "As needed use" (also known as PRN) of an extended release opioid since the delivery mechanism is insufficient to treat pain immediately[10].
5. Coverage for use in non-approved indication not meeting MVP Experimental and Investigational policy.
6. Coverage for concomitant use of long-acting pain medications without documented failure of single agents at maximal doses.
7. Coverage for any pain medication in member with active and untreated alcohol or substance abuse without documentation of frequent ongoing evaluation including blood testing for abuse prevention.
8. Combination of buprenorphine medications with opioids

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## References

1. World Health Organization (WHO). WHO's pain ladder. Available: www.who.int/cancer/palliative/painladder/en/index.html. [Accessed 06/19/2015.]
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3. Avinza® (morphine sulfate) capsules. Prescribing Information. Bristol, TN: King Pharmaceuticals Inc.; May 2013
4. Duragesic® (fentanyl) patches. Prescribing Information. Titusville, NJ: Janssen Pharmaceuticals Inc.; September 2013
5. Fentora® (fentanyl) buccal tablets. Prescribing Information. Frazer, PA: Cephalon, Inc.; February 2013.
6. Kadian® (morphine sulfate) capsules. Prescribing Information. Morristown, NJ: Actavis Elizabeth LLC; April 2014.
7. MS Contin® (morphine sulfate) tablets. Prescribing Information. Stamford, CT: Purdue Pharma; September 2012.
8. Opana® ER (oxymorphone hydrochloride) tablets. Prescribing Information. Chadds Ford, PA: Endo Pharmaceuticals Inc.; May 2013.
9. Oxycontin® (oxycodone hydrochloride) tablets. Prescribing Information. Stamford, CT: Purdue Pharma; July 2013
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14. Butrans® (buprenorphine) Transdermal System. Prescribing Information. Stamford, CT: Purdue Pharma L.P.; July 2013
15. Abstral® (fentanyl citrate) sublingual tablets. Prescribing Information. Lincoln, NE: Novartis Consumer Health, Inc.; July 2013
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19. Conzip (tramadol) capsules. Prescribing Information. Mississauga, ON: Cipher Pharmaceuticals. May 2010.
20. McEvoy GK, Miller J. Opiate agonists. In: AHFS Drug Information. Bethesda: American Society of Health-System Pharmacists, Inc; 2011.
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26. Dolophine (methadone) tablets. Prescribing Information. Columbus, OH: Roxane Laboratories; October 2006
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| Member Product | Medical Management Requirements* |
|---|---|
| **New York Products** | |
| HMO | Prior Auth |
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| POS OOP | Prior Auth |
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| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D |
| 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).** | |
| *© 2024 MVP Health Plan, Inc. All rights reserved. Descriptions contained within MVP's Medical Policies are not a guarantee of coverage. Each MVP Group or Subscriber Contract contains specific limitations, exclusions and requirements that may affect a Policy. If there is any discrepancy between your Group or Subscriber Contract and a Policy, your Group or Subscriber Contract shall in all cases govern.* | |

***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 |

**MVP Health Care Medical Policy**

**Palforzia**

| | |
|---|---|
| **Type of Policy:** | **Drug Therapy** |
| **Prior Approval Date:** | **11/01/2023** |
| **Approval Date:** | **11/01/2024** |
| **Effective Date:** | **01/01/2025** |
| **Related Policies:** | **N/A** |

## Drug Requiring Prior Authorization (under the pharmacy benefit)

Refer to the MVP website for the Medicare Part D formulary for drugs that may covered under the Part D benefit.

Palforzia (peanut allergen powder)

## Overview

Palforzia (peanut arachis hypogaea allergen powder) is an oral immunotherapy indicated for the mitigation of allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanuts. Palforzia is approved for use in patients with a confirmed diagnosis of peanut allergy. Initial Dose Escalation may be administered to patients aged 1 through 17 years. Up-Dosing and Maintenance may be continued in patients 1 years of age and older. Palforzia is not a CURE for peanut allergy, it works by desensitizing the peanut allergy to reduce the intensity of an accidental exposure to peanuts. Palforzia is only available through PALFORZIA REMS program due to risk of anaphylaxis.

## Indications/Criteria

### Initial Request

- Must be prescribed by a Board-Certified Allergist or Immunologist

- Palforzia must be prescribed **AND** administered by a certified provider who is able to properly monitor patient after administration of Initial Dose Escalation and the first dose of Up-Dosing level at a REMS certified clinic
- Documentation of allergy verified by skin testing
- Provider attestation that the member is adhering to a peanut avoidant diet
- Documentation that the member does not have a history of eosinophilic esophagitis and/or other eosinophilic gastrointestinal disease
- For members with asthma
    - Provider attestation indicating that the member currently has asthma under control

**Initial authorization** will be approved for 6 months

**Continuation requests** will be approved for 12 months

- Must be prescribed by a PALFORZIA REMS certified Allergist or Immunologist
- Member is compliant with therapy
- Controlled asthma

## Exclusions

- Uncontrolled asthma
- History of eosinophilic esophagitis and other eosinophilic gastrointestinal disease
- Indication, age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling

## References

1. Palforzia (peanut (Arachis hypogaea) allergen powder) package insert. Brisbane, CA: Aimmune Therapeutics, Inc; 2020 Jan. Revised 07/2024.
2. FDA New Release. FDA approves first drug for the treatment of peanut allergy for children. Accessed January 31, 2020.

| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |

| | |
|---|---|
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Complete Wellness | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D |
| USA Care 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 | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

**Parsabiv**

| | |
|---|---|
| **Type of Policy:** | **Drug Therapy** |
| **Prior Approval Date:** | **04/01/2024** |
| **Approval Date:** | **04/01/2025** |
| **Effective Date:** | **06/01/2025** |
| **Related Policies:** | **NA** |

## Drug Requiring Prior Authorization (covered under the medical benefit)

J0606 Parsabiv , etelcalcetide, 0.1 mg injection

## Overview

Parsabiv is indicated for the treatment of secondary hyperparathyroidism in adult patients with chronic kidney disease on hemodialysis. It binds to calcium-sensing receptors (CaSRs) and enhances activation of the receptors by extracellular calcium. Activation of these receptors on parathyroid chief cells decreases PTH secretion.

## Indications/Criteria

- Member has chronic kidney disease on hemodialysis
- Member has moderate to severe hyperparathyroidism, with a PTH (parathyroid hormone) level of at least 400 pg/ml
- Corrected calcium level is at or above lower limit of normal (at least 8.3 mg/dl)
- Member is on stable doses of active vitamin D analogs or calcium supplements, or phosphate binders
- Previous trial and failure, contraindication, or intolerance to cinacalcet (Sensipar)
- If switching from cinacalcet to Parsabiv, cinacalcet must be discontinued at least 7 days prior to starting Parsabiv; dual therapy is not a covered benefit
- Parsabiv is prescribed by or in consultation with an endocrinologist or nephrologist

- For members with heart failure and/or risk factors for upper gastrointestinal bleeding (such as known gastritis, esophagitis, ulcers or severe vomiting), risks versus benefits of therapy have been evaluated.

**Initial approval will be for 6 months, continuation requests up to 12 months.**

- For continuation of coverage, member must have at least a 30% reduction in PTH levels from baseline

**Exclusions**

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling
- For the treatment of parathyroid carcinoma, primary hyperparathyroidism, and those with chronic kidney disease **not** on hemodialysis.
- Corrected serum calcium is less than the lower limit of normal for initial therapy
- Dual therapy with cinacalcet

**References**

1.Parsabiv (etelcalcetide) injection [Package Insert]. Thousand Oaks, CA: KAI Pharmaceuticals, Inc; 2017. Revised 12/2019.

2. National Kidney Foundation. Secondary Hyperparathyroidism. [Internet]. 2017 [cited 2018 Sep 25]. Available from: https://www.kidney.org/atoz/content/secondary-hyperparathyroidism.

3.Block GA, Bushinsky DA, Cunningham J, et al. Effect of Etelcalcetide vs Placebo on Serum Parathyroid Hormone in Patients Receiving Hemodialysis with Secondary Hyperparathyroidism. JAMA. 2017 Jan 10; 317(2):146–55.

4.Block GA, Bushinsky DA, Cheng S, et al. Effect of Etelcalcetide vs Cinacalcet on Serum Parathyroid Hormone in Patients Receiving Hemodialysis with Secondary Hyperparathyroidism. JAMA. 2017 Jan 10; 317(2):156-164.

5. Product Information: PARSABIV(R) intravenous injection, etelcalcetide intravenous injection. Amgen Inc (per FDA), Thousand Oaks, CA, 2019.

| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
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| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
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| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
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| 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 | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

**Patient Medication Safety**

| | |
|---|---|
| **Type of Policy:** | **Administrative/Drug Therapy** |
| **Prior Approval Date:** | **08/01/2023** |
| **Approval Date:** | **12/01/2024** |
| **Effective Date:** | **02/01/2025** |
| **Related Policies:** | N/A |

## Codes Requiring Prior Authorization

N/A

## Overview

Drugs are effective for their approved indications but carry side effects and adverse reactions and, when used inappropriately, can be detrimental to the member's overall health. Prescriptions written by multiple providers and filled at multiple pharmacies can cause drug-to-drug interactions.

To ensure pharmaceutical care, this policy details actions that will:

1. Detail a system for point of dispensing communications to identify and classify drug-to-drug interactions by severity
2. Notify dispensing providers at the point of dispensing of specific interactions when they meet pre-determined severity thresholds
3. Identify and notify members affected by Food and drug administration (FDA)-required or voluntary drug withdrawals from the market
4. Monitor and analyze relevant utilization data and take action to correct potential under-and over utilization

## Indications/Criteria

### I. Drug-to-Drug Interactions

The CVS/Caremark Concurrent Drug Utilization Review (DUR) is a systems-based, rule-driven review process that occurs at the point-of-sale and screens incoming prescriptions



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for a broad range of safety edits prior to dispensing. The incoming prescription is compared to the member's drug history and medical profile. The system identifies all potential drug utilization issues and sends messages to the dispensing pharmacist.

When a prescription violates one or more rules, pharmacists may receive either a warning message (soft alert) or a rejected claim (hard alert). "Warnings" defer documentation of alert resolution to the professional judgment of the pharmacist. "Rejects" alerts the dispensing pharmacist to the potential problems and rejects the claim for adjudication.

CVS/Caremark drug utilization review programs address the following three broad issues:

| Issues | Examples of Rules That Address These Issues |
|---|---|
| Overuse | • Maximum Daily Dose<br>• Excessive Duration<br>• Refill Too Soon |
| Misuse | • Drug-Drug Interactions<br>• Drug-Disease Interactions<br>• Drug-Age Interactions<br>• Drug-Gender Interaction |
| Under Use | • Under Minimum Daily Dose<br>• Under Utilization |

Because CVS/Caremark concurrent DUR prescription data is derived from paid pharmacy claims, interactions can be identified even if the medications were filled at different pharmacies. In addition, most pharmacy computers contain drug interaction software programs that provide additional drug utilization review screening for prescriptions filled on that computer system.

CVS/Caremark uses the following Medispan data for adjudication to classify interaction severity:

Level 1: Major
Level 2: Moderate
Level 3: Minor

For concurrent interventions that include both "rejects" and "warnings," CVS/Caremark relies on the professional judgment of pharmacists to determine the appropriate intervention with the member and/or prescriber for resolution of any clinical issues. CVS/Caremark has contractual commitments with most participating retail network pharmacies to use Concurrent DUR messages. However, in some instances, the retail pharmacy may block CVS/Caremark alerts while providing their own. CVS/Caremark measures and audits network pharmacy compliance and performance on a regular basis.

## II. Drugs Withdrawn from the Market or Drug Recalls



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Communications are sent to members and providers for significant drug recalls and product withdrawals which are published from the FDA, manufacturers, or press releases. Communication options include notifications to providers and/or members by the Plan, the Pharmacy Benefit Manager (PBM), Specialty Pharmacy, or other health partner (network pharmacy). Communications may be sent via mail and/or fax or posted on the Plan website depending on the severity and/or extent of the recall.

a. When a drug is withdrawn from the market, pharmacy paid claims data are used to identify members who filled a prescription for the medication and the prescriber who wrote the prescription. Letters are sent directly to each member and prescriber explaining the drug withdrawal. Pertinent information necessary to ensure a smooth transition to an alternate therapy if indicated is also included. Physician and member newsletters may also be used to communicate the information to providers and members for informational purposes.

b. Drug Recalls:

    1. An expedited process is in place whereby the Plan and/or the PBM will send notification to affected members and providers of Class 1 recalls. In expedited situations, impacted member and provider claims data is aggregated immediately upon the notification of the Class 1 recall and written communications are sent within 10 business days. In addition, the PBM may post point of sale messaging to pharmacists advising them of the recall. They may also reach out to members via telephone calls or mailgrams as appropriate.
    2. Members and providers will be notified within 30 days for Class II recalls. Members who are identified as having a claim for the targeted or suspected targeted drug as identified in the recall notice will receive written communication within 30 days. Providers may receive notification of the recall via written communication, fax, or posting of the notice on the Plan website depending on the severity and/or extent of the recall.
    3. Recalls at the wholesale level only are exempt from this procedure.

## III. Medication Utilization Monitoring

Medication over-utilization or under-utilization, for purposes of this policy, shall be defined as a pattern of medication use that is greater or lesser than, and/or contraindicated based on generally accepted therapeutic regimens and/or FDA approved



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dosing. Over and underutilization can identify patterns of abuse. Pharmacy paid claims data can be used to identify patterns of abuse or overutilization.

A. **Identification of a Problem**

1. Member specific reports will be reviewed at designated intervals detailing drug claim and prescriber frequency.
2. Prescriber reports will be reviewed at designated intervals detailing prescribing patterns of drugs known to have a high incidence of abuse.
3. Departmental referrals will be made based on utilization patterns.

B. **Problem Resolution - Member**

If a potential pattern of abuse is identified, the following process will be followed:

1. A medical director or their designee will contact the member's provider(s) to discuss their drug profile OR written notification and a copy of the member's medication list will be sent to the prescribing provider(s). After this initial consultation/notification, if a problem is still deemed to exist, the following actions will be taken:
    i. The member will be referred to a case management program; AND/OR
    ii. The member's drug usage will be monitored for three (3) months, unless in MVP's discretion more immediate action is required.
2. At the conclusion of this three (3) month period, or sooner, when more immediate action was required under 1ii above, a second consult with the member's provider(s) will take place. After this consultation, if a problem still appears to exist, one or more of the following actions may be taken:
    (i) restrict the member's benefits to covered drugs obtained from one or more designated participating pharmacies.
    (ii) restrict the member's benefits to covered drugs prescribed by one or more designated participating prescribers.
    (iii) require that the member obtain prior approval before making any additional changes to his or her prescriber(s).

    Before administering any of the restrictions set forth in 2(i)-(iii) above, the member will be given at least thirty (30) days prior written notice and the opportunity to file a complaint and/or appeal the implementation of these restrictions.
3. If it is believed at any point that the member has made an intentional misrepresentation of material fact and/or has engaged in fraudulent



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conduct in order to obtain benefits for covered drugs, then this matter will be turned over to the Special Investigation Unit (SIU) for further investigation. The findings of the SIU shall also be disclosed to the appropriate state and federal regulators.

**Medicare Variation**

Refer to the Medicare Part D formulary for drugs that may be covered under the Part D benefit.

Refer to the Medicare Part D Overutilization Program Policy for Medicare Part D Medication Utilization Monitoring.

**Medicaid Variation**

Refer to MVP HEALTH CARE - Medicaid and Safety Net Programs Policies and Procedures: Recipient Restriction Program MVP Option, MVP Option SSI, MVP Option Family

**Exclusions**

- Members that do not have a prescription drug rider.

**References** N/A



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**MVP Health Care Medical Policy**

**PCSK9 Inhibitors**

| | |
|---|---|
| **Type of Policy:** | **Drug Therapy** |
| **Prior Approval Date:** | **08/01/2024** |
| **Approval Date:** | **04/01/2025** |
| **Effective Date:** | **06/01/2025** |

**Related Policies: Orphan Drug Policy**

## Drugs Requiring Prior Authorization (covered under the pharmacy benefit)

Praluent (alirocumab)

Refer to the MVP website for the Medicare Part D formulary for drugs that may covered under the Part D benefit.

## Overview

Praluent is indicated for the following:

- To reduce the risk of myocardial infarction, stroke, and unstable angina requiring hospitalization in adults with established cardiovascular disease.
- As adjunct to diet, alone or in combination with other low-density lipoprotein cholesterol (LDL-C)-lowering therapies, in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH), to reduce LDL-C.
- As an adjunct to other LDL-C lowering therapies in adult members with homozygous familial hypercholesterolemia (HoFH) to reduce LDL-C.
- As an adjunct to diet and other LDL-C-lowering therapies in pediatric members aged 8 years and older with HeFH to reduce LDL-C.

## Indications/ Criteria

A. **For all indications, the following criteria must be provided for initial requests in addition to the specific diagnosis criteria below.**

- Prior and current lipid treatments-including dose, duration of treatment, reason for discontinuation and LDL-C reduction
- Lipid panel obtained within previous 30 days of request.
- Provider attestation that the member has been adhering to lifestyle modifications (heart healthy diet, regular exercise)
- Must be prescribed by or in consultation with a cardiologist or endocrinologist

**B. For the treatment of Clinical Atherosclerotic Cardiovascular Disease (ASCVD)**

- Member has a history of ASCVD (must have one of the following):
    - ACS, MI, Stable or unstable angina, PTCA, CABG, TIA or findings from a CT angiogram or catheterization consistent with clinical ASCVD

- Member must meet one of the following:
    - Current LDL-C level ≥ 70mg/dL after a minimum of 3 months of therapy with a high potency statin in combination with ezetimibe 10mg or highest tolerated statin dose in combination with ezetimibe 10mg
        - High potency statins include atorvastatin 40mg, 80mg, and rosuvastatin 20mg, 40mg.
        - Member must be compliant with 3 months of high-intensity statin and ezetimibe therapy
        - Claims history will be used to verify compliance
    - Current LDL-C level ≥ 70mg/dL and the member is intolerant to statin therapy (see appendix A)

**C. For the Treatment of Familial Hypercholesterolemia (FH) or Primary Hyperlipidemia**

- Member must have diagnosis of heterozygous FH (see Appendix B) primary hyperlipidemia, or homozygous FH (see Appendix C)

- Members with ASCVD must meet above criteria for ASCVD

- Members without ASCVD must meet one of the following:

- Current LDL-C level ≥ 100mg/dL after a minimum of 3 months of therapy with a high potency statin in combination with ezetimibe 10mg or highest tolerated statin dose in combination with ezetimibe 10mg
  - High potency statins include atorvastatin 40mg, 80mg, and rosuvastatin 20mg, 40mg.
  - Member must be compliant with 3 months of high-intensity statin and ezetimibe therapy
  - Claims history will be used to verify compliance
- Current LDL-C level ≥ 100mg/dL and the member is intolerant to statin therapy (see appendix A)

**Initial approval and continuation of therapy**

Initial approval will be for 6 months

Extension requests will be approved for up to 12 months if the member has a continued benefit to therapy and the following are met:

- Member continues to have at least a 35% reduction in LDL-C from baseline **OR**
- Reduction below the goal LDL-C of 70mg/dL for ASCVD or 100mg/dL for FH

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## Appendices

**APPENDIX A. Statin Intolerance ("Statin-Associated Side Effects")**

- Member must have one of the following:
  - Intolerable muscle pain
    - Other causes/conditions that may cause muscle pain must be ruled out
    - Pain must significantly improve or resolve upon discontinuation of the statin
  - Muscle pain with a CK>5 x ULN
  - Hepatic transaminases >3 x ULN

- Confirmation of at least two attempts of different statin re-challenges must be provided (one of the statins must be rosuvastatin (Crestor))

- Statin re-challenge is not required if while on statin therapy the member had an elevation of CK level ≥ 10 times ULN or experienced rhabdomyolysis

**APPENDIX B. Diagnosis of Primary Hyperlipidemia (Including Heterozygous Familial Hypercholesterolemia)**

For Heterozygous Familial Hypercholesterolemia one of the following must be met:

- Genetic confirmation
  - LDL-receptor mutation, Apo B defect or PCSK9 gain-of-function mutation
- Simon-Broome Diagnostic Criteria
  - Total cholesterol >290mg/dL or LDL-C. >190 mg/dL, plus tendon xanthomas in first (parent, sibling or child) or second degree relative (grandparent, uncle, aunt)
- Dutch Lipid Clinic Network
  - Total score >8

For Primary Hyperlipidemia:

- Currently on an intensive statin therapy must have fasting LDL-C ≥ 80 mg/dL OR
- Members unable to tolerate a statin must have fasting LDL-C of at least 150 mg/dL

**Appendix C. Diagnosis of Homozygous Familial Hypercholesterolemia**

- Presence of xanthomas at an early age (<10 years) AND;
- Untreated LDL-C > 500mg/dL or treated LDL-C ≥ 330mg/dL OR;
- Genetic confirmation

**Exclusions**

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling.

**References**

1. Robinson JG., Farnier M, Krempf M, et al. Efficacy and safety of alirocumab in reducing lipids and cardiovascular events. N Engl J Med 2015; 372(16):1489-99
2. Blom DJ, Bolognese M, Lillestol MJ, et al. A 52-week placebo-controlled trial of evolocumab in hyperlipidemia. N Engl J Med. 2014 May 8;370(19):1809-19
3. Robinson JG, Nedergaard BS, Rogers WJ, Fialkow J, Neutel JM, Ramstad D, Somaratne R, Legg JC, Nelson P, Scott R, Wasserman SM, Weiss R; LAPLACE-2

Investigators. Effect of evolocumab or ezetimibe added to moderate- or high-intensity statin therapy on LDL-C lowering in patients with hypercholesterolemia: the LAPLACE-2 randomized clinical trial. JAMA. 2014 May 14;311(18):1870-82. doi: 10.1001/jama.2014.4030.

4. Grundy S.M, Stone N.J, et al. Guideline on the Management of Blood Cholesterol: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Circulation (2018); 139 (25): e1082-e1143.
5. Praluent™(alirocumab) injection. Prescribing Information. Bridgewater, NJ: Sanofi-aventis U.S. LLC. March 2024.

| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
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| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Complete Wellness | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| USA Care PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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).** | |
| *© 2025 MVP Health Plan, Inc. All rights reserved. Descriptions contained within MVP's Medical Policies are not a guarantee of coverage. Each MVP Group or Subscriber Contract contains specific limitations, exclusions and requirements that may affect a Policy. If there is any discrepancy between your Group or Subscriber Contract and a Policy, your Group or Subscriber Contract shall in all cases govern.* | |

***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 |

**MVP Health Care Medical Policy**

**Pharmacy Management Programs**

| | |
|---|---|
| **Type of Policy:** | **Administrative** |
| **Prior Approval Date:** | **11/01/2024** |
| **Approval Date:** | **02/01/2025** |
| **Effective Date:** | **04/01/2025** |
| **Related Policies:** | **NA** |

**Codes Requiring Prior Authorization** N/A

**Overview**

The Plan is committed to offering a comprehensive, cost-effective pharmacy benefit to those members and employer groups that elect prescription drug coverage. This policy is a guide to pharmacy programs under the MVP pharmacy benefits. This policy will be reviewed annually by the Pharmacy & Therapeutics (P&T) committee.

Formulary

MVP's formularies list covered generic and brand name medications. The formularies include FDA-approved legend drugs and biologics (NDA/ANDA/BLA). Formularies are published on the MVP website. Members and prescribers should refer to the formulary associated with the plan benefit (e.g. Commercial, Health Insurance Marketplace, or Medicare). Each formulary will include a guide (key) to assist members and prescribers in identifying the pharmacy management programs associated with a particular drug.

Pharmacy Management Programs

Prior Authorization

- MVP requires that the prescriber or member (depending on the member's benefit) obtain prior authorization approval for coverage of a medication before a prescription is filled.
- Medications subject to prior authorization are noted on the printed formularies.

- New drugs entering the marketplace also require prior authorization while under P&T Committee review for formulary and utilization management status. Members must have received and failed an adequate trial of all other medications to treat their condition (unless there is a contraindication), regardless of the prior authorization status of the other medications before a new drug will be approved. Sample use alone does not satisfy the criteria.
- Injectable medications with therapeutically equivalent oral formulations may require prior authorization.
- Medications may require prior authorization if being used for a medical condition that is not recognized as an FDA-approved indication or supported in the FDA-approved label, supported in one of the approved compendia, used in conjunction with a procedure or treatment that is not covered in the member's contract.
- No payment will be made for prescriptions filled or services rendered prior to the approval of a prior authorization request.
    - Members may be allowed a 72-hour emergency supply of a medication or a 5-day supply of a substance use medication while awaiting a review for a prior authorization or formulary exception request.
- Prior authorization processes are subject to the applicable state or federal regulations of the member's contract or certificate of coverage.
- Prior authorization approvals (medical and/or pharmacy) do not transfer with the member when a change in eligibility to another line of business occurs.

Step Therapy

- MVP may require the member to try select medications prior to approval of other medications to treat the medical condition. We will use recognized evidence-based and peer reviewed clinical review criteria that is appropriate for the medical condition.
- Medications subject to Step Therapy may be noted on the formulary or in a specific prior authorization policy.
- For NY Commercial, NY Exchange, and NY Medicaid, additional criteria for a step therapy protocol apply as follows: The request for a Step Therapy override must be submitted with a supporting rationale and documentation from the prescriber and <u>not</u> meet the following conditions:
    - The required prescription drug is contraindicated or will likely cause an adverse reaction or physical or mental harm to the member;

- The required prescription drug is expected to be ineffective based on the member's known clinical history, condition, and prescription drug regimen;
- The member has tried the required prescription drug while covered by MVP, or under previous health insurance coverage, or another prescription drug in the same pharmacologic class or with the same mechanism of action, and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event;
- The member is stable on a prescription drug selected by the requesting health care professional for the medical condition, unless the required prescription drug is an AB-rated generic equivalent; or
- The required prescription drug is not in the member's best interest because it will likely cause a significant barrier to adherence to or compliance with the member's plan of care, will likely worsen a comorbid condition, or will likely decrease the member's ability to achieve or maintain reasonable functional ability in performing daily activities.

- Standard Review. We will make a step therapy protocol override determination within 24 hours of receipt of the supporting rationale and documentation.

- If a determination is not made within the standard step therapy prior authorization timeframes, the step therapy protocol override request will be approved. If the preauthorization, concurrent or retrospective utilization review timeframes are also applicable to the step therapy protocol override prior authorization request, the shortest timeframe will apply.

Quantity Limits

- MVP may limit the quantity of a medication that may be obtained within a 30 day period.
- Medications subject to Quantity Limits will be noted on the formulary.

Formulary Exception **(NY Commercial (Lg Group), NY Exchange (Small Group, Individual, Essential Plan), VT Exchange; NY CHP and Medicaid excluded)**

- A prescriber or member (depending on the member's benefit) may request coverage of a medication that is non-formulary or excluded.

- Requests must be submitted with clinical documentation to support the medical necessity of the exception and may include:

    - Allergic/adverse reaction to all formulary agents
    - Therapeutic failure of all clinically appropriate formulary agents
    - Patient therapy stability issues where a formulary agent is contraindicated or a change in therapy is inadvisable
    - Patient-specific contraindication or reason formulary agents are inappropriate
    - Policy and/or benefit interpretation
    - Member contract and/or prescription drug rider
    - Sample use alone does not satisfy the criteria

- Standard Review. We will make a formulary exception determination within 72 hours upon provider receipt and documentation.

- Expedited (Urgent) Review. If the requesting health care professional asserts that the member has a medical condition that places the member's health in serious jeopardy without the prescription drug prescribed by the requesting health care professional the formulary exception will be made within 24 hours upon provider receipt and documentation

Brand/Generic Difference Program (refer to the member's contract to determine if this program applies)

- MVP encourages the use of FDA "A"-rated generics whenever available.
- When the prescriber writes Dispense as Written ("DAW") on the prescription for a Brand name drug when a therapeutically equivalent "A"-rated generic is available, the member will receive the brand name drug but will be responsible for the difference in cost between the generic and brand name drug plus their applicable generic copayment.
- The difference in cost between the brand and generic drug will not apply to the member's deductible or Out of Pocket maximum.

Patient Assistance Programs

- If a patient is eligible to receive a medication for no cost via a prescription assistance program, MVP will deny the claim and not provide coverage for the medication.

Member Submitted Prescription Claim

- Members are encouraged to use par pharmacy providers to obtain their prescriptions.
- Members who request reimbursement for a prescription obtained without using their MVP prescription benefit may submit their prescription claim for reimbursement subject to benefits as outlined in plan coverage documents. Members must complete the applicable claim reimbursement form in full and submit to CVS Caremark with a valid receipt. Reimbursement is based on the pharmacy network rate minus any applicable copayments as defined by the member's pharmacy benefit. All UM and DUR edits will apply to the adjudicated submitted claim.

Excluded Providers

- Prescribers who are excluded by CMS, OMIG, OIG, or other regulatory entity will be deemed "excluded" and prescriptions will reject at the pharmacy and request for coverage of medications will be denied.

Specialty Pharmacy

- Select oral and injectable medications require provider and/or member acquisition through a contracted specialty vendor.
- Medications which must be obtained through a contracted specialty pharmacy are noted on the printed formulary.
- Typically, specialty drugs are limited to a 30-day supply
- See Medicaid section for specialty pharmacy information

Preferred Pharmacies or Home Infusion Vendors

- MVP may require select pharmaceutical agents be obtained through a preferred pharmacy or home infusion vendor as noted in the clinical policy. Use of an alternative pharmacy or home infusion vendor requires a separate medical necessity review and may be subject to out-of-network cost sharing.

Site of Care Program

- MVP may direct members to the most cost effective clinically appropriate location to receive an infused drug.
- Requests for medications to be administered in a location other than home infusion will be directed to a preferred alternative site of care. Infusions for these medications are excluded from payment when administered in a non-preferred site of care.
- For medications included in the Site of Care Program:
    - A provider office cannot buy and bill
    - A provider office cannot obtain from specialty for office administration
    - Outpatient hospital cannot buy and bill
    - Outpatient hospital cannot obtain from specialty for hospital administration
- Site of Care program MVP Medicare and Medicaid, CHP members
- To prevent delay in care and allow adequate transition time, MVP will allow 60 days after prior authorization approval for members to transfer to a preferred infusion site.

Duplicate therapy overrides

- Duplicate therapy overrides for new onset allergy will be allowed. Duplicate therapy for other reasons, such as patient preference, will be the member responsibility.

Lost/stolen/damaged medications

- Replacement of lost, forgotten, stolen or damaged medications is the responsibility of the member.

Vacation overrides

- Vacation overrides are allowed dependent on the line of business when the member is traveling to an area without access to a network pharmacy where a refill may be obtained while traveling away from home. Members should attempt to use the Mail benefit whenever possible to ensure access to adequate medication or to assist with delivery of medication while away from home.
- Commercial and Off-Exchange: Plan allows for one (1) vacation override per drug per 180 days. Override cannot exceed the maximum allowable benefit (e.g. 90-day supply). Vacation overrides for controlled substances or specialty medications are not allowed.
- ASO: For requests for lost or stolen medication for ASO groups, refer to the pharmacy section of the group's SPD. For vacation overrides for ASO groups,

typically MVP standard is followed but MVP can check with the MVP Marketing representative for the group for requests for extended periods of time.

- On-Exchange: Plan allows for one (1) vacation override per drug per 180 days. Override cannot exceed the maximum allowable benefit (e.g. 30-day supply). Vacation overrides for controlled substances or specialty medications are not allowed.
- Medicaid/CHP and Essential Plan: No vacation overrides are allowed. Members who will not have an adequate supply of medication due to a temporary absence should make alternative arrangements.
- Medicare: Plan allows for one (1) vacation override per drug per 180 days if greater than 50% of the current prescription is used. Override cannot exceed the maximum allowable benefit (e.g. 90-day supply). Vacation overrides for controlled substances or specialty medications are not allowed.

Cancer Guidance Program

The Optum® Cancer Guidance Program promotes value-based care by following evidence-based guidelines and encourages the use of cancer therapy pathways. The clinical criteria that will be utilized for prior authorization review in Optum Cancer Guidance Program (CGP) determining coverage for oncology medications under medical (including, but not limited to chemotherapy, immunotherapy, targeted therapies, oral oncolytics, leucovorin, gonadotropin releasing hormonal analogs, bone modifying agents, somotostatin analogs, white blood cell growth factors, red blood growth factors, other supportive drugs) may be found in the Cancer Guidance Program-Oncology Medication Coverage and Review Policy.

Government Programs Variations

**Medicare:**

Prior Authorization, Step Therapy, Quantity Limits, Formulary Exceptions, and Tier Exceptions

- Prescribers and Medicare members with an MVP Medicare Part D benefit should refer to the Medicare Part D formulary on the MVP website.
- Medications that are subject to Step Therapy will be noted on the formulary and will follow Step Therapy Criteria.
- Prescribers and members may request an exception for a non-formulary medication or a tier exception for a medication on the formulary. Refer to the Medicare section of the MVP website for additional information.

- Some medications require a determination of benefit (B/D) before the medication can be dispensed.
- Physician-administered medications obtained by the member from the pharmacy will take the applicable Medicare Part D copay.
- Medicare Part B drug policies are reviewed at least annually by the MVP P&T Committee and a Utilization Management (UM) Committee led by a Medical Director. The UM Committee reviews utilization management, including prior authorization policies and keeps current of guidelines for Traditional Medicare, Local Coverage Determinations (LCDs), National Coverage Determinations (NCDs), and relevant current clinical guidelines. Medicare Part B policies are available at www.mvphealthcare.com.
- A minimum 90-day transition period is required for any ongoing active course of treatment, including where the active course of treatment is taking a physician-administered drug covered under Part B, when an enrollee has enrolled in a Medicare Advantage (MA) coordinated care plan.
    - After starting a course of treatment, even if the treatment was commenced with an out-of-network provider. A MA organization must not disrupt or require authorization for an active course of treatment for new plan enrollees for a period of at least 90 days.

Excluded Drugs

- CMS excludes specific medications or categories: DESI drugs, non-FDA approved drugs (NDA/ANDA/BLA), drugs used to treat sexual or erectile dysfunction, drugs used to promote weight gain or weight loss, vitamins and minerals, drug used to treat infertility, and drugs used for conditions not supported by FDA-approved labeling or approved compendia.
    - Some enhanced employer group riders may include coverage of excluded drugs. Prior authorization criteria and quantity limits for these medications.

**Medicaid:**

Prior Authorization, Step Therapy, and Formulary Exceptions

- Medications that are a pharmacy benefit are covered and billed to New York State Fee-For-Service (FFS) program NYRX. They are defined as medications that go through a retail or specialty pharmacy, including self administered injectable products. Pharmacy medications are subject to FFS's clinical criteria including (but

not limited to) coverage, quantity limit, step therapy, and prior authorization. Pharmacy benefit information can be found here: https://www.emedny.org/info/fullform.pdf

- Medical drug request review for coverage (PA, ST, formulary exception ) will be made within 24 hours of the receipt of the request.
- Foster Care Transition fills
    - Transition fills apply to ensure access to care for medications that require prior authorization. Prior authorizations that were approved in Medicaid Fee-For-Service (FFS) will not carry through to MVP Medicaid Managed Care.
    - A member is allowed a one-time fill up to a thirty (30) day supply within the first ninety (90) days of foster care placement as a transitional fill. This transition fill is not limited to new enrollees.
    - Transition fill allows exceptions to refill timeframes and rapidly replace lost medications
    - Transition fill applies to DME replacement

Emergency Supply of Medication

- Medications that are a pharmacy benefit are covered and billed to New York State Fee-For-Service (FFS) program. They are defined as medications that go through a retail or specialty pharmacy, including self administered injectable products. Pharmacy medications are subject to FFS's clinical criteria including (but not limited to) coverage, quantity limit, step therapy, and prior authorization. Pharmacy benefit information can be found here: https://www.emedny.org/info/fullform.pdf
- Members may be allowed immediate access without prior authorization to a 72-hour emergency supply of a medication for a member experiencing an emergency condition or a member with a behavioral health condition experiencing an emergency condition or Excluded Drugs:
    - Medicaid excludes specific medications or categories: drugs used to treat sexual or erectile dysfunction, weight loss drugs, select drugs used to treat infertility, cough and cold products, cosmetic, marked "sample" or "not for sale", DESI drugs, drugs without an NDC, non-FDA approved drugs (NDA/ANDA/BLA), used for radiological testing, packaged in unit dose when bulk packaging is available, regularly supplied to public free of charge, and viscosupplementation products.

Medicaid Non-Enrolled Providers

- Effective September 1, 2022, the NYS Department of Health Medicaid Program implemented a new policy which requires all Medicaid Managed Care network and out-of-network furnishing, ordering, prescribing, and referring providers and pharmacies to enroll in the NYS Medicaid Fee-for-Service (FFS) Program.
- Prescribing, ordering, referring practitioners must enroll with the NYS Medicaid Program as a billing provider or as an Order/Prescribe/Refer/Attend (OPRA) provider.
- Per NYS DOH, network overrides are allowed in the following situations
    - Emergency (such as traveling and requiring acute care)
    - Foster care, behavioral health and/or "unmet need"
    - Transition supplies

Specialty Pharmacy

For medical benefit drugs, buy and bill is the preferred method of obtaining. If the provider is unable to buy and bill, the provider can work with MVP's preferred medical pharmacy provider CVS Specialty to obtain the drug. CVS Specialty will then bill MVP via a medical claim. If CVS Specialty is unable to provide the medications, such as a limited distribution drugs, MVP would consider a single case agreement with an alternative pharmacy.

Medically Fragile Children

For medically fragile children, MVP conducts utilization reviews and coverage determinations that are not exclusively based on review standards applicable to adults. MVP considers the specific needs and circumstances pertaining to growth and development of a medical fragile child.

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- Prescribers should refer to specific prior authorization policies for medical necessity criteria.
- Prescribers and members should refer to the member’s certificate of coverage or contract for more specific coverage requirements.

## Exclusions

None

**MVP Health Care Medical Policy**

**Phenylketonuria Agents**

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|---|---|
| **Type of Policy:** | **Drug Therapy** |
| **Prior Approval Date:** | **02/01/2024** |
| **Approval Date:** | **02/01/2025** |
| **Effective Date:** | **04/01/2025** |
| **Related Policies:** | |

Refer to the MVP Medicare website for the Medicare Part D Formulary and Part D policies for drugs that may be covered under the Part D benefit.

## Drugs Requiring Prior Authorization

*(Both brands and generics will require prior authorization)*

Kuvan™ (sapropterin dihydrochloride)
Palynziq™ (pegvaliase-pqpz) injection, for subcutaneous use

## Overview

Kuvan™ (sapropterin dihydrochloride) is indicated to reduce blood phenylalanine (Phe) levels in patients with hyperphenylalaninemia (HPA) due to tetrahydrobiopterin (BH4)-responsive Phenylketonuria (PKU). Approximately 25-50% of patients with PAH deficiency are sapropterin-responsive. Kuvan is to be used in conjunction with a Phe-restricted diet. Ideally, dietary modifications should begin within the first week of life and continue indefinitely with the goal of obtaining and maintaining blood Phe in the normal range (120-360 µmol per L) throughout life. Kuvan is a synthetic form of BH4, the cofactor for the enzyme phenylalanine hydroxylase (PAH). PAH hydroxylates Phe through an oxidative reaction to form tyrosine. In patients with PKU, PAH activity is absent or deficient. Treatment with BH4 can activate residual PAH enzyme, improve the normal oxidative metabolism of Phe, and decrease Phe levels in some patients.

Palynziq™ is indicated in adult patients with phenylketonuria (PKU) who have uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on existing therapies. Palynziq is a PEGylated phenylalanine ammonia lyase enzyme that metabolizes phenylalanine thereby reducing blood phenylalanine levels. It is a

substitute for the deficient phenylalanine hydroxylase enzyme in patients with phenylketonuria. **It is only available through a REMS program.**

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**Indications/Criteria**

Kuvan may be considered for coverage if **all** the following criteria are met:

- The drug must be prescribed by a specialist or prescriber with experience in the intensive management of PKU patients.
- Patient, parents and caregivers (if minor) are motivated to control PKU and maintain dietary restrictions.
- Patient must have a have a history of adherence to routine follow-up for the diagnosis of PKU with at least annual visits.
- Diagnosis of phenylketonuria and current mean blood phenylalanine concentration above the upper limit of the recommended ranges which are:
  - Infants < 1 years of age: 120-360µmol per L (2-6mg/dL).
  - Patients ≥2 years of age including pregnant women: 60-360µmol per L (1-6mg/dL).
- Phe-restricted diet has been continuously and appropriately utilized for a period of at least 6 months prior to initiation of the request and a mean blood Phe concentration less than or equal to the **upper limits above** was not attainable during the period.
- While on the diet, adherence was substantiated by the availability of 3-day diet logs or food frequency questionnaires (FFQs) prior to a minimum of three (3) lab measurements within the past 6 months.
- Interventions by a dietitian and/or nutritionist for diet education and diet adjustment to meet recommended levels must be documented.
- If the patient has been using the medication prior to the initial MVP request, the above criteria must have been met prior to initiation and evidence demonstrating a 30% decrease from the baseline mean blood Phe concentration after one month of sapropterin must be documented in the medical record.

**Initial authorization up to a maximum of 2 months. Continued authorization up to 3 years will be considered if documentation supports:**

- Patient, including parents and caregivers (if minor), continue to be motivated to control PKU and maintain dietary restrictions.
- Patient adheres to follow-up appointments, 3-day diet logs or FFQs and lab visits.
- Phe-restricted diet has been continuously utilized since initiation of sapropterin treatment and a mean blood Phe concentration with at least a 30 percent decrease of blood Phe from mean pretreatment levels continues.

- Maintenance of diet which is at least as stringent as the pretreatment diet unless the dietary needs of the patient have changed.
- While on the sapropterin and diet, adherence was substantiated by the availability of 3-day diet logs or FFQs prior to a minimum of three (3) lab measurements within the past 6 months.

Palynziq may be considered for coverage if **all** the following criteria are met:

- Patient is 18 years of age or older
- Medication is being prescribed by a specialist in the management of PKU
- **Patient has a history of failure, contraindication, or intolerance to Kuvan**
- Patient has uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on existing management.
- Patient was adherent to both diet and previous therapy
- Patient has discontinued Kuvan at least 2 weeks and LNAAs (large neutral amino acids) at least 2 days before initiation of Palynziq.

**Initial authorization will be considered up to 6 months. Continued authorization up to 12 months will be considered if documentation supports:**

- At least a 20% reduction in blood phenylalanine levels from pre-treatment baseline or a level less than 600 micromol/L
- Patient must maintain current diet and remain consistent while on therapy.

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**Exclusions**

Indication, age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling.

Kuvan

- Neonates less than 1 month of age or infants < 2 years of age with blood Phe <360µmol per L.
- Noncompliance with Phe-restricted diet.
- Non-responders (i.e. do not have a decrease in blood Phe with sapropterin treatment after one month of treatment at the maximum dose).
- Not maintaining Phe levels below baseline.
- Dosing exceeding 20mg/kg/day.
- Previous failure of Kuvan.

- Use with Palynziq.

Palynziq
- Use with Kuvan.
- Doses greater than 60 mg daily.
- Does not respond to a trial of 60 mg daily for 16 weeks or Phe levels above 600 micromol/L despite therapy.
- Those under the age of 18.
- Those with a baseline Phe level less than 600 micromol/L.

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## References


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2. Phenylketonuria: screening and management. NIH Consensus Statement Online 2000 October 16-18; 17(3): 1-27. Available: http://consensus.nih.gov/2000/2000Phenylketonuria113PDF.pdf.
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7. Palynziq™ (pegvaliase-pqpz). Prescribing Information. Novato, CA: BioMarin Pharmaceutical Inc; November 2020.
8. Thomas, Janet, et al. Pegvaliase for the treatment of phenylketonuria: Results of a long-term phase 3 clinical trial program (PRISM), Molecular Genetics and Metabolism 124 (2018) 27-38


| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |

| | |
|---|---|
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Complete Wellness | Refer to the MVP website for the Medicare Part B and Part D |
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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 |
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| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

**Physician Prescriptions Eligibility**

| | |
|---|---|
| **Type of Policy:** | **Drug Therapy** |
| **Prior Approval Date:** | **02/01/2024** |
| **Approval Date:** | **02/01/2025** |
| **Effective Date:** | **04/01/2025** |
| **Related Policies:** | MVP Provider Policies |

**Drugs Requiring Prior Authorization: None**

## Overview

Participating physicians are eligible to write prescriptions within their scope of practice for members if the member has prescription drug coverage.
Physicians who terminate participation need to have their patients transitioned to alternate providers. This policy will define time frames for this transition.

## Indications/Criteria

Prescriptions written by participating providers are covered subject to the terms of conditions of the prescription drug rider, contract or specific benefit design. Physicians terminating their participation will be subject to the following:

- **Physicians who terminate voluntarily:**
  Will be allowed a 90-day grace period at which time their patients should find another physician to write their prescriptions. Refills of existing prescriptions will be allowed for only 90 days.
- **Physicians who terminate involuntarily:**
  Will be allowed a 30-day grace period at which time their patients should find another physician to write their prescriptions. This 30-day notification is effective once the member has been notified, and is subject to review.

## Exclusions

Members without the prescription drug coverage.

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**References None**

**MVP Health Care Medical Policy**

**Prescribers Treating Self or Family Members**

| | |
|---|---|
| **Type of Policy:** | **Drug Therapy** |
| **Prior Approval Date:** | **02/01/2024** |
| **Approval Date:** | **02/01/2025** |
| **Effective Date:** | **04/01/2025** |
| **Related Policies:** | |

**Drugs Requiring Prior Authorization: None**

**Overview**

- The Plan concurs with and endorses the position of the American Medical Association as stated in Opinion E-8.19: *Self-Treatment or Treatment of Immediate Family Members*. The American Medical Association, American Pharmacists Association, and American Society of Health-System Pharmacists issued a joint statement on inappropriate ordering, prescribing, or dispensing of medications to treat COVID-19. The organizations issued this joint statement to highlight the important role that physicians, pharmacists and health systems play in being just stewards of health care resources during times of emergency and national disaster.

    - The joint statement is in response to reports of physicians and others prescribing or dispensing medications currently identified as potential treatments for COVID-19 (e.g., chloroquine or hydroxychloroquine, azithromycin, ivermectin) for themselves, their families, or their colleagues. MVP Health Care concurs with and endorses the position of the American Medical Association.

- The Plan concurs and endorses the position of the American Medical Association as stated in Opinion 1.2.1 Code of Medical Ethics: Treating Self or Family.

Practitioners generally should not treat themselves or members of their immediate families.

- Professional objectivity may be compromised when an immediate family member (spouse, child, father, mother, siblings including step-relations) or the practitioner is the patient, as:
- The practitioner's personal feelings may influence his/her professional medical judgment, thereby interfering with the care being delivered.
- Practitioners may fail to probe sensitive areas when taking the medical history or may fail to perform intimate parts of the physical examination. Similarly, patients may feel uncomfortable disclosing sensitive information or undergoing an intimate examination when the practitioner is an immediate family member.
- When treating themselves or immediate family members, practitioners may be inclined to treat problems that are beyond their expertise or training.
- If tensions develop in a practitioner's professional relationship with a family member, perhaps because of a negative medical outcome, these difficulties may extend into their personal relationship as well.
- Concerns regarding patient autonomy and informed consent may arise when practitioners attempt to treat members of their immediate family.
- Family members may be reluctant to state their preference for another practitioner or decline a recommendation for fear of offending the practitioner. Practitioners may feel obligated to provide care to immediate family members even if they feel uncomfortable providing care.
- The self-prescribing of medications to potentially treat COVID-19, or stockpile medications for the treatment of COVID-19 violates New York State and federal law and MVP Health Care policy.

- The AMA recognizes it may be acceptable in limited circumstances:
  - Emergency situations where there is no other qualified physician available.
  - For short-term, minor problems

**Indications/Criteria**

Claims submitted in violation of this policy will be subject to review. Additional action may be taken as deemed necessary including but not limited to the following:

- Pharmacy claims will be reviewed to determine prescribing patterns
- Referral for further investigation to MVP's Special Investigations Unit

- The MVP Certificate of Coverage states the following:

  EXCLUSIONS

  **Non-Medically Necessary Services**

  No Benefits will be provided for services, which in MVP's judgment are not Medically Necessary. Services will be deemed Medically Necessary only if:

  A. they are recommended by your treating Professional Provider

  **Family Services:**

  We do not provide benefits for services provided by a member of your immediate family. This applies even if charges are billed.

  **OR**

  **Services Usually Given Without Charge or Services Provided by a Member of the Covered Persons Immediate Family**

  We will not provide Benefits for a service if it is usually provided without charge to the patient or for services provided by a member of your immediate family. This exclusion applies even if charges are billed.

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**Exclusions**

None

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REVISED JANUARY 2024

# Preventive Care Drug List

**Preventive care drugs are medications that the MVP Pharmacy & Therapeutics (P&T) Committee has determined may prevent the onset or recurrence of a disease or condition when taken correctly.**

High-Deductible Health Plans (HDHPs) may provide benefits only after a deductible has been met. However, Federal regulations allow safe harbor coverage for qualifying preventive services and medications (those listed below) prior to the deductible being met. The preventive safe harbor does not include any drug or medication used to treat an existing illness, injury, or condition. A rider to allow this preventive coverage is required.

Medications on the Preventive Care Drug List are subject to Formulary and Tier status as well as pharmacy management programs such as prior authorization, step therapy, brand/generic difference pricing, and/or quantity limits. Visit **mvphealthcare.com/prescriptions** and refer to the Prescription Drug Formulary for more detailed information about coverage and Tier information.

This list is not a guarantee of coverage. Your specific plan documents determine your benefits, limitations, and exclusions. While every effort has been made to ensure accuracy, some information may be out of date. The Preventive Care Drug List is subject to change based on decisions made by the P&T Committee.

For drugs on this list that have a generic equivalent, the member will be responsible for an additional cost-share if there is a difference in cost between the brand and the generic drug. Some plans do not cover brand drugs when a generic is available.

If you need more information about the content of this list, contact the MVP Customer Care Center at the number listed on the back of your MVP Member ID card.



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## Anticoagulants/Antiplatelets

**ANTICOAGULANTS**

*warfarin*
*Jantoven*
ELIQUIS
XARELTO

**PLATELET AGGREGATION INHIBITORS**

*anagrelide*
*cilostazol*
*clopidogrel*
*dipyridamole*
*dipyridamole ext-rel/aspirin*
*prasugrel*
AGRYLIN
BRILINTA
EFFIENT
PLAVIX
PLETAL
YOSPRALA
ZONTIVITY

## Anticonvulsants

*carbamazepine*
*carbamazepine ext-rel*
*divalproex sodium delayed-rel*
*divalproex sodium ext-rel*
*felbamate*
*lamotrigine*
*lamotrigine ext-rel*
*phenobarbital*
*topiramate*
*topiramate ext-rel*
*valproic acid*
*Epitol*
CARBATROL
DEPAKOTE
DEPAKOTE ER
DEPAKENE SOLN
DIACOMIT
EPRONTIA
FINTEPLA
LAMICTAL
LAMICTAL XR
QUDEXY XR
SUBVENITE
TEGRETOL
TEGRETOL-XR
TOPAMAX
TROKENDI XR

## Cardiovascular Conditions—Other

**ANTIARRHYTHMIC AGENTS**

*amiodarone*
*flecainide*
*sotalol*
*Pacerone*
BETAPACE

## Coronary Artery Disease

**ANTIHYPERLIPIDEMICS**

*atorvastatin*
*cholestyramine*
*colesevelam*
*colestipol*
*ezetimibe*
*fenofibrate*
*fenofibrate micronized*
*fenofibric acid*
*fenofibric acid delayed-rel*
*fluvastatin*
*fluvastatin ext-rel*
*gemfibrozil*
*icosapent ethyl*
*lovastatin*
*niacin ext-rel*
*omega-3-acid ethyl esters*
*pravastatin*
*rosuvastatin*
*simvastatin*
*Niacor*
*Prevalite*
ANTARA
ATORVALIQ
COLESTID
CRESTOR
EZALLOR SPRINKLE
FENOFIBRIC ACID
FENOGLIDE
FIBRICOR
FLOLIPID
JUXTAPID
LESCOL XL
LIPITOR
LIPOFEN
LIVALO
LOPID
LOVAZA
QUESTRAN LIGHT
TRICOR
TRILIPIX
VASCEPA
WELCHOL
ZETIA
ZOCOR
ZYPITAMAG

**COMBINATION ANTIHYPERLIPIDEMICS**

amlodipine/atorvastatin
ezetimibe/simvastatin
CADUET
VYTORIN

Some strengths or dosage forms may not be included in the Preventive Therapy Drug List and certain products or categories may not be covered, regardless of their appearance in this document. Please check with your plan provider should you have any questions about coverage.

Please note: This list represents brand products in CAPS, branded generics in upper- and lowercase italics or all uppercase italics, and generic products in all lowercase italics.

## Diabetes

### DIAGNOSTIC AGENTS AND SUPPLIES

*alcohol swabs/skin cleanser*
BLOOD GLUCOSE MONITORS—ALL
BLOOD GLUCOSE STRIPS—ALL
CONTROL SOLUTIONS
INSULIN DELIVERY DEVICES
INSULIN SYRINGES, INFUSION SETS, AND NEEDLES—ALL
KETONE BLOOD TEST STRIPS—ALL
LANCETS, LANCET DEVICES
URINE TESTING STRIPS—ALL

Over-the-Counter (OTC) products require a prescription. Coverage may vary by plan.

### INHALED DIABETES AGENTS

AFREZZA

### INJECTABLE DIABETES AGENTS

ADMELOG
APIDRA
BASAGLAR
BYDUREON BCISE
BYETTA
FIASP
HUMALOG
HUMULIN
INSULIN ASPART
INSULIN DEGLUDEC
INSULIN GLARGINE
INSULIN LISPRO
LANTUS
LEVEMIR
LYUMJEV
MOUNJARO
MYXREDLIN
NOVOLIN
NOVOLOG
OZEMPIC
REZVOGLAR
SEMGLEE
SOLIQUA
SYMLINPEN
TOUJEO
TRESIBA
TRULICITY
VICTOZA

### ORAL DIABETES AGENTS

*acarbose*
*alogliptin/metformin*
*diazoxide*
*glimepiride*
*glipizide*
*glipizide ext-rel*
*glipizide/metformin*
*glyburide*
*glyburide micronized*
*glyburide/metformin*
*metformin*
*metformin ext-rel*
*miglitol*
*nateglinide*
*pioglitazone*
*pioglitazone/glimepiride*
*pioglitazone/metformin*
*repaglinide*
ACTOPLUS MET
ACTOS
AMARYL
CYCLOSET
DUETACT
FARXIGA
GLUCOTROL XL
GLUMETZA
GLYNASE
GLYXAMBI
INVOKAMET
INVOKAMET XR
INVOKANA
JANUMET
JANUMET XR
JANUVIA
JARDIANCE
JENTADUETO
JENTADUETO XR
KAZANO
RIOMET
RYBELSUS
SYNJARDY
SYNJARDY XR
TRADJENTA
TRIJARDY XR
XIGDUO XR

## Hypertension

### ACE INHIBITORS/ANGIOTENSIN II RECEPTOR ANTAGONISTS AND COMBINATION AGENTS

*amlodipine/benazepril*
*benazepril*
*benazepril/hydrochlorothiazide*
*candesartan*
*candesartan/hydrochlorothiazide*
*captopril*
*enalapril*
*enalapril/hydrochlorothiazide*
*fosinopril*
*fosinopril/hydrochlorothiazide*
*irbesartan*
*irbesartan/hydrochlorothiazide*
*lisinopril*
*lisinopril/hydrochlorothiazide*
*losartan*
*losartan/hydrochlorothiazide*
*moexipril*
*olmesartan*
*olmesartan/hydrochlorothiazide*
*perindopril*
*quinapril*
*quinapril/hydrochlorothiazide*
*ramipril*
*telmisartan*
*telmisartan/hydrochlorothiazide*
*trandolapril*

Please note: This list represents brand products in CAPS, branded generics in upper- and lowercase italics or all uppercase italics, and generic products in all lowercase italics.

***Hypertension*** *continued.*

*trandolapril/verapamil ext-rel*
*valsartan*
*valsartan/ hydrochlorothiazide*
ACCUPRIL
ACCURETIC
ALTACE
ATACAND
AVALIDE
AVAPRO
BENICAR
BENICAR HCT
COZAAR
DIOVAN
DIOVAN HCT
EDARBI
EDARBYCLOR
EPANED
HYZAAR
LOTENSIN
LOTENSIN HCT
LOTREL
MICARDIS
MICARDIS HCT
PRESTALIA
QBRELIS
VALSARTAN
VASERETIC
VASOTEC
ZESTORETIC
ZESTRIL

**BETA-BLOCKERS AND COMBINATION AGENTS**

*acebutolol*
*atenolol*
*atenolol/chlorthalidone*
*betaxolol*
*bisoprolol*
*bisoprolol/ hydrochlorothiazide*
*carvedilol*
*carvedilol phosphate ext-rel*
*labetalol*
*metoprolol*
*metoprolol succinate ext-rel*
*metoprolol/ hydrochlorothiazide*
*nadolol*
*nebivolol*
*pindolol*
*propranolol*
*propranolol ext-rel*
*timolol maleate*
BYSTOLIC
COREG
COREG CR
CORGARD
LOPRESSOR
TENORETIC
TENORMIN
TOPROL-XL
TRANDATE
ZIAC

**CALCIUM CHANNEL BLOCKERS AND COMBINATION AGENTS**

*amlodipine*
*diltiazem*
*diltiazem ext-rel*
*diltiazem XR*
*felodipine ext-rel*
*isradipine*
*nicardipine*
*nifedipine*
*nifedipine ext-rel*
*nimodipine*
*nisoldipine ext-rel*
*verapamil*
*verapamil ext-rel*
*Cartia XT*
*Dilt-XR*
*Matzim LA*
*Nifediac CC*
*Taztia XT*
*CARDIZEM*
*CARDIZEM CD*
*CARDIZEM LA*
*KATERZIA*
*NORLIQVA*
*NORVASC*
*NYMALIZE*
*PROCARDIA XL*
*SULAR*
*TIAZAC*
*VERAPAMIL ER*
*VERELAN*
*VERELAN PM*

**DIURETICS**

*amiloride*
*amiloride/ hydrochlorothiazide*
*bumetadine*
*chlorthalidone*
*furosemide oral solution*
*hydrochlorothiazide*
*indapamide*
*metolazone*
*spironolactone*
*spironolactone/ hydrochlorothiazide*
*torsemide*
*triamterene*
triamterene/ hydrochlorothiazide
ALDACTONE
ALDACTAZIDE
BUMEX
DIURIL
DYRENIUM
LASIX
MAXZIDE

**OTHER ANTIHYPERTENSIVE AGENTS**

*aliskiren*
*amlodipine/olmesartan*
*amlodipine/telmisartan*
*amlodipine/valsartan*
*amlodipine/valsartan/ hydrochlorothiazide*
*clonidine*
*clonidine transdermal*
*doxazosin*
*eplerenone*
*guanfacine*
*hydralazine*
*isoxsuprine*
*methyldopa*
*olmesartan/amlodipine/ hydrochlorothiazide*
*prazosin*
*terazosin*
AZOR
CARDURA
CATAPRES-TTS
EXFORGE
EXFORGE HCT
TEKTURNA
TEKTURNA HCT
TRIBENZOR

**SUPPLIES**

BLOOD PRESSURE MONITORING—ACCESSORIES, DEVICE, KIT

Over-the-Counter (OTC) products require a prescription. Coverage may vary by plan.

Please note: This list represents brand products in CAPS, branded generics in upper- and lowercase italics or all uppercase italics, and generic products in all lowercase italics.

## Mental Health

### ANTIDEPRESSANTS

*amitriptyline*
*amoxapine*
*bupropion*
*bupropion ext-rel*
*citalopram*
*desipramine*
*desvenlafaxine ext-rel*
*doxepin*
*duloxetine delayed-rel*
*escitalopram*
*fluoxetine*
*fluoxetine delayed-rel*
*imipramine HCl*
*imipramine pamoate*
*mirtazapine*
*Nefazodone*
*nortriptyline*
*olanzapine/fluoxetine*
*paroxetine HCl*
*paroxetine HCl ext-rel*
*phenelzine*
*protriptyline*
*sertraline*
*tranylcypromine*
*trazodone*
*trimipramine*
*venlafaxine*
*venlafaxine ext-rel*
*vilazodone*
ANAFRANIL
CELEXA
CYMBALTA
DESVENLAFAXINE ER
EFFEXOR XR
EMSAM
FETZIMA
FLUOXETINE 60 mg
FORFIVO XL
LEXAPRO
NARDIL
NORPRAMIN
PAMELOR
PARNATE
PAXIL
PAXIL CR
PEXEVA
PRISTIQ
PROZAC
REMERON
SERTRALINE
SYMBYAX
TRINTELLIX
WELLBUTRIN SR
ZOLOFT

### ANTIPSYCHOTICS

*aripiprazole*
*asenapine*
*chlorpromazine*
*clozapine*
*fluphenazine*
*haloperidol*
*haloperidol lactate*
*lithium carbonate*
*loxapine*
*lurasidone*
*olanzapine*
*olanzapine orally disintegrating tabs*
*paliperidone*
*perphenazine*
*quetiapine*
*quetiapine ext-rel*
*risperidone*
*thioridazine*
*thiothixene*
*trifluoperazine*
*ziprasidone*
ABILIFY
ABILIFY ASIMTUFII
ABILIFY MAINTENA
ABILIFY MYCITE
ARISTADA
CLOZARIL
EQUETRO
FANAPT
GEODON
HALDOL DECANOATE
INVEGA
INVEGA SUSTENNA
INVEGA TRINZA
LATUDA
LITHOBID
LYBALVI
PERSERIS
REXULTI
RISPERDAL
RISPERDAL CONSTA
SAPHRIS
SEROQUEL
SEROQUEL XR
VERSACLOZ
VRAYLAR
ZYPREXA
ZYPREXA ZYDIS

### OBSESSIVE COMPULSIVE DISORDER

*clomipramine*
*fluvoxamine*
*fluvoxamine ext-rel*

## Osteoporosis

*alendronate*
*calcitonin*
*calcitonin/salmon*
*ibandronate*
*raloxifene*
*risedronate*
ACTONEL
ATELVIA
BINOSTO
EVISTA
FORTEO
FOSAMAX
FOSAMAX PLUS D
MIACALCIN NASAL SPRAY
PROLIA
TERIPARATIDE
TYMLOS

## Preventive Care Services

### AGENTS FOR CHEMICAL DEPENDENCY

*acamprosate calcium*
*buprenorphine sublingual*
*buprenorphine/naloxone sublingual*
*disulfiram*
*naltrexone*
SUBOXONE FILM
VIVITROL
ZUBSOLV

Please note: This list represents brand products in CAPS, branded generics in upper- and lowercase italics or all uppercase italics, and generic products in all lowercase italics.

## Respiratory Disorders

**RESPIRATORY AGENTS**

*albuterol inh solution*
*arformoterol inh soln*
*budesonide suspension*
*budesonide/formoterol*
*fluticasone furoate/ vilanterol ellipta*
*fluticasone propionate HFA*
*fluticasone/salmeterol*
*ipratropium inh solution*
*levalbuterol inh soln*
*montelukast*
*terbutaline*
*zafirlukast*
*zileuton ext-rel*
*Breyna*
*Wixela Inhub*
ACCOLATE
ADVAIR
ADVAIR HFA
AIRDUO RESPICLICK
ANORO ELLIPTA
ARMONAIR DIGIHALER
ARNUITY ELLIPTA
ASMANEXHFA
BROVANA
BREO ELLIPTA
FLOVENT DISKUS
FLOVENT HFA
INCRUSE ELLIPTA
PULMICORT
PULMICORT FLEXHALER
QVAR REDIHALER
SEREVENT DISKUS
SINGULAIR
SPRIVA HANDIHALER
SPIRIVA RESPIMAT 1.25 mcg
STIOLTO
SYMBICORT
XOPENEX
ZYFLO

**SUPPLIES**

PEAK FLOW METERS

**DENTAL CARIES PREVENTION**

PEDIATRIC MULTIVITAMINS WITH FLUORIDE—ALL MARKETED PRODUCTS

**IMMUNOSUPPRESSIVE AGENTS**

*cyclosporine caps*
*everolimus*
*mycophenolate mofetil*
*mycophenolate sodium delayed-rel*
*sirolimus*
*tacrolimus*
*Gengraf*
ASTAGRAF XL
CELLCEPT
ENVARSUS XR
MYFORTIC
NEORAL
PROGRAF
RAPAMUNE
SANDIMMUNE
ZORTRESS

**PRENATAL VITAMINS**

PRENATAL VITAMINS

Please note: This list represents brand products in CAPS, branded generics in upper- and lowercase italics or all uppercase italics, and generic products in all lowercase italics.

**MVP Health Care Medical Policy**

**Preventive Services – Medication**

**Type of Policy:** **Drug Therapy**
**Prior Approval Date:** **07/01/2024**
**Approval Date:** **04/01/2025**
**Effective Date:** **06/01/2025**
**Related Policies:** **Quantity Limits for Prescription Drugs**

## Drugs Requiring Prior Authorization

### Overview

Beginning in 2010, the Departments of Health and Human Services (HHS), Labor, and Treasury has issued regulations requiring new plans and issuers to cover certain preventive services without any cost-sharing for the enrollee when delivered by in-network providers. These services are recommended by the U.S. Preventive Services Task Force (USPTF).

### Indications/Criteria

Medications listed in the table below will be covered at no cost share when criteria are met.

Table 1.

| Item / Quantity | USPTF Criteria | Coverage is provided as follows: |
|---|---|---|
| Aspirin | Use of aspirin by:<br>• Persons who are at high risk for preeclampsia after 12 weeks of gestation.<br>• 81mg per day | • Age limit 12-49 (preeclampsia)<br>• Quantity Limit of 100 units/fill<br>• Generics only<br>• Single ingredient OTC dosages of 81mg |
| Folic Acid | • Daily supplement recommended for persons who are planning or capable of pregnancy.<br>• Dose 0.4 to 0.8 mg per day | • Age limit ≤ 55<br>• Quantity Limit of 100 units/fill<br>• Generics only<br>• Single ingredient OTC dosages 0.4mg or 0.8mg |
| Fluoride | • For preschool children (age > 6 mos and <6 yr) w/ low fluoride exposure (water source deficient of fluoride), primary | • Age limit < 6 years<br>• Brand and generics<br>• Single ingredient oral dosages ≤ 0.5mg |

| | | |
|---|---|---|
| | care physicians should prescribe oral fluoride supplements | |
| Counseling and Intervention for Tobacco Use (30 days supply per month*) | • Counseling and intervention for tobacco use for all adults<br>• For non-pregnant adults (>18 years) available therapy includes nicotine replacement therapy (gum, lozenge, patch, inhaler and nasal spray) and sustained release bupropion & varenicline. | • Quantity Limit of 168-day supply per year<br>• Generic only nicotine replacement products<br>• Generic only bupropion<br>• OTC and Rx products |
| Bowel Preparation Medications | Screening for colorectal cancer using fecal occult blood testing, sigmoidoscopy or colonoscopy, in adults, beginning at age 45 years and continuing until age 75 years | • Age limit 45 through 75 years<br>• Rx products only<br>• Select generics and single-source brands |
| Contraceptives | Provide coverage for oral, injectable, vaginal, topical, implantable, OTC and emergency contraceptives (including male condoms, female condoms, barrier methods, vaginal sponge, spermicides) | • Rx and OTC products<br>• Generics and single source brands<br>• Quantity Limit for injectable products (1/75 days, 4/300 days)<br>• Quantity Limit for implantable=1/300 days<br>• Quantity Limit for IUD (1/300 days)<br>• Quantity Limit for vaginal ring (13/300 days)<br>• Quantity Limit for diaphragms and caps (1/300 days) |
| Raloxifene tamoxifen, anastrozole, and exemestane | The USPSTF recommends that clinicians offer to prescribe risk-reducing medications, such as tamoxifen, raloxifene, or aromatase inhibitors (anastrozole and exemestane), to women who are at increased risk for breast cancer and at low risk for adverse medication effects | • Age 35 and older<br>• Generics only |
| Low to moderate dose statins | Low to moderate dose statins to prevent Cardiovascular Disease (CVD) events and mortality in adults 40 to 75 with no history of CVD with 1 or more CVD risk factors | • Age limit 40 to 75 years<br>• Generics only:<br>Atorvastatin 10-20mg<br>Fluvastatin 20-40mg<br>Fluvastatin ER 80mg<br>Lovastatin 10-40mg<br>Pravastatin 10-80mg |

| | | |
|---|---|---|
| | | Rosuvastatin 5-10mg<br>Simvastatin 5-40mg |
| Preexposure Prophylaxis (PrEP) | The USPSTF recommends that clinicians offer pre-exposure prophylaxis (PrEP) with effective antiretroviral therapy to persons who are at high risk of HIV acquisition. | • Medications approved for PrEP:<br>o Emtricitabine/tenofovir disoproxil fumarate (generic Truvada)<br>o Truvada (brand name requires prior authorization)<br>o Descovy<br>o Apretude |
| Type 2 Diabetes | The USPSTF recommends screening for prediabetes and type 2 diabetes in adults aged 35 to 70 years who have overweight or obesity. Clinicians should offer or refer patients with prediabetes to effective preventive interventions | • Age limit 35 to 70 years old<br>• Metformin 850mg (generic)<br>• Member has no claim for an anti-diabetic agent in their history (other than metformin 850mg) in the past 180 days. |

* or smallest package size available meeting this criteria.

Additional criteria are met:

- A prescription for both legend and OTC items must be written by a provider licensed to prescribe medications and obtained at a participating pharmacy.

Coverage is provided for a maximum of a 30 days supply per month or as indicated in Table 1.

**Medicare Variation**
Policy does not apply to Medicare.

**Medicaid Variation**
Policy does not apply to Medicaid

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**Exclusions**

- Preventive drugs not listed in this policy.

- Combination products containing the listed item are not covered under this policy. Brand name and combination prescription drugs may be covered at the applicable member copayment.

**References**


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**MVP Health Care Medical Policy**

**Prostate Cancer**

| | |
|---|---|
| **Type of Policy:** | **Drug Therapy/Medical** |
| **Prior Approval Date:** | **11/01/2023** |
| **Approval Date:** | **11/01/2024** |
| **Effective Date:** | **01/01/2025** |

**Codes Requiring Prior Authorization (covered under the medical benefit)**

Q2043 Sipuleucel-T, minimum of 50 million autologous CD54+ cells (Provenge)

Refer to the MVP website for the Medicare Part D formulary and policies for drugs that may covered under the Part D benefit.

Refer to the MVP website for the Medicare Part B policies for coverage criteria of drugs covered under the medical benefit.

**Overview**

Prostate cancer is the most common cancer in American men. The American Cancer Society estimates that 1 man in 6 will be diagnosed with prostate cancer during his lifetime. Prostate cancer can be a serious disease but most men will not die from prostate cancer. Treatment options for prostate cancer include active surveillance (watchful waiting), radical prostatectomy, radiotherapy, chemotherapy, cryosurgery, vaccine treatment and hormone therapy.

**Provenge** (sipuleucel-T) is made from the patient's own immune cells and is designed to stimulate the immune system and develop an immune response against the prostate cancer. Provenge is the first immunotherapy for prostate cancer to receive FDA approval.

## Indications/Criteria

**Provenge will be considered medically necessary when all of the following are met:**

- Diagnosis of asymptomatic or minimally symptomatic, metastatic castrate-resistant (hormone-refractory) prostate cancer
- Prescribed by an oncologist/hematologist or urologist
- Life expectancy greater than 6 months
- ECOG performance status of 0-1
- Documentation with radiological evidence and/or progression of Prostate Specific Antigen (PSA) identifying progression following bilateral orchiectomy or after adequate hormone therapy (surgical or medical castration)
- Baseline testosterone levels <50 ng/dl

Criteria and use must follow the FDA package label and the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. MVP reserves the right to deviate from the NCCN guidelines if new safety information becomes available prior to updated NCCN guidelines.

**Approval will be for 16 weeks for 3 complete infusions/doses**

- Additional infusions/doses are considered investigational/experimental and are not covered

## Exclusions

- Used in combination with chemotherapy or immunosuppressive agents
- Liver/Visceral metastases
- Small Cell/neuroendocrine prostate cancer
- Indication, age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling

## References

1. National Comprehensive Cancer Network (NCCN). Prostate Cancer. NCCN Clinical Practice Guidelines in Oncology, v.4.2024. May 17, 2024
2. Provenge® (Sipuleucel-T) Injection. Prescribing Information. Seattle, WA: Dendreon Corporation; June 2011. Revised: 07/2017

| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Complete Wellness | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D |
| USA Care 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 | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

**Proton Pump Inhibitor Therapy**

| | |
|---|---|
| **Type of Policy:** | **Drug Therapy** |
| **Prior Approval Date:** | **10/01/2023** |
| **Approval Date:** | **12/01/2024** |
| **Effective Date:** | **02/01/2025** |
| **Related Policies:** | **NA** |

## Drugs Requiring Prior Authorization

See chart below under the Indications/Criteria section.

Refer to the MVP website for the Medicare Part D formulary for drugs that may covered under the Part D benefit.

## Overview

Proton Pump Inhibitors (PPIs) suppress gastric acid secretion by specific inhibition of the adenosine triphosphate enzyme system at the secretory surface of the gastric parietal cell. Therefore, they block the final step of acid production.

All PPIs are considered to be therapeutically equivalent and interchangeable in the management of gastric or duodenal ulcers, gastroesophageal reflux disease (GERD), erosive esophagitis (EE), and eradication of H. pylori infections. The literature does not demonstrate significant superiority of one or more PPI in comparison to the others in safety and/or efficacy.

Several published observational studies suggest that proton pump inhibitor (PPI) therapy may be associated with an increased risk for osteoporosis-related fractures of the hip, wrist, or spine. The risk of fracture was increased in members who received high-dose, defined as multiple daily doses, and long-term PPI therapy (a year or longer). Members should use the lowest dose and shortest duration of PPI therapy appropriate to the condition being treated. Members at risk for osteoporosis-related fractures should be managed according to the established treatment guidelines.

The package labeling for PPIs includes warnings and precautions for the class of PPIs. Studies suggest that PPI therapy may be associated with an increased risk of Clostridium difficile associated diarrhea, especially in hospitalized members. Hypomagnesemia has been reported rarely with prolonged treatment. Members should use the lowest dose and shortest duration of PPI therapy appropriate to the condition being treated. There are still questions surrounding the use of PPIs in combination Plavix®. Not all PPIs have a documented interaction with Plavix. The addition of a PPI to a clopidogrel regimen should be assessed on a case-by-case basis to determine benefits and risks to the individual member. .

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**Indications/Criteria**

Drugs requiring Prior Authorization and/or Quantity limits

| Drug Name | Prior Authorization Required* | Quantity Limits |
|---|---|---|
| Aciphex tablets | Yes | Yes (2 per day) |
| Dexilant | Yes | Yes (2 per day) |
| dexlansoprazole | No | Yes (2 per day) |
| esomeprazole | No | Yes (2 per day) |
| lansoprazole | No | Yes (2 per day) |
| Nexium | Yes | Yes (2 per day) |
| omeprazole | No | No |
| omeprazole & sodium bicarbonate (omeppi) | Yes | Yes (2 per day) |
| omeprazole & sodium bicarbonate powder pack for suspension | Yes | No |
| pantoprazole | No | Yes (2 per day) |
| rabeprazole capsules | Yes | Yes (2 per day) |
| rabeprazole tablets | No | Yes (2 per day) |
| Prevacid Capsules | Yes | Yes (2 per day) |
| Prevacid SoluTabs | No | Yes (2 per day) |
| Prilosec powder packets | Yes | Yes (2 per day) |
| Protonix | Yes | Yes (2 per day) |
| Zegerid capsules | Yes | Yes (2 per day) |
| Zegerid powder | Yes | No |
| Voquezna tablets | Yes | No |
| Voquezna dual/triple packs | No | No |

Refer to formulary for tier based and for formulary updates

## Indications/Criteria

1. The use of Aciphex®(brand), rabeprazole capsules, Dexilant (brand), Prevacid® (brand) capsulesPrilosec® (brand), Protonix® (brand), Nexium (brand),Zegerid® (brand), or omeprazole/sodium bicarbonate (brand and generic), (generic), Voquezna tablets (dual/triple packs do not require PA) may be covered if:
    - Clinical chart notes documenting that the member has experienced treatment failure for a minimum trial of 4 weeks for ALL the following at the **maximum allowed quantity**:
        - dexlansoprazole (or Dexilant) AND
        - esomeprazole 40mg (or Nexium), omeprazole (or Prilosec) 40mg, AND
        - lansoprazole (or Prevacid) 30 mg; AND
        - pantoprazole (or Protonix); AND
        - rabeprazole(or Aciphex)

        **OR**

        - The member has experienced significant intolerance (e.g. sensitivity, drug allergy, adverse effect) or has a contraindication to ALL of the following: dexlansoprazole (Dexilant), esomeprazole (Nexium), omeprazole (Prilosec), lansoprazole (Prevacid), pantoprazole, rabeprazole (Aciphex)
    - Prescription history or chart notes must be provided substantiating trial or intolerance for each medication

**Initial approval** for dosage forms requiring prior authorization may be considered up to a maximum of 12 months.

**Extension of therapy** may be approved for a maximum of 12 months if documentation provided identifies continued benefit from therapy AND prescription history identifies compliance.

**2. Quantities of proton pump inhibitors greater than the quantity of 60 doses per month** may be considered covered if the member has one of the following conditions:

- Barrett's Esophagus.
- Zollinger-Ellison Syndrome.
- Severe reflux with ulceration and/or stricture formation (after trial of omeprazole 40mg, or esomeprazole 40mg twice daily).

**OR**

Documentation must identify failure of the following at the **maximum allowed quantity of 2 per day** for a minimum of 4 weeks of:

- omeprazole 40mg or esomeprazole **AND**
- lansoprazole at 30mg; **AND**
- pantoprazole 40mg; **AND**
- rabeprazole 20mg; **AND**
- dexlansoprazole 60mg; **AND**
- requested drug

**Initial approval** for quantities greater than two per day may be considered up to a maximum of 6 months.

**Extension of therapy** may be approved for a maximum of 6 months if documentation provided identifies continued benefit from therapy AND prescription history identifies compliance.

3. **Prior authorization is NOT required** for the treatment of H. pylori with duodenal ulcer disease for up to 2 doses per day up to 14 days of therapy for formulary proton pump inhibitors.

4. **Omeprazole + suspension syrspend and First-Lansoprazole** will require prior authorization for members 7 years of age and older. Documentation must be submitted identifying why all commercially available proton pump inhibitors would not be appropriate.

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**Exclusions**

- Indication, age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling.
- 
- Esomeprazole Strontium is excluded from coverage.

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**References**

1. DeVault K, Catell D (2005) Updated Guidelines for the Diagnosis and Treatment of Gastroesophageal Reflux disease. Am J Gastroenterol 2005; 100:190–200.
2. Richardson P, Hawkey CJ, Stack WA. Proton pump inhibitors: Pharmacology and rationale for use in gastrointestinal disorders. Drugs 1998;56(3):307-335.
3. Eslick GD, Fass R. Noncardiac chest pain: evaluation and treatment. Gastroenterol. Clin. North Am. 2003; 32: 531-52
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8. Protonix® (pantoprazole) Tablets. Prescribing Information. Philadelphia, PA: Wyeth Pharmaceuticals Inc; Updated 06/2023
9. Steward DL, Wilson KM, etal. Proton pump inhibitor therapy for chronic laryngo-pharyngitis: a randomized placebo-control trial. Otolaryngol Head Neck Surg. 2004 Oct;131(4):342-50.
10. Peterson, W. American Gastroenterological Association Consensus Development Panel. Improving the Management of Gerd. Evidence-based Therapeutic Strategies. 1994.
11. Zegerid® (omeprazole/sodium bicarbonate) Capsules. Prescribing Information. San Diego, CA: Santarus, Inc. November 2012.
12. Hiltz SW, Black E, Modlin IM, Johnson SP, Allen J, Brill JV, American Gastroenterological Association. American Gastroenterological Association Medical Position Statement on the management of gastroesophageal reflux disease. Gastroenterology 2008 Oct;135(4):1383-91.
13. Dexilant ™ (dexlansoprazole) Capsules. Prescribing Information. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; August 2013.
14. Plavix® (clopidogrel) Tablets. Prescribing Information. Bridgewater, NJ: Bristol-Myers Squibb/Sanofi Pharmaceuticals Partnership; September 2013.
15. University of Illinois Chicago. What is the clinical relevance of the clopidogrel/proton pump inhibitor (PPI) interaction? October 2019. https://dig.pharmacy.uic.edu/faqs/2019-2/october-2019-faqs/what-is-the-clinical-relevance-of-the-clopidogrel-proton-pump-inhibitor-ppi-interaction/. (Accessed January 25, 2022).
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17. Katz OP, Gerson LB, Vela MF. Diagnosis and Management of Gastroesophageal Reflux Disease, Am J Gastroenterol 2013; 108:308-328
18. Katz PO, Dunbar KB, Schnoll-Sussman FH, Greer KB, Yadlapati R, Spechler SJ. ACG Clinical Guideline for the Diagnosis and Management of Gastroesophageal Reflux Disease. Am J Gastroenterol. 2022 Jan 1;117(1):27-56. doi: 10.14309/ajg.0000000000001538. PMID: 34807007; PMCID: PMC8754510.

| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Complete Wellness | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| USA Care PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

**Pulmonary Hypertension (Advanced Agents) Commercial**

| | |
|---|---|
| **Type of Policy:** | **Drug/Medical Therapy** |
| **Prior Approval Date:** | 06/01/2024 |
| **Approval Date:** | 06/01/2025 |
| **Effective Date:** | 08/01/2025 |
| **Related Policies:** | Pulmonary Hypertension (Advanced Agents) Medicaid and HARP |

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies.

**Codes Requiring Prior Authorization (covered under the medical benefit)**
J1325 Flolan (Injection, epoprostenol, 0.5mg)
J3285 Remodulin (Injection, treprostinil, 1mg)
J3490 Revatio (Injection, sildenafil)
J1325 Veletri (Injection, epoprostenol, 0.5mg)
J3490 Uptravi (Injection, selexipag, 1800mcg)

**Drugs Requiring Prior Authorization (covered under the pharmacy benefit except as noted above)**
Adcirca, Alyq, Tadliq (tadalafil)
Adempas (riociguat)
Letairis (ambrisentan)
Opsumit (macitentan)
Orenitram (treprostinil)
Revatio suspension (sildenafil)
Revatio Oral Tablet (sildenafil)
Tracleer (bosentan)
Tyvaso (Inhalation solution, treprostinil)
Uptravi (selexipag)
Ventavis (iloprost)
Winrevair (sotatercept)

**Medicare Variation**

J7686 Tyvaso (Inhalation solution, treprostinil, 1.74mg) covered under the medical benefit and must be obtained through a pharmacy

Q4074 Ventavis (Inhalation solution, iloprost, up to 20mcg) covered under the medical benefit and must be obtained through a pharmacy

J3490 Revatio (Injection, sildenafil) B/D coverage dependent upon place of service

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**Overview**

Pulmonary arterial hypertension (PAH) is a condition resulting from restricted flow through the pulmonary arterial circulation causing increased pulmonary vascular resistance and ultimately right heart failure.[12] The World Health Organization (WHO) has classified the different types of pulmonary hypertension. The drugs identified in this policy are indicated for WHO Group I. The WHO classifications identify the causes of PAH. The New York Heart Association (NYHA) has developed classes of PAH according to the level of function and associated symptoms. The drugs identified in this policy are indicated for a variety of NYHA functional classes.

| Class | WHO Modified New York Heart Association Functional Classification (WHO 1998) |
|---|---|
| **I** | Patients with pulmonary hypertension but without resulting limitation of physical activity. Ordinary physical activity does not cause undue dyspnea or fatigue, chest pain or near syncope. |
| **II** | Patients with pulmonary hypertension resulting in slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity causes undue dyspnea or fatigue, chest pain or near syncope. |
| **III** | Patients with pulmonary hypertension resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary activity causes undue dyspnea or fatigue, chest pain or near syncope. |
| **IV** | Patients with pulmonary hypertension with inability to carry out any physical activity without symptoms. These patients' manifest signs of right heart failure. Dyspnea and/or fatigue may be present at rest. Discomfort is increased by any physical activity. |

---

## Indications/Criteria

| Drug/ PAH Indication | Chemical Name | Mechanism of Action |
|---|---|---|
| Adcirca , Alyq, Tadliqare indicated to improve exercise ability. | tadalafil tablets, suspension | phosphodiesterase 5 (PDE5) inhibitor |

| | | |
|---|---|---|
| Adempas® is indicated to improve exercise capacity, improve WHO functional class, and to delay clinical worsening. | riociguat tablets | Stimulator of soluble guanylate cyclase (sGC) |
| Flolan® is indicated to improve exercise capacity | epoprostenol injection | prostacyclin vasodilator and platelet aggregation inhibitor |
| Letairis™ is indicated to improve exercise ability and delay clinical worsening. | ambrisentan tablets | endothelin receptor antagonist (ERA) |
| Opsumit® is indicated to delay disease progression which includes death, IV or subcutaneous prostanoids initiation, decreased 6-minute walk distance, worsened symptoms, and need for additional treatment. Also reduced hospitalization due to pulmonary arterial hypertension. | macitentan tablets | endothelin receptor antagonist |
| Orenitram® is indicated to improve exercise capacity | treprostinil tablets | prostacyclin vasodilator and platelet aggregation inhibitor |
| Remodulin™ is administered as a continuous SQ or IV (for those not able to tolerate SQ) infusion. It is indicated to diminish symptoms associated with exercise. It is also indicated to diminish the rate of clinical deterioration for patients requiring transition from epoprostenol. | treprostinil injection | prostacyclin vasodilator and platelet aggregation inhibitor |
| Revatio® oral tablets are indicated to improve exercise ability and delay clinical worsening (when used with epoprostenol) | sildenafil tablets | phosphodiesterase 5 (PDE5) inhibitor |
| Revatio® Injection is for patients who are currently prescribed oral Revatio and who are temporarily unable to take oral medication. | sildenafil injection | phosphodiesterase 5 (PDE5) inhibitor |
| Tracleer® is indicated to improve exercise ability and decrease the rate of clinical worsening. | bosentan tablets | endothelin receptor antagonist |
| Tyvaso® is to increase walk distance. | treprostinil inhalation soln | prostacyclin vasodilator and platelet aggregation inhibitor |
| Uptravi is indicated to delay disease progression and reduce risk of hospitalization | Selexipag | Prostacyclin receptor agonist |
| Ventavis™ is to improve exercise ability, improve symptoms, and decrease the rate of clinical worsening. | iloprost inhalation soln | prostacyclin vasodilator and platelet aggregation inhibitor |
| Veletri is indicated to improve exercise capacity | epoprostenol injection | prostacyclin vasodilator and platelet aggregation inhibitor |
| Winrevair is indicated for the treatment of pulmonary hypertension (WHO Group 1) to increase exercise capacity, improve WHO functional class and redice the risk of clinical worsening events | Sotatercept, powder for injection | Activin signaling inhibitors for PAH |

A. For all medications, all of the following criteria must be met in addition to the specific medication criteria in Section B:

- The specific medication is being prescribed for an FDA approved indication and is appropriate for the functional class diagnosis.
- Prescribed by or in consult with pulmonologist or cardiologist

- Member has a confirmed diagnosis of WHO Group I idiopathic Pulmonary Arterial Hypertension (PAH), heritable PAH, or PAH associated with connective tissue diseases.
    - A diagnosis of congenital heart disease with left-to-right shunts is also acceptable for Tracleer
    - A diagnosis of congenital systemic-to-pulmonary shunts is acceptable for Remodulin.
    - Adempas is also indicated for persistent/recurrent Chronic Thromboembolic Pulmonary Hypertension (WHO Group 4) if inoperable or after surgical treatment.
- Documented right heart catheterization identifying the following:
    - Mean pulmonary artery pressure (mPAP) greater than or equal to 20 mmHg at rest
- Documentation of vasoreactive testing
    - Documentation with rationale must be provided for members that have not been tested. A limited number of patients with idiopathic, familial, or anorexigen-induced PAH who are vasoreactive positive may respond favorably to calcium channel blockers.
- Documentation that PAH is not secondary to pulmonary venous hypertension (e.g., left sided atrial or ventricular disease, left sided valvular heart disease, etc.) or disorders of the respiratory system (e.g., chronic obstructive pulmonary disease, interstitial lung disease, obstructive sleep apnea or other sleep disordered breathing, alveolar hypoventilation disorders, etc.)[17].
- Baseline six-minute walk test results must be provided with initial request. Documentation of a current six-minute walk test must be provided with requests for continuation of therapy.
- Provider attestation that a risk/benefit evaluation and adequate patient counseling was performed for members who are pregnant and are prescribed these medications.
    - Note: Letairis, Opsumit, Tracleer, and Adempas are contraindicated in pregnancy and can only be prescribed and dispensed through a restricted distribution program.
- Oral agents are preferred for initial therapy except for patients that present with functional class IV.
- Member specific clinical documentation and supporting clinical literature will be reviewed for members not meeting the criteria contained in this policy.
- Combination requests will be reviewed when monotherapy has failed and supporting clinical literature is provided and is consistent with the American College of College of Cardiology consensus statement

B. Member must meet the criteria in Section A and the drug specific criteria below:

- Adempas
    - For new starts only: documented failure with either an oral PDE-5 inhibitor approved for the treatment of PAH OR an endothelin receptor antagonist
    - 
- Flolan
    - When used for the treatment of pulmonary hypertension associated with scleroderma spectrum of disease, the documentation of one of the following is provided:
        - Rapidly progressive NYHA Class III **OR**
        - NYHA Class IV heart failure who have progressed while on Remodulin or Tracleer therapy.
- Orenitram
    - Documentation that Orenitram is add-on therapy after failure of maximized dose of oral PDE5 or ERA.
    - The use of inhaled treprostinil is preferred and documentation must identify contraindication to inhaled or rationale for oral use.
- Opsumit
    - For new starts only: documented failure with Letairis
- Remodulin
    - Oral agents are preferred for initial therapy for class II and class III.
- Revatio
    - For new starts only: Supporting documentation must identify failure or intolerance to Adcirca
- Tracleer
    - For new starts only: supporting documentation must identify failure or intolerance to Letairis.
    - For members with class II, documentation of  risk of liver injury vs benefit must be provided
- Tyvaso
    - Documentation that Tyvaso is add-on therapy after failure of oral therapy of PDE5 or ERA.
- Uptravi
    - Documentation that Uptravi is add-on therapy after failure of oral therapy of PDE5 or ERA
- Veletri
    - When used for the treatment of pulmonary hypertension associated with scleroderma spectrum of disease, the documentation of one of the following is provided:
        - Rapidly progressive NYHA Class III **OR**
        - NYHA Class IV heart failure who have progressed while on Remodulin or Tracleer therapy.

- Winrevair
    - Documentation of a failure to double therapy for PAH for at least 2 months. Documentation must include dates of use.
    - Documentation that the member has baseline WHO Group I
    - Documentation that the member has baseline functional class II or III
    - Provider attestation that hemoglobulin and platelet count will be obtained prior to the first five doses
        - Treatment cannot be initiated if platelet count is <50,000mm3
    - For female members, a negative serum pregnancy test must be confirmed
    - Documentation of left ventricular ejection fraction >45%
    - Member does not human immunodeficiency virus (HIV)-associated PAH, PAH associated with portal hypertension, schistosomiasis, associated PAH, and pulmonary veno occlusive disease.

**Initial authorization** will be limited to 3 months except for Revatio injection which will be approved for 4 weeks. Revatio Injection is for short-term use only.

**Extended authorizations** will be up to 3 years except for Winrevair which will be approved for 1 year. All extension requests require documentation of clinical response including but not limited to

- Improvement in exercise capacity (6-minute walk test) versus baseline;
- Improvement in NYHA class versus baseline;
- Lack of deterioration. Deterioration is defined as at least two of the following:
    - refractory systolic arterial hypotension (blood pressure, < 85mm Hg);
    - worsening right ventricular failure (e.g. development of refractory edema or ascites);
    - rapidly progressing cardiogenic, hepatic, or renal failure;
    - decrease of at least 30% in the 6-minute walk test;
    - decline in measures of hemodynamic function such as central venous pressure and mixed oxygen saturation.

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**Exclusions**

- Age, dose, indication, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling
- Treatment of erectile dysfunction.
- Use in COPD, severe asthma, CHF, lung resection, ischemic vascular disease.
- Adempas

    - Use with nitrate or nitric donors in any form
    - Use with PDE inhibitors
    - Concomitant use of other soluble guanylate cyclase
    - Pulmonary hypertension associated with idiopathic interstitial pneumonias
    - Members with pulmonary veno-occlusive disease (PVOD)
    - Creatine clearance <15mL/min or on dialysis
    - Severe hepatic impairment (Child Pugh C)
- Adcirca
    - Use with nitrate or nitric donors in any form
    - Concomitant guanylate cyclase stimulators
    - Members with pulmonary veno-occlusive disease (PVOD)
- Flolan
    - Members with congestive heart failure due to severe left ventricular systolic dysfunction
- Letairis
    - Members with idiopathic pulmonary fibrosis
    - Members with moderate or severe hepatic impairment
- Opsumit
    - Members with severe anemia at the start of therapy
    - OrenitramSevere hepatic impairment (Child Pugh C)
- Remodulin
    - Severe hepatic impairment (Child Pugh C)
- Revatio
    - Use with nitrate or nitric donors in any form
    - Members with pulmonary veno-occlusive disease (PVOD)
    - Pulmonary hypertension secondary to sickle cell disease
- Tracleer
    - Moderate to severe hepatic impairment (Child Pugh B and C)
    - Members with pulmonary veno-occlusive disease (PVOD)
    - Aminotransferases >3 x ULN
    - Severe hepatic impairment (Child Pugh C)
- Veletri
    - Congestive heart failure due to severe left ventricular systolic dysfunction
- Winrevair
    - Members with pulmonary veno-occlusive disease (PVOD)
    - Human immunodeficiency virus (HIV)-associated PAH
    - PAH associated with portal hypertension
    - Schistosomiasis associated PAH
    - Members with WHO groups 2,3,4 or 5
    - Left ventricular ejection fraction <45%

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2. Flolan® (epoprostenol) injection. Prescribing Information. Research Triangle Park, NC: GlaxoSmithKline; March 2011.
3. Letairis™ (ambrisentan) tablets. Prescribing Information. Foster City, CA: Gilead Sciences, Inc.; Jan 2014.
4. Remodulin™ (treprostinil). Prescribing Information. Research Triangle Park, NC: Baxter Pharmaceutical Solutions/United Therapeutics Corp; Oct 2023.
5. Ventavis™ (iloprost) inhalation solution. Prescribing Information. South San Francisco, CA: Cotherix Inc.; Nov 2013.
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19. National Government Services, Inc. Local Coverage Determination (LCD) for Nebulizers (L11499). Original Determination Effective Date 4/1/1997. Revision Effective Date 8/2/2011.
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25. Revised Definition of Pulmonary Hypertension and Approach to Management: A Clinical Primer | Journal of the American Heart Association (ahajournals.org)
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| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |

| | |
|---|---|
| MVP Complete Wellness | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| USA Care PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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).** | |
| *© 2025 MVP Health Plan, Inc. All rights reserved. Descriptions contained within MVP's Medical Policies are not a guarantee of coverage. Each MVP Group or Subscriber Contract contains specific limitations, exclusions and requirements that may affect a Policy. If there is any discrepancy between your Group or Subscriber Contract and a Policy, your Group or Subscriber Contract shall in all cases govern.* | |

***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 |

**MVP Health Care Medical Policy**

**Pulmonary Hypertension (Advanced Agents) Medicaid and HARP**

**Type of Policy:** **Drug/Medical Therapy**
**Prior Approval Date:** **08/01/2024**
**Approval Date:** **06/01/2025**
**Effective Date:** **08/01/2025**

**Related Policies:** Pulmonary Hypertension (Advanced Agents) Commercial,

Prescription Drugs with Sexual Dysfunction/Erectile Dysfunction Indication (Medicaid and HARP)

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies.

**Codes Requiring Prior Authorization (covered under the medical benefit)**
J1325 Flolan (Injection, epoprostenol, 0.5mg)
J3285 Remodulin (Injection, treprostinil, 1mg)
J3490 Revatio (Injection, sildenafil)
J1325 Veletri (Injection, epoprostenol, 0.5mg)
J3490 Uptravi (Injection, selexipag, 1800mcg)

**Overview**
Pulmonary arterial hypertension (PAH) is a condition resulting from restricted flow through the pulmonary arterial circulation causing increased pulmonary vascular resistance and ultimately right heart failure.[12] The World Health Organization (WHO) has classified the different types of pulmonary hypertension. The drugs identified in this policy are indicated for WHO Group I. The WHO classifications identify the causes of PAH. The New York Heart Association (NYHA) has developed classes of PAH according to the level of function and associated symptoms. The drugs identified in this policy are indicated for a variety of NYHA functional classes.

| Class | WHO Modified New York Heart Association Functional Classification (WHO 1998) |
|---|---|
| I | Patients with pulmonary hypertension but without resulting limitation of physical activity. Ordinary physical activity does not cause undue dyspnea or fatigue, chest pain or near syncope. |

| | |
|---|---|
| **II** | Patients with pulmonary hypertension resulting in slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity causes undue dyspnea or fatigue, chest pain or near syncope. |
| **III** | Patients with pulmonary hypertension resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary activity causes undue dyspnea or fatigue, chest pain or near syncope. |
| **IV** | Patients with pulmonary hypertension with inability to carry out any physical activity without symptoms. These patients' manifest signs of right heart failure. Dyspnea and/or fatigue may be present at rest. Discomfort is increased by any physical activity. |

## Indications/Criteria

Medications that are a pharmacy benefit are covered and billed to New York State Fee-For-Service (FFS) program. They are defined as medications that go through a retail or specialty pharmacy, including self administered injectable products. Pharmacy medications are subject to FFS's clinical criteria including (but not limited to) coverage, quantity limit, step therapy, and prior authorization. Pharmacy benefit information can be found here: https://www.emedny.org/info/fullform.pdf

| Drug/ PAH Indication | Chemical Name | Mechanism of Action |
|---|---|---|
| **Flolan**® is indicated to improve exercise capacity | epoprostenol injection | prostacyclin vasodilator and platelet aggregation inhibitor |
| **Remodulin**™ is administered as a continuous SQ or IV (for those not able to tolerate SQ) infusion. It is indicated to diminish symptoms associated with exercise. It is also indicated to diminish the rate of clinical deterioration for patients requiring transition from epoprostenol. | treprostinil injection | prostacyclin vasodilator and platelet aggregation inhibitor |
| **Revatio**® Injection is for patients who are currently prescribed oral Revatio and who are temporarily unable to take oral medication. | sildenafil injection | phosphodiesterase 5 (PDE5) inhibitor |
| **Veletri** is indicated to improve exercise capacity | epoprostenol injection | prostacyclin vasodilator and platelet aggregation inhibitor |
| **Uptravi** is indicated to delay disease progression and reduce risk of hospitalization | Selexipag | Prostacyclin receptor agonist |

A. For all medications, all of the following criteria must be met in addition to the specific medication criteria in Section B:

- The specific medication is being prescribed for an FDA approved indication and is appropriate for the functional class diagnosis. Prescribed by or in consult with pulmonologist or cardiologist

- Member has a confirmed diagnosis of WHO Group I idiopathic Pulmonary Arterial Hypertension (PAH), heritable PAH, or PAH associated with connective tissue diseases.
    - A diagnosis of congenital systemic-to-pulmonary shunts is acceptable for Remodulin.
- Documented right heart catheterization identifying the following:
    - Mean pulmonary artery pressure (mPAP) greater than 20mmHg at rest
- Documentation of vasoreactive testing
    - Documented rationale must be provided for members that have not been tested. A limited number of patients with idiopathic, familial, or anorexigen-induced PAH who are vasoreactive positive may respond favorably to calcium channel blockers.
- Documentation that PAH is not secondary to pulmonary venous hypertension (e.g., left sided atrial or ventricular disease, left sided valvular heart disease, etc.) or disorders of the respiratory system (e.g., chronic obstructive pulmonary disease, interstitial lung disease, obstructive sleep apnea or other sleep disordered breathing, alveolar hypoventilation disorders, etc.)[17].
- Baseline six-minute walk test results must be provided with initial request. Documentation of current six-minute walk test must be provided with requests for continuation of therapy.
- Provider attestation that a risk/benefit evaluation and adequate patient counseling was performed for members who are pregnant and are prescribed these medications
- PDE5 inhibitors (including sildenafil), will only be covered when prescribed to treat a condition other than sexual or erectile dysfunction, for which the drug has been approved by the Food and Drug Administration (FDA). PDE5 inhibitors for the treatment of erectile dysfunction are excluded from coverage.
    - Per the Prescription Drugs with Sexual Dysfunction/Erectile Dysfunction Indication (Medicaid and HARP) policy, all requests will require validation with the Erectile Dysfunction Verification System (EDVS) each time a drug with SD/ED indication is requested, to determine the enrollees sex offender status

- Oral agents are preferred for initial therapy except for members that present with functional class IV.
- Member specific clinical documentation and supporting clinical literature will be reviewed for patients not meeting the criteria contained in this policy.
- Combination requests will be reviewed when monotherapy has failed and supporting clinical literature is provided and is consistent with the American College of College of Cardiology consensus statement.

B . Member must meet the criteria in Section A and the drug specific criteria below:

- Flolan
  - When used for the treatment of pulmonary hypertension associated with scleroderma spectrum of disease, the documentation of one of the following is provided:
    - Rapidly progressive NYHA Class III **OR**
    - NYHA Class IV heart failure who have progressed while on Remodulin or Tracleer therapy.
- Remodulin
  - Supporting documentation must identify failure or intolerance to self-administered products as initial therapy for class II and class III. Covered products can be found in the NYS Reimbursable Drug List https://www.emedny.org/info/fullform.pdf and the NYS Preferred Drug Program https://newyork.fhsc.com/downloads/providers/NYRx_PDP_PDL.pdf
- Revatio
  - Supporting documentation must identify failure or intolerance to self-administered products for new starts only. Covered products can be found in the NYS Reimbursable Drug List https://www.emedny.org/info/fullform.pdf and the NYS Preferred Drug Program https://newyork.fhsc.com/downloads/providers/NYRx_PDP_PDL.pdf
- Veletri
  - When used for the treatment of pulmonary hypertension associated with scleroderma spectrum of disease, the documentation of one of the following is provided:
    - Rapidly progressive NYHA Class III **OR**
    - NYHA Class IV heart failure who have progressed while on Remodulin or Tracleer therapy.
- Uptravi
  - Documentation that Uptravi is add-on therapy after failure of oral therapy of PDE5 or ERA

**Initial authorization** will be limited to 3 months except for Revatio injection which will be approved for 4 weeks. (Revatio Injection is for short-term use only.)

**Extended authorizations** will be up to one year. All extension requests require documentation of clinical response including but not limited to:

- Improvement in exercise capacity (6-minute walk test) versus baseline;
- Improvement in NYHA class versus baseline;
- Lack of deterioration. Deterioration is defined as at least two of the following:
    - refractory systolic arterial hypotension (blood pressure, < 85mm Hg);
    - worsening right ventricular failure (e.g. development of refractory edema or ascites);
    - rapidly progressing cardiogenic, hepatic, or renal failure;
    - decrease of at least 30% in the 6-minute walk test;
    - decline in measures of hemodynamic function such as central venous pressure and mixed oxygen saturation.

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## Exclusions

- Age, dose, indication, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling
- Treatment of erectile dysfunction.
- Use in COPD, severe asthma, CHF, lung resection, ischemic vascular disease.
- Flolan
    - Members with congestive heart failure due to severe left ventricular systolic dysfunction
- Remodulin
    - Severe hepatic impairment (Child Pugh C)
- Revatio
    - Use with nitrate or nitric donors in any form
    - Members with pulmonary veno-occlusive disease (PVOD)
    - Pulmonary hypertension secondary to sickle cell disease
- Veletri
    - Congestive heart failure due to severe left ventricular systolic dysfunction

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6. Tracleer® (bosentan) tablets. Prescribing information. South San Francisco, CA: Acetelion Pharmaceuticals Jul 2013.
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17. National Government Services, Inc. Local Coverage Determination (LCD) for External Infusion Pumps (L27215). Original Determination Effective Date 10/01/1993. Revision Effective Date 2/4/2011.
18. National Government Services, Inc. Local Coverage Article for nebulizers (A24944). Original Article Effective Date 4/1/2005. Revision Effective Date 2/4/2011.
19. National Government Services, Inc. Local Coverage Determination (LCD) for Nebulizers (L11499). Original Determination Effective Date 4/1/1997. Revision Effective Date 8/2/2011.
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22. Opsumit (macitentan) tablets. Prescribing Information. South San Francisco, CA: Actelion Pharmaceuticals US, Inc.; Oct 2013.

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26. Revised Definition of Pulmonary Hypertension and Approach to Management: A Clinical Primer | Journal of the American Heart Association (ahajournals.org)

| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Complete Wellness | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| USA Care PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

**Quantity Limits for Prescription Drugs**

**Type of Policy:** **Drug Therapy**

**Prior Approval Date:** **04/01/2024**

**Approval Date:** **10/01/2024**

**Effective Date:** **01/01/2025**

**Related Policies:** Pain Medications, Hypnotics (Select), Pharmacy Programs Administration, Male Hypogonadism, Proton Pump Inhibitor Therapy, Calcitonin Gene-Related Peptide (CGRP) Antagonists, Infertility Drug Therapy (Commercial/Marketplace)

Refer to the MVP website for the Medicare Part D formulary for drugs that may be covered under the Part D benefit.

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Refer to the MVP website for the Medicare Part D formulary for drugs that may be covered under the Part D benefit.

**Drugs Requiring Prior Authorization (covered under the pharmacy benefit)**

- Drugs identified in this policy if the prescribed amount exceeds the specified quantity
- Drugs identified on the formularies with designation "QL" if the prescribed amount exceeds the specified quantity.

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**Overview**

Prescribing information details, approved indications, and dosing. This policy establishes quantity limits on certain medications with potential for overuse to ensure that quantities are medically necessary.

The member is responsible for the applicable pharmacy copayment at each prescription fill/refill including any difference in cost between the generic and the brand name drug if a generic is available.

**Indications/Criteria**

Intended use above the quantities listed below requires prior authorization. Quantity limits apply to all brand and generic products. **The following criteria must be met for quantity limit exceptions:**

- Requests must include rationale for drug therapy
- Documentation:
    - Of alternate treatment failures and anticipated treatment plan

- Must demonstrate that the quantity exceeding that noted below is medically necessary

**Initial approval** will be for 6 months

**Extensions requests** will be approved up to 12 months when the following criteria is met:

- Current documentation is provided indicating the member has a continued benefit to therapy **AND**
- Current documentation must demonstrate that the quantity exceeding that noted below is medically necessary **AND**
- Extension requests where exceeding the quantity limit did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing

**The following categories are subject to quantity limitations and noted on the formularies:**

**ADHD Long-Acting Stimulants (brand and generic)**

Quantity of 2 capsules/tablets per day

| **Brand Name** |
|---|
| Adderall XR |
| Adhansia XR |
| Concerta |
| Dexedrine caps |
| Focalin XR |
| Jornay PM |
| Metadate CD (generic only covered) |
| Mydayis |
| Qelbree |
| Quillichew (generic only covered) |
| Quillivant Suspension- 360ml/30 days |
| Relexxii |
| Ritalin LA |
| Vyvanse |

**ADHD Non-Stimulant Medications**

- Strattera/atomoxetine -- 3 capsules per day

**ANAPHYLAXIS THERAPY AGENTS- (2 PENS PER 30 DAYS)**

- Epinephrine solution auto-injector 0.3 mg/0.3ml (1:1000)
- Epinephrine solution auto-injector 0.15 mg/0.3ml (1:2000)
- Epinephrine solution auto-injector 0.15 mg/0.15ml (1:1000)
- EPIPEN 2-PACK & EPIPEN-JR
- SYMJEPI INJ 0.3MG & 0.15MG

**Antibiotic/Antiprotozoal**

- Atovaquone suspension 750 mg/5ml - 140ml per 180 days
- Ceftriaxone 250mg vial- 4 vials per 23 days
- Ceftriaxone 500mg vial- 8 vials per 23 days
- Coremino – 84 capsules per 365 days
- Mepron suspension – 140ml per 180 days
- SOLODYN/Minocycline ER: 84 per 365 days
- Xifaxan **550mg**- 126 tablets per lifetime; Quantities exceeding the 126 tablets per lifetime will be reviewed on a case-by-case basis.
- Xifaxan **200mg**- 9 tablets per 180 days
- Oracea/Doxycycline DR tablets- 120 capsules per 365 days

**ANTI-CATAPLECTIC AGENTS (540 ML every 30 days)**

- XYREM SOL 500MG/ML
- XYWAV SOL 0.5GM/ML

**ANTIFUNGALS (ORAL)**

- Terbinafine 250 mg tablets – 168 tablets per 365 days
- Itraconazole 100 mg capsules – 360 capsules per 365 days
- Itraconazole 10 mg/ml oral solution – 3600ml per 365 days

**Antiemetic Drugs**

| **Brand Name** | **Chemical Name** | **Quantity Limit** |
|---|---|---|
| Akynzeo | netupitant/palonosetron | 2 capsules per 23 days |
| Anzemet 50mg | dolasetron | 14 tablets per 23 days |
| Bonjesta | doxylamine/pyridoxine | 60 tablets per 30 days |
| Diclegis | doxylamine/pyridoxine | 60 tablets per 30 days |
| Emend 40mg | aprepitant | 1 capsule per 21 days |
| Emend 80mg | aprepitant | 8 capsules per 21 days |
| Emend 125mg | aprepitant | 2 capsules per 21 days |
| Emend Tri-fold Pack | aprepitant | 2 packs or 6 caps per 21 days |

| | | |
|---|---|---|
| Emend Suspension 125mg | aprepitant | 2 kits per 23 days |
| Kytril 1mg | granisetron | 14 tablets per 23 days |
| Sancuso 3.1 mg /24 hours | granisetron | 2 patches per 23 days |
| Varubi 90mg tablet | rolapitant | 4 tablets per 30 days |

**Antimalarial Drugs**

| **Brand Name** | **Chemical Name** | **Quantity Limit per 365 days** |
|---|---|---|
| Aralen | Chloroquine 250mg & 500mg | 16 tablets |
| Coartem | Artemether/lumefantrine | 24 tablets |
| Malarone | Atovaquone/proguanil | 42 tablets |
| Mefloquine | Mefloquine | 14 tablets |
| Primaquine | Primaquine phosphate | 46 tablets |
| Qualaquin | Quinine | 84 capsules |

**Antiretrovirals**

- Paxlovid 150mg-100mg tablets- 40 tablets per 30 days
- Paxlovid 300mg-100mg tablets – 60 tablets per 30 days

**Anthelmintics**

- EMVERM CHW 100MG – 2 each every 135 days

**CARDIOVASCULAR AGENTS**

- CAMZYOS CAPSULES – 30 capsules per 30 days

**Contraceptives**

- Depo-Provera/Depo-SQ Provera (Medroxyprogesterone inj (IM & SQ)) – 4 injections per 300 days

**Diabetic Medications and Supplies**

- Victoza injection – 9ml (3 pens) per 30 days
- Alcohol swabs – 200 swabs per 30 days
    - $20 claim limit per claim for all alcohol pads/swabs
- Glucose test strips – 200 strips per 30 days or 600 strips per 90 days
- Omnipod kit- 1 kit per 365 days
- Omnipod pods- 10 pods per 30 days
- V-Go 20, 30, 40 kit- 30 devices (1 box) per 30 days

- Dexcom receivers- 1 receiver every 365 days
- Dexcom sensors- 1 sensor every 10 days
- Dexcom Transmitter- 1 transmitter every 90 days
- Freestyle sensor- 1 sensor every 14 days
- Freestyle Reader- 1 reader every 365 days
- Lancets- $30 claim dollar limit on lancets per 30 day supply

**Erectile Dysfunction Drugs**

| **Brand Name** | **Chemical Name** | **Quantity Limit per 30 days** |
|---|---|---|
| Caverject | alprostadil injection | 6 injections |
| Cialis | tadalafil | 4 tablets |
| Edex | alprostadil injection | 6 injections |
| Levitra | vardenafil | 4 tablets |
| Muse | alprostadil urethral pellet | 6 pellets |
| Staxyn | vardenafil ODT | 4 tablets |
| Viagra | sildenafil | 4 tablets |

- Above limits apply per month regardless of dosing considerations. Refills will be allowed every 30 days
- Quantity limits apply to both formulary agents and those that are approved through the medical exception prior authorization process

**Ergot alkaloids**

- Methergine - 28 tablets per 365 days

**LIVE FECAL MICROBIOTA**

- VOWST CAPSULES - 12 capsules per 30 days

**Flu Drugs (brand and generic)**

- Relenza: A member will be allowed one course for treatment once every 180 days without prior approval. One course of treatment is defined as 5 days.
- Tamiflu/oseltamivir capsules: 21 capsules every 180 days
- Tamiflu/oseltamivir suspension: 180ml of suspension per 180 days.
- Xofluza: 2 tablets per 180 days

**GABA RECEPTOR MODULATOR - NEUROACTIVE STEROID**

- ZURZUVAE 20MG and 25MG CAPSULES – 28 capsules per 270 days
- ZURZUVAE 30MG CAPSULES – 14 capsules per 270 days

**GOUT AGENTS**

- Colchicine 0.6 mg capsules/tablets – 60 every 23 days

- COLCRYS 0.6MG TABLETS – 60 tablets per 23 days
- MITIGARE 0.6MG CAPSULES - 60 capsules per 23 days

**Hyponatremia**

- Samsca/ tolvaptan tablets – 60 tablets every 180 days

**Inhalers**

- Armonair digihaler- 2 inhalers per 30 days

**Migraine Agents**

| **Name** | **Quantity Limit every 30 days unless indicated otherwise** |
|---|---|
| Alsuma™ 6mg/0.5ml injection/**Sumatriptan** | 4 kits (8 injections) |
| Amerge® 1mg/**Naratriptan** | 18 tablets |
| Amerge® 2.5mg /**Naratriptan** | 9 tablets |
| Axert™ 6.25mg /**Almotriptan** | 12 tablets |
| Axert ™12.5mg /**Almotriptan** | 8 tablets |
| butorphanol nasal spray | 10 mls (4 canisters) |
| Cambia™ 50mg /**Diclofenac** | 9 packets/45 days |
| D.H.E. 45 inj. /**Dihydroergotamine mesylate** | 20 ampules |
| Ergotamine-Caffeine tablets | 40 tablets |
| Elyxyb Solution | 1 box (6 bottles) per 45 days |
| Frova® 2.5mg/ **frovatriptan** | 12 tablets |
| Imitrex® 4mg injection /**Sumatriptan** | 6 kits (12 injections) |
| Imitrex® 6mg injection **Sumatriptan** | 4 kits (8 injections) |
| Imitrex® 5mg & 20mg Nasal Spray **Sumatriptan** | 12 units |
| Imitrex® 25mg & 50mg **Sumatriptan** | 18 tablets |
| Imitrex® 100mg **Sumatriptan** | 9 tablets |
| Maxalt®/MLT 5mg & 10mg **Rizatriptan** | 12 tablets |
| Migergot Suppositories /**Ergotamine/caffeine** | 20 suppositories |
| Migranal® Nasal Spray /**dihydroergotamine mesylate** | 8 units |
| Onzetra 11mg Nasal /**Sumatriptan** | 8 doses (16 nosepieces) |
| Relpax® 20mg /**eletriptan** | 12 tablets |
| Relpax® 40mg/ **eletriptan** | 8 tablets |
| Reyvow 50mg, 100mg (100mg dose) /lasmiditan | 4 tablets |
| Reyvow 100mg (200mg dose) /lasmiditan | 8 tablets |
| Sumavel™ DosePro™ /**Sumatriptan** | 1 kit (6 injections) |
| Sumatriptan-Naproxen tablets (generic for Treximet) | 9 tablets |
| Treximet™ | 9 tablets |
| Tosymra /**Sumatriptan** | 18 sprays |
| Zembrace SymTouch/ **Sumatriptan** | 6 kits (12 injections) |

| | |
|---|---|
| +Zomig®/ZMT 2.5mg/ **Zolmitriptan** | 12 tablets |
| +Zomig®/ZMT 5 mg/ **Zolmitriptan** | 8 tablets |
| +Zomig® Nasal Spray /**Zolmitriptan** | 12 units |

**CGRPs-**

- Nurtec – 30 tablets per 30 days
- Ubrelvy – 30 tablets per 30 days
- Qulipta – 30 tablets per 30 days
- Emgality – 300mg injection once per month OR 120mg injection once per month
- Aimovig – 1 (one) 70mg injection OR 1 (one) 140mg pen per 28 days

**NSAIDS**

- Mefenamic acid 250mg capsules – 14 caps per 30 days
- Sprix Spray 15.75mg – 5 bottles per 23 days

**NEUROMUSCULAR AGENTS**

- EVRYSDI SOLUTION – 240ml per 30 days

**Smoking Cessation Medications**

| **Brand Name** | **Chemical Name** | **Quantity Limit** |
|---|---|---|
| Chantix | Varenicline, apo-varenicline (starter pack not included) | 168-day supply per calendar year (365 days) |
| Nicotrol | nicotine | 168-day supply per calendar year (365 days) |
| Nicotrol NS | nicotine | 168-day supply per calendar year (365 days) |
| Zyban* | bupropion | 168-day supply per calendar year (365 days) |

*****only generic Zyban is covered

**Over-the-counter nicotine replacement** therapy may be covered with the following quantity limitations*:

| **Dosage form** | **Example brand name(s)** | **Quantity Limit** |
|---|---|---|
| Gum | Nicorette, Thrive | 168-day supply per calendar year (365 days) |
| Lozenge/troche | Commit | 168-day supply per calendar year (365 days) |
| Patch | Habitrol, Nicoderm CQ | 168-day supply per calendar year (365 days) |

**Opioid Withdrawal Agents**

| **Brand Name** | **Chemical Name** | **Quantity Limit** |
|---|---|---|
| Lucemyra | Lofexidine | 168 tablets per 180 days |

**PROSTATIC HYPERTROPHY AGENTS**

- Tadalafil 2.5 mg and 5mg tablets – 30 tablets per 30 days

**Substance Abuse Disorder**

| **Brand Name** | **Generic Name** | **Quantity allowed per 30 days** |
|---|---|---|
| SUBOXONE MIS 2-0.5MG | BUPRENORPHINE HCL-NALOXONE HCL SL FILM 2-0.5 MG (BASE EQUIV) | 90 films |
| SUBOXONE MIS 4-1MG | BUPRENORPHINE HCL-NALOXONE HCL SL FILM 4-1 MG (BASE EQUIV) | 90 films |
| SUBOXONE MIS 8-2MG | BUPRENORPHINE HCL-NALOXONE HCL SL FILM 8-2 | 90 films |
| SUBOXONE MIS 12-3MG | BUPRENORPHINE HCL-NALOXONE HCL SL FILM 12-3 MG (BASE EQUIV) | 60 films |
| ZUBSOLV SUB 0.7-0.18 | BUPRENORPHINE HCL-NALOXONE HCL SL TAB 0.7-0.18 | 90 SL tablets |
| ZUBSOLV SUB 1.4-0.36 | BUPRENORPHINE HCL-NALOXONE HCL SL TAB 1.4-0.36 | 90 SL tablets |
| ZUBSOLV SUB 2.9-0.71 | BUPRENORPHINE HCL-NALOXONE HCL SL TAB 2.9-0.71 | 90 SL tablets |
| ZUBSOLV SUB 5.7-1.4 | BUPRENORPHINE HCL-NALOXONE HCL SL TAB 5.7-1.4 | 90 SL tablets |
| ZUBSOLV SUB 8.6-2.1 | BUPRENORPHINE HCL-NALOXONE HCL SL TAB 8.6-2.1 | 60 SL tablets |
| ZUBSOLV SUB 11.4-2.9 | BUPRENORPHINE HCL-NALOXONE HCL SL TAB 11.4-2.9 MG | 30 SL tablets |

**Topical Agents**

| **Drug name** | **Quantity limit** |
|---|---|
| Calcipotriene ointment/cream/solution | 60 grams/ml per 30 days |

| | |
|---|---|
| calcitrene | 60 grams per 30 days |
| Ciclodan | 20ml per 365 days |
| ciclopirox solution 8% | 20ml per 365 days |
| Clobetasol ointment | 120 grams per 30 days |
| Diflorasone 0.05% ointment/cream | 60 grams per 30 days |
| DOVONEX CREAM 0.005% | 60 grams per 30 days |
| Flurandrenolide cream/ointment | 60 grams per 30 days |
| Flurandrenolide lotion | 120mL per 30 days |
| Hydrocortisone butyrate lotion 0.1% | 59ml per 30 days |
| ketoconazole cream 2% | 120mL per 30 days |

**Wakefulness-promoting agents**

| Brand Name | Chemical Name | Quantity Limit per 30 days |
|---|---|---|
| Provigil® | modafinil | 60 tablets |
| Nuvigil® | armodafinil | 60 tablets |
| Sunosi® | solriamfetol | 60 tablets |

**Weight loss products (non GLP-1's)- brand and generic:**

All medications listed in the chart below will be covered at a **maximum of 12 months per lifetime**. Coverage beyond 12 months will be reviewed on a case-by-case basis for life threating medical conditions related to obesity

| Drug Name | Chemical Name |
|---|---|
| Adipex-P®, Lomaira, Suprenza | phentermine |
| Bontril PDM® | phendimetrazine |
| Contrave | naltrexone/bupropion |
| Qsymia™ | phentermine/topiramate |
| Regimex | benzphetamine |
| Tenuate®/Dospan® | diethylpropion |
| Xenical® | Orlistat |

**Wound products**

- Santyl 250unit/g Topical Ointment — 90gm per 30 days.
    - Requests for quantities over the allowed amount will be approved based on the dosing calculator found at http://www.santyl.com/hcp/dosing-calculator.
    - Chart notes identifying wound size must be provided with each request.

**Vaccines**

| Brand Name | Chemical Name | Quantity Limit |
|---|---|---|
| Flu vaccine (i.e. Fluzone, Afluria, etc.) | Influenza virus vaccine | 1 per 180 days |

**Medicaid Variation:** Medications that are a pharmacy benefit are covered and billed to New York State Fee-For-Service (FFS) program. They are defined as medications that go through a retail or specialty pharmacy, including self administered injectable products. Pharmacy medications are subject to FFS's clinical criteria including (but not limited to) coverage, quantity limit, step therapy, and prior authorization. Pharmacy benefit information can be found here: https://www.emedny.org/info/fullform.pdf

**Exclusions**

- Quantity limit exceptions for Medicare members are excluded from this policy and require prior authorization when applicable per Medicare regulations. Refer to Medicare Part D coverage and guidance
- Using multiple tablets per dose when there is an appropriate higher strength available is not considered medically necessary. For example, drug A is available in a 10mg and 20mg tablet. Using two tablets of 10mg per dose is not considered medically necessary since there is a 20mg dose available.
- Use of multiple agents within each drug class per 30 days from date of first prescription filled in that class

**References:**

1. Manufacturer Prescribing Information
2. Clinical Pharmacology
3. Micromedex

| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Medicare Gold Giveback | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |

| | |
|---|---|
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D |
| 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).** | |
| *© 2024 MVP Health Plan, Inc. All rights reserved. Descriptions contained within MVP's Medical Policies are not a guarantee of coverage. Each MVP Group or Subscriber Contract contains specific limitations, exclusions and requirements that may affect a Policy. If there is any discrepancy between your Group or Subscriber Contract and a Policy, your Group or Subscriber Contract shall in all cases govern.* | |

***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 |

**MVP Health Care Medical Policy**

**Radicava**

**Type of Policy:** **Medical Therapy** (administered by the pharmacy department)
**Prior Approval Date:** **11/01/2023**
**Approval Date:** **11/01/2024**
**Effective Date:** **01/01/2025**
**Related Policies:** **N/A**

**Codes Requiring Prior Authorization (covered under the medical benefit)**
J1301 Radicava (edaravone, 1mg)

**Drugs Requiring Prior Authorization (covered under the pharmacy benefit)**
Radicava ORS (edaravone) oral suspension 105 mg/5 mL

Refer to the MVP website for the Medicare Part D formulary for drugs that may be covered under the Part D benefit.

Refer to the MVP website for the Medicare Part B policies for coverage criteria of drugs covered under the medical benefit.

**Overview**
Amyotrophic lateral sclerosis (ALS) is a progressive neurodegenerative disorder that causes muscle weakness, disability, and eventually death. The median survival is three to five years after diagnosis with 10 to 20 percent of patients surviving for greater than 10 years. Long-term survival is associated with a younger age at symptom onset, male gender, and limb rather than bulbar symptom onset.

The mechanism by which Radicava exerts its therapeutic effect in patients with ALS is unknown. It has been characterized as a free radical scavenger, which is thought to block radicals that mediate both neuronal and vascular damage.

Radicava IV is dosed as 60 mg IV once daily for 14 days followed by a 14-day drug-free period for an initial treatment cycle. For subsequent treatment cycles, administer for 10 days out of 14-day periods followed by 14-day drug-free periods. Members treated

with intravenous Radicava (edaravone) may be switched to oral edaravone using the same dosing frequency.

Radicava oral is dosed as 105 mg PO once daily for 14 days followed by a 14-day drug-free period for an initial treatment cycle. For subsequent treatment cycles, administer for 10 days out of 14-day periods followed by 14-day drug-free periods.

**Medicaid Variation:** Medications that are a pharmacy benefit are covered and billed to New York State Fee-For-Service (FFS) program. They are defined as medications that go through a retail or specialty pharmacy, including self administered injectable products. Pharmacy medications are subject to FFS's clinical criteria including (but not limited to) coverage, quantity limit, step therapy, and prior authorization. Pharmacy benefit information can be found here: https://www.emedny.org/info/fullform.pdf

## Indications/Criteria

Radicava/edaravone IV or oral suspension may be considered for coverage when the following criteria are met:

- Prescribed by a Neurologist
- Chart notes documenting a confirmed diagnosis of ALS Diagnosis of ALS within the past 2 years
- Submission of the most recent ALS Functional Rating Scale-Revised (ALSFRS-R) score with results identifying a score of 2 points or better on each individual item showing that the member has functionality retained most activities of daily living. http://www.outcomes-umassmed.org/als/alsscale.aspx
- Chart notes identifying current % forced vital capacity (%FVC) greater than or equal to 80%
- The member is currently receiving riluzole unless contraindicated
- Site of Care for Radicava/edaravone IV (medical benefit)
    - Commercial and Exchange members
        - Per the MVP Health Care Pharmacy Management Programs policy, Radicava is subject to Site of Care requirements and must be obtained through a preferred home infusion vendor. Prior Authorization and medical justification is required for Radicava obtained and administered in other outpatient settings such as a provider's office or hospital facility. The first dose which may be given in a supervised outpatient setting.

    - MVP will allow 60 days after prior authorization approval for members to transfer to a preferred infusion site.
    - This requirement does not apply to MVP Medicare and Medicaid, CHP members

    - Radicava is to be administered in the home setting, with the exception of the first dose which may be given in a supervised outpatient setting. Medical necessity for administering in places of services other than the home must be documented in the medical record
- Medicaid and Child Health Plus: Members are not required to receive Radicava in the home setting

**Initial approval** will be for 6 cycles or 24 weeks (64 doses)

Extension requests will be approved if the member meets the following criteria:

- Member must not be dependent on invasive ventilation
- Member has not experienced rapid disease progression while on therapy and can still perform some activities of daily living independently.
- ALSFRS-R score must not have declined 50% from baseline
- Approval will be for 24 weeks (60 doses)

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## Exclusions

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling Member is dependent on invasive ventilation
- Member requires total assistance for activities of daily living

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## References


1. Radicava (edaravone) Injection. Prescribing Information. Jersey City, NJ: MT Pharma America, Inc. May 2017. Revised November 2022.
2. The ALS Care Program . ALS Functional Rating Scale (outcomes-umassmed.org)
3. Amyotrophic lateral sclerosis (ALS). Mayo Clinic. Accessed October 3 2024. Amyotrophic lateral sclerosis (ALS) - Diagnosis and treatment - Mayo Clinic


| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Complete Wellness | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D |
| USA Care 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 | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

**Medicare Part B: Radicava**

**Type of Policy:** **Medical Therapy**
**Prior Approval Date:** **11/01/2023**
**Approval Date:** **11/01/2024**
**Effective Date:** **01/01/2025**
**Related Policies:** **N/A**

Refer to the MVP website for the Medicare Part D formulary for drugs that may be covered under the Part D benefit.

**Please refer to relevant CMS LCDs/NCDs/Policy Articles for most up to date Medicare Part B guidance if available**

## Codes Requiring Prior Authorization (covered under the medical benefit)

J1301 Radicava (edaravone, 1mg)

## Overview/Summary of Evidence

Amyotrophic lateral sclerosis (ALS) is a progressive neurodegenerative disorder that causes muscle weakness, disability, and eventually death. The median survival is three to five years after diagnosis with 10 to 20 percent of patients surviving for greater than 10 years. Long-term survival is associated with a younger age at symptom onset, male gender, and limb rather than bulbar symptom onset.

The mechanism by which Radicava exerts its therapeutic effect in patients with ALS is unknown. It has been characterized as a free radical scavenger, which is thought to block radicals that mediate both neuronal and vascular damage.

Radicava IV is dosed as 60 mg IV once daily for 14 days followed by a 14-day drug-free period for an initial treatment cycle. For subsequent treatment cycles, administer for 10 days out of 14-day periods followed by 14-day drug-free periods. Members treated with intravenous Radicava (edaravone) may be switched to oral edaravone using the same dosing frequency.

## Indications/Criteria

Radicava/edaravone IV or oral suspension may be considered for coverage when the following criteria are met:

- Prescribed by a Neurologist
- Chart notes documenting a confirmed diagnosis of ALS Diagnosis of ALS within the past 2 years
- Submission of the most recent ALS Functional Rating Scale-Revised (ALSFRS-R) score with results identifying a score of 2 points or better on each individual item showing that the member has functionality retained most activities of daily living. http://www.outcomes-umassmed.org/als/alsscale.aspx
- Chart notes identifying current % forced vital capacity (%FVC) greater than or equal to 80%
- The member is currently receiving riluzole unless contraindicated

Initial approval will be for 6 cycles or 24 weeks (64 doses)

Extension requests will be approved if the member meets the following criteria:

- Member must not be dependent on invasive ventilation
- Member has not experienced rapid disease progression while on therapy and can still perform some activities of daily living independently. ALSFRS-R score must not have declined 50% from baseline
- Approval will be for 24 weeks (60 doses)

## Exclusions

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling
- Member is dependent on invasive ventilation
- Member requires total assistance for activities of daily living

## References

1. Radicava (edaravone) Injection. Prescribing Information. Jersey City, NJ: MT Pharma America, Inc. May 2017. Revised November 2022.

2. The ALS Care Program . ALS Functional Rating Scale (outcomes-umassmed.org)
3. Amyotrophic lateral sclerosis (ALS). Mayo Clinic. Accessed October 3 2024. Amyotrophic lateral sclerosis (ALS) - Diagnosis and treatment - Mayo Clinic

**MVP Health Care Medical Policy**

**Remestemcel**

**Type of Policy:** Medical therapy (administered by the pharmacy department)

**Prior Approval Date:** NA
**Approval Date:** 07/01/2025
**Effective Date:** 07/01/2025
**Related Policies:** NA

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies.

## Drugs Requiring Prior Authorization under the medical benefit

**J3590** Ryoncil (remestemcel-L-rknd, intravenous, injection)

## Overview

Ryoncil (remestemcel-L-rknd) is an allogeneic bone marrow-derived mesenchymal stromal cell (MSC) therapy indicated for the treatment of steroid-refractory acute graft versus host disease (SR-aGvHD) in pediatric patients 2 months of age and older.

GvD is a complication that may occur after receiving a transplant of donor stem cells (allogeneic transplant). The donated stem cell (graft) sees the patient's cells (host) as a threat. The donated stem cells attack the patients' cells which leads to complications. The complications can range from mild (such as rash/itching) to life threatening. GvD is fatal for more than 10% of patients. Acute GvD occurs soon after transplant, within the first 100 days whereas Chronic GvD appears at any time and generally within 2 years.

## Indications/Criteria

**A. Acute Graft-Versus-host Disease (aGVHD)**

Ryoncil may be considered for coverage when:

- Member has a diagnosis of Acute Graft-Versus-host Disease (aGVHD) **AND**
- Member is aged 2 months to ≤17 years old **AND**
- Prescribed by or in consultation with an oncologist, hematologist or bone marrow transplant specialist **AND**
- Documentation that the member has steroid refractory disease **AND**
- Documentation that the member is negative for human immunodeficiency virus (HIV) **AND**
- Documentation that the member is negative for active hepatitis B or C virus infection within 3 months prior to screening **AND**
- Documentation that the member does not have evidence of severe hepatic VOD (hepatic veno-occlusive disease) requiring treatment or sinusoidal obstruction **AND**
- Documentation that the member has a glomerular filtration rate (GFR) ≥30mL/min **AND**
- Member does not have skin-only involvement or evidence of encephalopathy or diffuse alveolar hemorrhage or other active pulmonary disease; **AND**
- Provider attestation that the member does not have a known hypersensitivity to dimethyl sulfoxide (DMSO) or porcine and bovine proteins; **AND**
- Member is post-allogeneic stem cell transplant
    - Note: Symptoms of aGVHD typically appear before day 100; **AND**
- For members 12 years and older, documentation indicating that the member has had an inadequate response to an adequate trial of, or contraindication or intolerance to ruxolitinib

- Criteria and use of this agent must follow the FDA package label and, when available, the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. MVP reserves the right to deviate from the NCCN guidelines if new safety information becomes available prior to updated NCCN guidelines. The NCCN guidelines may be accessed at www.nccn.org
    - The National Comprehensive Cancer Network (NCCN) guidelines for Hematopoietic Cell Transplantation (version 2.2025 June 3, 2025) do not address Ryoncil.

**Initial approval** will be for 8 infusions within 1 month

Requests for replacement due to lost or damaged product will not be covered. Coverage is contingent on eligibility at the time of infusion.

**Extension requests**

- Treatment with four additional (weekly) doses may be approved when the following criteria is met:
    - Documentation that the member has experienced a partial response or a mixed response.
        - Partial response is defined as organ improvement of at least one stage without worsening in any other organ.
        - Mixed response is defined as improvement of at least one evaluable organ with worsening in another organ
- Treatment with eight additional (twice weekly) doses may be approved when the following criteria is met:
    - Documentation that the member is experiencing an aGVHD flare after achieving a complete response
- Ryoncil for more than 12 doses total will be reviewed on a case-by-case basis
- Requests for replacement due to lost or damaged product will not be covered. Coverage is contingent on eligibility at the time of infusion.

| **Recommended Treatment Based on Day 28 Response** | |
|---|---|
| **Response** | **Recommendation** |
| Complete Response (CR) | No further treatment with Ryoncil |
| Partial or Mixed Response | Repeat administration of Ryoncil once a week for an additional 4 weeks (4 infusions total) |
| No Response | Consider alternative treatments |

| | |
|---|---|
| Recurrence of GvHD after CR | Repeat administration of Ryoncil twice a week for an additional 4 consecutive weeks (8 infusions total) |

**Exclusions**

The use of remestemcel will not be covered for the following situations:

- Renewals/extensions for members who experience a complete response or no response
- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling
- Member has received HSCT transplant for a solid tumor disease or currently being treated for a solid tumor malignancy
- Member has a diagnosis of pulmonary hypertension or heart failure

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**References**


1. Mesoblast, Inc. (2023). *Ryoncil (remestemcel-L) prescribing information* [PDF]. Revised January 2025. Ryoncil prescribing-information.pdf

2. ClinicalTrials.gov. NCT02336230. A Single-arm, Prospective Study of Remestemcel-L, Ex-vivo Culture-Expanded Adult Human Mesenchymal Stromal Cells, for the Treatment of Pediatric Patients Who Have Failed to Respond to Steroid Treatment for Acute GVHD.

3. ClinicalTrials.gov. ClinicalTrials.gov. NCT00366145. A Phase III, Randomized, Double Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Prochymal® (Ex-vivo Cultured Adult Human Mesenchymal Stem Cells) Infusion for the Treatment of Patients Who Have Failed to Respond to Steroid Treatment for Acute GVHD. | ClinicalTrials.gov.

4. National Comprehensive Cancer Network. *NCCN Clinical Practice Guidelines in Oncology: Hematopoietic Cell Transplantation. Version 1.2025.* Available at: https://www.nccn.org/guidelines/guidelines-detail?category=3&id=1501

5. NCT02336230: A Single-arm, Prospective Study of Remestemcel-L, Ex-vivo Culture-Expanded Adult Human Mesenchymal Stromal Cells, for the Treatment of Pediatric Patients Who Have Failed to Respond to Steroid Treatment for Acute GVHD

| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Complete Wellness | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| USA Care PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

**Medicare Part B: Remestemcel**

**Type of Policy:** Medical therapy (administered by the pharmacy department)

**Prior Approval Date:** NA
**Approval Date:** 07/01/2025
**Effective Date:** 07/01/2025
**Related Policies:** NA

Refer to relevant CMS LCDs/NCDs/Policy Articles for most up to date Medicare Part B guidance if available.

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies.

**Drugs Requiring Prior Authorization under the medical benefit**

**J3590** Ryoncil (remestemcel-L-rknd, intravenous, injection)

**Overview**

Ryoncil (remestemcel-L-rknd) is an allogeneic bone marrow-derived mesenchymal stromal cell (MSC) therapy indicated for the treatment of steroid-refractory acute graft versus host disease (SR-aGvHD) in pediatric patients 2 months of age and older.

GvD is a complication that may occur after receiving a transplant of donor stem cells (allogeneic transplant). The donated stem cell (graft) sees the patient's cells (host) as a threat. The donated stem cells attack the patients' cells which leads to complications. The complications can range from mild (such as rash/itching) to life threatening. GvD is fatal for more than 10% of patients. Acute GvD occurs soon after transplant, within the first 100 days whereas Chronic GvD appears at any time and generally within 2 years.

**Indications/Criteria**

**A. Acute Graft-Versus-host Disease (aGVHD)**

Ryoncil may be considered for coverage when:

- Member has a diagnosis of Acute Graft-Versus-host Disease (aGVHD) **AND**
- Member is aged 2 months to ≤17 years old **AND**
- Prescribed by or in consultation with an oncologist, hematologist or bone marrow transplant specialist **AND**
- Documentation that the member has steroid refractory disease **AND**
- Documentation that the member is negative for human immunodeficiency virus (HIV) **AND**
- Documentation that the member is negative for active hepatitis B or C virus infection within 3 months prior to screening **AND**
- Documentation that the member does not have evidence of severe hepatic VOD (hepatic veno-occlusive disease) requiring treatment or sinusoidal obstruction **AND**
- Documentation that the member has a glomerular filtration rate (GFR) ≥30mL/min **AND**
- Member does not have skin-only involvement or evidence of encephalopathy or diffuse alveolar hemorrhage or other active pulmonary disease, which is likely to require more than 2L of oxygen via face mask, or an estimated fractional inspired oxygen concentration (FiO2) of 28% via other delivery methods in order to sustain an O2 saturation of 92%; **AND**
- Provider attestation that the member does not have a known hypersensitivity to dimethyl sulfoxide (DMSO) or porcine and bovine proteins; **AND**
- Member is post-allogeneic stem cell transplant
    - Note: Symptoms of aGVHD typically appear before day 100; **AND**

- For members 12 years and older, documentation indicating that the member has had an inadequate response to an adequate trial of, or contraindication or intolerance to ruxolitinib

- Criteria and use of this agent must follow the FDA package label and, when available, the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. MVP reserves the right to deviate from the NCCN guidelines if new safety information becomes available prior to updated NCCN guidelines. The NCCN guidelines may be accessed at www.nccn.org
    - The National Comprehensive Cancer Network (NCCN) guidelines for Hematopoietic Cell Transplantation (version 2.2025 June 3, 2025) do not address Ryoncil.

**Initial approval** will be for 8 infusions within 1 month

Requests for replacement due to lost or damaged product will not be covered. Coverage is contingent on eligibility at the time of infusion.

**Extension requests**

- Treatment with four additional (weekly) doses may be approved when the following criteria is met:
    - Documentation that the member has experienced a partial response or a mixed response.
        - Partial response is defined as organ improvement of at least one stage without worsening in any other organ.
        - Mixed response is defined as improvement of at least one evaluable organ with worsening in another organ
- Treatment with eight additional (twice weekly) doses may be approved when the following criteria is met:
    - Documentation that the member is experiencing an aGVHD flare after achieving a complete response
- Ryoncil for more than 12 doses total will be reviewed on a case-by-case basis
- Requests for replacement due to lost or damaged product will not be covered. Coverage is contingent on eligibility at the time of infusion.

| **Recommended Treatment Based on Day 28 Response** | |
|---|---|
| **Response** | **Recommendation** |
| Complete Response (CR) | No further treatment with Ryoncil |

| | |
|---|---|
| Partial or Mixed Response | Repeat administration of Ryoncil once a week for an additional 4 weeks (4 infusions total) |
| No Response | Consider alternative treatments |
| Recurrence of GvHD after CR | Repeat administration of Ryoncil twice a week for an additional 4 consecutive weeks (8 infusions total) |

**Exclusions**

The use of remestemcel will not be covered for the following situations:

- Renewals/extensions for members who experience a complete response or no response
- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling
- Member has received HSCT transplant for a solid tumor disease or currently being treated for a solid tumor malignancy
- Member has a diagnosis of pulmonary hypertension or heart failure

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**References**

1. Mesoblast, Inc. (2023). *Ryoncil (remestemcel-L) prescribing information* [PDF]. Revised January 2025. Ryoncil prescribing-information.pdf

2. ClinicalTrials.gov. NCT02336230. A Single-arm, Prospective Study of Remestemcel-L, Ex-vivo Culture-Expanded Adult Human Mesenchymal Stromal Cells, for the Treatment of Pediatric Patients Who Have Failed to Respond to Steroid Treatment for Acute GVHD.

3. ClinicalTrials.gov. ClinicalTrials.gov. NCT00366145. A Phase III, Randomized, Double Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Prochymal® (Ex-vivo Cultured Adult Human Mesenchymal Stem Cells) Infusion for the Treatment of Patients Who Have Failed to Respond to Steroid Treatment for Acute GVHD. | ClinicalTrials.gov.

4. National Comprehensive Cancer Network. *NCCN Clinical Practice Guidelines in Oncology: Hematopoietic Cell Transplantation. Version 1.2025.* Available at: https://www.nccn.org/guidelines/guidelines-detail?category=3&id=1501

5. NCT02336230: A Single-arm, Prospective Study of Remestemcel-L, Ex-vivo Culture-Expanded Adult Human Mesenchymal Stromal Cells, for the Treatment of Pediatric Patients Who Have Failed to Respond to Steroid Treatment for Acute GVHD

**MVP Health Care Medical Policy**

**Resmetirom**

**Type of Policy:** Drug therapy
**Prior Approval Date:** NA
**Approval Date:** 10/01/2024
**Effective Date:** 01/01/2025

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies.

## Drugs Requiring Prior Authorization under the pharmacy benefit

Rezdiffra (resmetirom)

## Overview

Resmetirom is an oral thyroid hormone receptor-beta (THR-beta) agonist indicated in conjunction with diet and exercise for the treatment of adults with noncirrhotic metabolic-dysfunction associated steatohepatitis (MASH; also known as nonalcoholic steatohepatitis or NASH) with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis).

Rezdiffra for NASH was approved under accelerated approval based on improvement of NASH and fibrosis. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

## Indications/Criteria

**A. Noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH; formerly NASH)**

Rezdiffra may be considered for coverage when:

- Rezdiffra is prescribed by or in consultation with a gastroenterologist or hepatologist
- Documentation is provided indicating that the member has a confirmed diagnosis of noncirrhotic metabolic dysfunction-associated steatotic liver disease (MASH/NASH).
- Documentation within the past 6 months that the member has either stage F2 fibrosis OR stage F3 fibrosis
- Provider attestation, supported by chart notes, that other causes of liver disease or hepatic steatosis have been ruled out (such as alcoholic steatohepatitis, acute fatty liver, autoimmune hepatitis, Hepatitis A, B, or C, hemochromatosis, drug-induced liver disease, etc.)
- Provider attestation, supported by chart notes, that the member has received counseling regarding lifestyle modifications (i.e. dietary or caloric restriction, exercise) and that the member is adherent to a diet and exercise regimen.
- Provider attestation that the member meets one of the following:
    - Biologically Female member: Alcohol consumption is < 20 grams/day; OR
        - Note: One standard drink (or one alcoholic drink equivalent) contains roughly 14 grams of pure alcohol, which is found in 12 ounces of beer with 5% alcohol, 5 ounces of wine with 12% alcohol, or 1.5 ounces of liquor or distilled spirits.
    - Biologically Male member: Alcohol consumption < 30 grams/day;
        - Note: One standard drink (or one alcoholic drink equivalent) contains roughly 14 grams of pure alcohol, which is found in 12 ounces of beer with 5% alcohol, 5 ounces of wine with 12% alcohol, or 1.5 ounces of liquor or distilled spirits.

**Initial approval** will be for 6 months

**Extension requests** will be approved for up to 12 months when the member has a continued benefit to therapy and the following:

- Documentation of an improvement or stabilization of fibrosis **AND**
- Member continues adherence to a diet and exercise regimen

Extension requests where Rezdiffra did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

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**Exclusions**

The use of Rezdiffra will not be covered for the following situations:

- Member with moderate to severe hepatic impairment (Child-Pugh Class B or C)
- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling

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## References


1. Resmetirom. In: Clinical Pharmacology [database on the Internet]. Tampa (FL): Elsevier; 2024 [cited 2024 July 30]. Available from: www.clinicalpharmacology.com. Subscription required to view.

2. Metabolic Dysfunction-Associated Steatohepatitis [Internet]. 2022 [cited 2024 Jul 31]. Available at: Metabolic Dysfunction-Associated Steatohepatitis: What It Is, Causes (clevelandclinic.org)

3. Rinella, Mary E.[1]; Neuschwander-Tetri, Brent A.[2]; Siddiqui, Mohammad Shadab[3]; Abdelmalek, Manal F.[4]; Caldwell, Stephen[5]; Barb, Diana[6]; Kleiner, David E.[7]; Loomba, Rohit[8]. AASLD Practice Guidance on the clinical assessment and management of nonalcoholic fatty liver disease. Hepatology 77(5):p 1797-1835, May 2023. | DOI: 10.1097/HEP.0000000000000323

4. About Standard Drink Sizes. 2024 [cited 2024 Jul 31]. Available at: About Standard Drink Sizes | Alcohol Use | CDC


| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Medicare Gold Giveback | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |

| | |
|---|---|
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

**Respiratory Syncytial Virus/Synagis® (palivizumab)**

**Type of Policy:** Medical *(administered by the pharmacy department)*
**Prior Approval Date:** **11/01/2023**
**Approval Date:** **11/01/2024**
**Effective Date:** **01/01/2025**
**Related Policies:** **Immunizations Childhood, Adolescent and Adults**

## Codes Requiring Prior Authorization

90378 Synagis (palivizumab-rsv-igm, per 50mg)

## Overview

Palivizumab is a monoclonal antibody indicated for the prevention of serious lower respiratory tract disease caused by RSV in certain pediatric patients. High risk pediatric patients include premature infants and children under age 2 with Chronic Lung Disease (CLD). Palivizumab has demonstrated safety and efficacy in reducing the incidence and days of RSV hospitalization. Palivizumab is administered intramuscularly for up to five monthly doses. The first dose is given in November, before the start of the RSV season if the child was born prior to November. (RSV season usually runs from November through March). Following the COVID-19 pandemic, there has been a change in RSV activity and circulation. The American Academy of Pediatrics has put out a statement supporting the use of palivizumab in eligible infants in any region, regardless of time of year in 2022, that is experiencing RSV rates that are similar to a typical fall-winter season. The data rates are available from the Centers for Disease Control (CDC) RSV Surveillance Data - NREVSS | CDC. Exposure to tobacco smoke should be restricted whenever feasible. High-risk infants should never be exposed to tobacco smoke.

## Medicare Variation

Refer to the Medicare Part D formulary for drugs that may be covered under the Part D benefit.

## Medicaid Variation

Medications that are a pharmacy benefit are covered and billed to New York State Fee-For-Service (FFS) program. They are defined as medications that go through a retail or specialty pharmacy, including self-administered injectable products. Pharmacy medications are subject to FFS's clinical criteria including (but not limited to) coverage, quantity limit, step therapy, and prior authorization. Pharmacy benefit information can be found here: https://www.emedny.org/info/fullform.pdf

## Indications/Criteria

**A. For all requests, the following criteria must be met in addition to the criteria in section B.**

- Palivizumab must be obtained from CVS Specialty Pharmacy Services or a participating network pharmacy able to dispense specialty medication. Requests for nursing services, if required, will be coordinated by case management or CVS Specialty. Documentation of medical necessity will be required for approval of the administration of palivizumab in settings other than the home.
- Approval will authorize one (1) dose every 28 days for up to the maximum of five (5) doses or through March 31. (Refer to Tables 1 and 2). Each monthly dose must be calculated based upon a recent weight and the appropriate combination of vials must be used to obtain the correct dose with the minimum of wastage.
- Infants living in a geographic region (e.g. southwest Florida) in which the RSV season has an earlier onset will be eligible to receive their doses at the start of the RSV season for that region.
- For all requests outside the typical RSV season or requests for more than 5 doses due to an atypical season will be reviewed on a **case-by case basis** in accordance with the current American Academy of Pediatrics and Centers of Disease Control (CDC) guidance
- Beyfortus (nirsevimab)
    - Documentation confirming Synagis is not administered with Beyfortus (nirsevimab)
    - Members who receive fewer than five doses of palivizumab in the 2023-'24 season can receive one dose of nirsevimab, but then should not receive any additional doses of palivizumab. Any children who receive nirsevimab should not receive palivizumab later that season.

- High-risk children who received palivizumab in their first RSV season should receive nirsevimab in their second season, if it is available and they remain eligible. If it is unavailable, they should receive palivizumab.

**B.** Palivizumab will be considered for prophylactic treatment (**full prophylactic course - up to 5 doses. Refer to Tables 1 and 2**) for the prevention of RSV when the following specific criteria: below are met.

a. During the first RSV season, infants born before 29 weeks, 0 days gestation, AND who are less than or equal to 12 months postnatal age.
b. Infants and children younger than two (2) years of age who meet the criteria below for Chronic Lung Disease (CLD) of prematurity, or CLD in the second year of life.[1]
    i. CLD of prematurity (first year of life) is defined by the following criteria:
        1. Gestational age <32 weeks, 0 days AND
        2. A requirement of >21% oxygen for at least the first 28 days after birth.[1]
    ii. CLD in the second year of life is defined by the following criteria:
        1. Met the criteria for CLD of prematurity AND
        2. Have continued to require medical support during the 6-month period before the start of their second RSV season, including chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen.
c. Infants with hemodynamically significant congenital heart disease (CHD) who are less than or equal to 12 months of age at the onset of the first RSV season and who have not had surgical correction, including the following:
    i. infants receiving medication to control congestive heart failure; or
    ii. infants with moderate to severe pulmonary artery hypertension; or
    iii. infants with cyanotic congenital heart disease.
d. Infants born before 35 weeks of gestation who are less than 12 months old who have anatomic pulmonary abnormalities or severe neuromuscular disease, who are in their first RSV season
e. Infants younger than 24 months who will be profoundly immunocompromised during the RSV season, including solid organ transplant and hematopoietic stem cell transplant recipients
    i. Efficacy in this cohort is not known and will be considered on a **case-by-case basis.**
f. Infants younger than 12 months of age with pulmonary or neurological abnormality that impairs the ability to clear the upper airway.

g. Infants in their first year of life with cystic fibrosis AND nutritional compromise will be considered on a **case-by-case basis**.
h. Infants in their second year of life with cystic fibrosis who have abnormalities on chest radiography/computed tomography OR have weight less than the 10th percentile will be considered on a **case-by-case basis.**
i. Children under 2 years of age who have undergone cardiac transplantation during the RSV season.

Approvals for eligible infants will be for a maximum of 5 doses per season using Table 1 and Table 2 below

- Hospitalized infants who qualify for prophylaxis during the RSV season should receive the first dose of palivizumab 48 to 72 hours prior to discharge from the hospital (or promptly after discharge).

- Children less than 2 years who are receiving RSV prophylaxis with palivizumab should receive a post-operative dose after any cardiac bypass or extracorporeal membrane oxygenation.

- For all requests outside the typical RSV season or requests for more than 5 doses due to an atypical season will be reviewed on a **case-by case basis** in accordance with the current American Academy of Pediatrics and Centers of Disease Control (CDC) guidance

**Table 1: Maximum Number of Monthly Doses of Palivizumab for Respiratory Syncytial Virus Prophylaxis[1]**

| **Infants Eligible for a Maximum of 5 Doses** |
|---|
| Preterm infants born at 28 weeks, 6 days of gestation or less who are less than 12 months old at the start of the RSV season. |
| Preterm infants born at 31 weeks, 6 days of gestation or less with Chronic Lung Disease (CLD) (see section 1 above) |
| Preterm infants now between age 1 and 2 who required medical support for CLD in the 6 months before the start of the RSV season (see section 1). |
| Infants younger than 12 months of age who require medical therapy for Congenital Heart Disease (see section 2). |
| Certain infants with Neuromuscular Disease or Anatomic Pulmonary Abnormalities. |
| Children younger than 24 months who will be profoundly immunocompromised during the RSV season. |
| Children younger than 24 months who undergo cardiac transplantation during the RSV season. |

**Table 2: Maximum Number of Palivizumab Doses for RSV Prophylaxis of Preterm Infants Without Chronic Lung Disease, on the Basis of Birth Date, and Gestational Age (Shown for Geographic Areas Beginning Prophylaxis on November 1st)[a, 2]**

| Maximum No. of Doses for Season Beginning November 1 | |
|---|---|
| **Month of Birth** | **Born 28 Weeks, 6 Days of Gestation AND <12 Months of Age at Start of Season** |
| November 1–March 31 of previous RSV season | 5[b] |
| April | 5 |
| May | 5 |
| June | 5 |
| July | 5 |
| August | 5 |
| September | 5 |
| October | 5 |
| November | 5 |
| December | 4 |
| January | 3 |
| February | 2 |
| March | 1 |
| [a]If infant is discharged from the hospital during RSV season, fewer doses may be required. | |
| [b]Some of these infants may have received 1 or more doses of palivuzimab in the previous RSV season if discharged from the hospital during that season; if so, they still qualify for up to 5 doses during their second RSV season. | |

## Exclusions

Palivizumab is NOT covered for infants with the following conditions:

- Infants and children with hemodynamically insignificant heart disease (e.g. secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta or patent ductus ateriosus),
- Infants with lesions adequately corrected by surgery unless they continue to require medication for congestive heart failure; or
- Infants with mild cardiomyopathy who are not receiving medical therapy.
- Children with Down syndrome with no other risk factors

- Palivizumab is NOT covered for infants in the following situations: Coverage for more than 5 doses during the RSV season. Trough serum concentrations of palivizumab 30 days after the 5th dose are well above the protective concentration for most infants, providing more than 20 weeks of protective serum antibody concentration.[2]

- Coverage of more than 4 doses if the initial dose is administered in an inpatient setting.
- Coverage for a second season for conditions other than those listed above.
- Doses given more frequently than every 28 days.
- Doses exceeding 15 mg/kg.
- Use to prevent primary asthma exacerbation or wheezing.
- Use to prevent healthcare-associated RSV disease,[1] when not otherwise indicated.
- If an infant who is receiving palivizumab prophylaxis experiences a breakthrough RSV infection, monthly prophylaxis should be discontinued.

## References


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11. American Academy of Pediatrics. *Pediatrics* (2023) 152 (1): e2023061803. Palivizumab Prophylaxis in Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection | Pediatrics | American Academy of Pediatrics (aap.org) https://doi.org/10.1542/peds.2023-061803

| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Complete Wellness | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D |
| USA Care 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 | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

**Risankizumab**

| | |
|---|---|
| **Type of Policy:** | **Drug/Medical Therapy** |
| **Prior Approval Date:** | **12/01/2023** |
| **Approval Date:** | **10/01/2024** |
| **Effective Date:** | **01/01/2025** |
| **Related Policies:** | **Adalimumab** |
| | **Apremilast** |
| | **Etanercept** |
| | **Infliximab** |
| | **Secukinumab** |
| | **Tofacitinib** |
| | **Upadacitinib** |
| | **Ustekinumab** |
| | **Zeposia** |

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies.

**Drugs Requiring Prior Authorization under the pharmacy benefit**

Skyrizi (risankizumab) Prefilled Pen

Skyrizi (risankizumab) Prefilled Syringe

Skyrizi (Risankizumab) Prefilled Cartridge Kit

**Drugs Requiring Prior Authorization under the medical benefit**

Skyrizi (risankizumab) 60mg/mL solution –J2327

## Overview

Skyrizi (Risankizumab), an interleukin-23 antagonist, is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy, the treatment of active psoriatic arthritis in adults as monotherapy or in combination with non-biologic disease-modifying antirheumatic drugs (DMARDs) and for the treatment of adults with moderate to severely active Crohn's disease (CD) for induction and remission maintenance.

Providers should perform screening for tuberculosis (TB) according to the local practice.

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**Medicaid Variation:** Medications that are a pharmacy benefit are covered and billed to New York State Fee-For-Service (FFS) program. They are defined as medications that go through a retail or specialty pharmacy, including self administered injectable products. Pharmacy medications are subject to FFS's clinical criteria including (but not limited to) coverage, quantity limit, step therapy, and prior authorization. Pharmacy benefit information can be found here: https://www.emedny.org/info/fullform.pdf.
Initial approval duration will be for 6 months and continuation approval duration will be for 12 months for applicable medical benefit drugs.

## Indications/Criteria

**A. For all indications, the following criteria must be met in addition to the specific diagnosis criteria below.**

- Prescription drugs covered under the pharmacy benefit must be self-administered. If office administration is being requested documentation must be provided identifying why the member or caregiver is unable to administer the medication
- Must be ordered by or with consult from an appropriate specialist: rheumatologist, immunologist, dermatologist, or colorectal surgeon
- Must be prescribed for an FDA approved indication

**B. Crohn's Disease**

Risankizumab may be considered for coverage for Crohn's Disease when the following criteria is met:

- Diagnosis of moderate to severe active Crohn's disease confirmed by endoscopy (or capsule endoscopy when appropriate) **AND**

- Documentation including the assessment of growth, nutrition, extraintestinal complications, therapy-induced complications and functional ability and any clinical signs and symptoms outlined in Crohn's Disease Activity Index (CDAI) such as frequent liquid stools >4/day, severity grade and frequency of abdominal pain, presence of an abdominal mass, general well-being, extra-intestinal symptoms (arthralgia, uveitis, erythema, stomatitis, abscess, fever >37.5 in the last week), taking opiates or diphenoxylate/atropine for diarrhea, anemia, and weight loss >10%.

**Initial approval** duration will be 12 months

**Extension requests** will be approved for up to 3 years if the member has a continued benefit to therapy. Extension requests where the Risankizumab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

**Medicaid Variation:** Initial approval duration will be for 6 months and continuation approval duration will be for 12 months for applicable medical benefit drugs.

**C. Plaque Psoriasis**

Risankizumab may be considered for coverage for Plaque Psoriasis when the following criteria is met:

- The medication is ordered by or in consultation with a dermatologist
- A diagnosis of moderate to severe chronic plaque psoriasis and one of the following:
    - Crucial body areas (e.g. hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected OR
    - At least 10% of the body surface area (BSA) is affected OR
    - At least 3% of the body surface area (BSA) is affected AND the member meets any of the following criteria:
        - Member has had an inadequate response or intolerance to either phototherapy (e.g. UVB, PUVA) OR
        - Member has had an inadequate response or intolerance to pharmacologic treatment with methotrexate, cyclosporine, or acitretin

**Initial approval** duration will be 12 months

**Extension requests** will be approved for up to 3 years if the member has a continued benefit to therapy. Extension requests where the Risankizumab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

**Medicaid Variation:** Initial approval duration will be for 6 months and continuation approval duration will be for 12 months for applicable medical benefit drugs.

**D. Psoriatic Arthritis (PsA):**

Risankizumab may be considered for coverage for PsA when the following criteria is met:

- Member has a diagnosis of moderate to severe psoriatic arthritis as indicated by three or more tender joints AND three or more swollen joints on two separate occasions at least one month apart **AND**
- Chart notes are provided documenting a failure of at least one NSAID at maximum tolerated dose unless the member has contraindications to NSAID therapy such as cardiovascular disease, peptic ulcer disease or renal disease **AND**
- Chart notes are provided documenting a failure to an adequate trial of at least one of the following nonbiologic disease modifying anti-rheumatic drugs (DMARDs): leflunomide, sulfasalazine, or methotrexate.
    - **Members with pure axial manifestations** do not have to have a trial of nonbiologic disease modifying anti-rheumatic drugs (DMARDs)
    - If a trial of methotrexate is not appropriate due to alcohol use and **both** leflunomide and sulfasalazine are not clinically appropriate, chart notes must be provided indicating that the member has been counseled on the need to abstain from alcohol use while taking methotrexate and is unwilling to abstain from alcohol use.

**Initial approval** duration will be 12 months

**Extension requests** will be approved for up to 3 years if the member has a continued benefit to therapy. Extension requests where the Risankizumab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

**Medicaid Variation:** Initial approval duration will be for 6 months and continuation approval duration will be for 12 months for applicable medical benefit drugs.

## E. Ulcerative Colitis

Risankizumab may be considered for coverage for ulcerative colitis when the following criteria is met:

- A diagnosis of moderate to severe Ulcerative Colitis
- Chart notes are provided identifying inadequate response, intolerance, or contraindication to conventional therapy for maintenance of remission (i.e., anti-inflammatory aminosalicylates [e.g., mesalamine (5-ASA), sulfasalazine], 6-mercaptopurine, and azathioprine)
    - If conventional therapy is not considered medically appropriate, documentation must be provided

**Initial approval** duration will be 12 months

**Extension requests** will be approved for up to 3 years if the member has a continued benefit to therapy. Extension requests where the Risankizumab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

**Medicaid Variation:** Initial approval duration will be for 6 months and continuation approval duration will be for 12 months for applicable medical benefit drugs.

## Exclusions

The use of Skyrizi will not be covered for the following situations:

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling
- Combination therapy that is not supported by current guidelines

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**References**


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| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Medicare Gold Giveback | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D |
| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

**Medicare Part B: Risankizumab**

**Type of Policy:** **Drug/Medical Therapy**
**Prior Approval Date:** **11/01/2023**
**Approval Date:** **10/01/2024**
**Effective Date:** **12/01/2024**
**Related Policies:** **Abatacept, Certolizumab, Golimumab, Infliximab, Tocilizumab, Ustekinumab**

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies for drugs that may be covered under the Part D benefit.

## Drugs Requiring Prior Authorization under the medical benefit

Skyrizi (risankizumab) 60mg/mL solution –J2327

## Overview/Summary of Evidence

Skyrizi (Risankizumab), an interleukin-23 antagonist, is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy, the treatment of active psoriatic arthritis in adults as monotherapy or in combination with non-biologic disease-modifying antirheumatic drugs (DMARDs) and for the treatment of adults with moderate to severely active Crohn's disease (CD) for induction and remission maintenance.

Providers should perform screening for tuberculosis (TB) according to the local practice.

## Indications/Criteria

**A. For all indications, the following criteria must be met in addition to the specific diagnosis criteria below.**

- Must be ordered by or with consult from an appropriate specialist: rheumatologist, immunologist, dermatologist, or gastroenterologist
- Must be prescribed for an FDA approved indication

**B. Crohn's Disease**

Risankizumab may be considered for coverage for Crohn's Disease when the following criteria is met:

- Documentation of moderate to severely active Crohn' disease
- Member must be intolerant to two different drug classes (examples such as, but not limited to, corticosteroids and immunomodulators such as azathioprine or mercaptopurine).

**Initial approval** duration will be6 months

**Extension requests** will be approved for **up to 12 months** if the member has a continued benefit to therapy. Extension requests where the Risankizumab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

**C. Plaque Psoriasis**

Risankizumab may be considered for coverage for Plaque Psoriasis when the following criteria is met:

- Documentation of moderate to severe chronic plaque psoriasis OR involvement of the palms, soles of feet and scalp.
- An appropriate trial was not effective or contraindicated with one of the following: methotrexate, oral retinoids, cyclosporine.

**Initial approval** duration will be 6 months

**Extension requests** will be approved for **up to 12 months** if the member has a continued benefit to therapy. Extension requests where the Risankizumab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

**D. Psoriatic Arthritis (PsA):**

Risankizumab may be considered for coverage for PsA when the following criteria is met:

- Documentation of active psoriatic arthritis with an inadequate response or intolerance to methotrexate or other disease-modifying antirheumatic drugs (DMARDs) and one (1) NSAID trial.

**Initial approval** duration will be 6 months

**Extension requests** will be approved for **up to 12 months** if the member has a continued benefit to therapy. Extension requests where the Risankizumab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

**E. Ulcerative Colitis**

Risankizumab may be considered for coverage for ulcerative colitis when the following criteria is met:

- A diagnosis of moderate to severe Ulcerative Colitis
- Chart notes are provided identifying inadequate response, intolerance, or contraindication to conventional therapy for maintenance of remission (i.e., anti-inflammatory aminosalicylates [e.g., mesalamine (5-ASA), sulfasalazine], 6-mercaptopurine, and azathioprine)
    - If conventional therapy is not considered medically appropriate, documentation must be provided

**Initial approval** duration will be 6 months

**Extension requests** will be approved for up to 12 months if the member has a continued benefit to therapy. Extension requests where the Risankizumab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

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**Exclusions**

The use of Skyrizi will not be covered for the following situations:

- Combination therapy that is not supported by current guidelines
- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling

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**References**


1. Skyrizi (risankizumab) injection package insert. North Chicago, IL: AbbVie Inc.; June 2024
2. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. *Journal of Psoriasis and Psoriatic Arthritis*. 2019;4(1):31-58. doi:10.1177/2475530318812244
3. Gordon KB, Strober B, Lebwohl M, et al. Efficacy and safety of risankizumab in moderate-to-severe plaque psoriasis (UltIMMa-1 and UltIMMa-2): results from two double-blind, randomised, placebo-controlled and ustekinumab-controlled phase 3 trials. *Lancet*. 2018;392(10148):650-661.
4. Menter, A., Strober, B., Kaplan, D., et al. (2019). Journal of the American Academy of Dermatology. Volume 80, Issue 4, P1029-1072. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics - Journal of the American Academy of Dermatology (jaad.org)
5. Gossec L, Baraliakos X, Kerschbaumer A, et al. European League Against Rheumatism (EULAR) recommendations for the management of psoriatic arthritis with pharmacological therapies: 2019 update. *Ann Rheum Dis*. 2020;79(6):700-712.
6. D'Haens G, Panaccione R, Baert F, et al. Risankizumab as induction therapy for Crohn's disease: results from the phase 3 ADVANCE and MOTIVATE induction trials. *Lancet.* 2022;399(10340):2015-2030.
7. Lichtenstein, Gary R MD, FACG[1]; Loftus, Edward V MD, FACG[2]; Isaacs, Kim L MD, PhD, FACG[3]; Regueiro, Miguel D MD, FACG[4]; Gerson, Lauren B MD, MSc, MACG (GRADE Methodologist)[5,†]; Sands, Bruce E MD, MS, FACG[6]. ACG Clinical Guideline: Management of Crohn's Disease in Adults. American Journal of Gastroenterology: April 2018 - Volume 113 - Issue 4 - p 481-517 doi: 10.1038/ajg.2018.27
8. ACG Clinical Guideline: Ulcerative Colitis in Adults. The American Journal of Gastroenterology: March 2019 - Volume 114 - Issue 3 - p 384-413 doi:

10.14309/ajg.0000000000000152. Accessed: ACG Clinical Guideline: Ulcerative Colitis in Adults : Official journal of the American College of Gastroenterology | ACG (lww.com)

**MVP Health Care Medical Policy**

**Ritlecitinib**

| | |
|---|---|
| **Type of Policy:** | Drug Therapy (administered by the pharmacy department) |
| **Prior Approval Date:** | **04/01/2024** |
| **Approval Date:** | **04/01/2025** |
| **Effective Date:** | **06/01/2025** |
| **Related Policies:** | Cosmetic Drug Agents,<br>Baricitinib |

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies.

## Drugs Requiring Prior Authorization under the pharmacy benefit

Ritlecitinib (Litfulo)

## Overview

Ritlecitinib is an oral kinase inhibitor indicated for the treatment of severe alopecia areata in adults and adolescents 12 years and older. It inhibits Janus kinase 3 (JAK3) and the tyrosine kinase expressed in hepatocellular carcinoma (TEC) family of kinases.

## Indications/Criteria

**Medicaid Variation:** Medications that are a pharmacy benefit are covered and billed to New York State Fee-For-Service (FFS) program. They are defined as medications that go through a retail or specialty pharmacy, including self administered injectable products. Pharmacy medications are subject to FFS's clinical criteria including (but not limited to) coverage, quantity limit, step therapy, and prior authorization. Pharmacy benefit information can be found here: https://www.emedny.org/info/fullform.pdf

**A. Alopecia areata**

Ritlecitinib may be considered for coverage for alopecia areata when all the following criteria below are met:

- Prescribed by or in consultation with a dermatologist
- Chart notes documenting a diagnosis of severe alopecia areata
- Chart notes documenting that other causes of hair loss have been ruled out
- Chart notes documenting a failure of another systemic therapy such as corticosteroids, methotrexate, prednisone and/or cyclosporine
- Member's current episode of alopecia areata has lasted ≥ 6 months
- Member has a ≥ 50% scalp hair loss

**Initial approval** for 6 months

**Extension requests** will be approved for up to 12 months if the member has a continued benefit to therapy. Extension requests where ritlecitinib did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

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**Exclusions**

The use of Ritlecitinib will not be covered for the following situations:

- Dosing, age, and/or frequency exceeding the FDA approved package labeling.
- Member has a current active or serious infection
- Avoid using ritlecitinib in members that may be at increased risk of thrombosis and thromboembolism; use with caution in those with thromboembolic disease
- Cosmetic use
- Combination use with other JAK inhibitors, immunomodulators, cyclosporine or other potent immunosuppressants

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**References**

1. Ritlecitinib. Clinical Pharmacology. Revised December 4, 2023. Accessed January 29, 2024.

2. National Institute of Arthritis and Musculoskeletal and Skin Diseases. Alopecia Areata - Hair loss Causes & Living With It | NIAMS (nih.gov). Accessed January 2024.

3. American Academy of Dermatology Association. Revised August 30, 2023. Accessed January 29, 2024. Hair loss types: Alopecia areata diagnosis and treatment (aad.org)

4. Litfulo. Prescribing Information. Pfizer. Revised June 2023. labeling.pfizer.com/ShowLabeling.aspx?id=19638#section-2.1

| 5. **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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Complete Wellness | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| USA Care PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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).** |
|---|
| *© 2025 MVP Health Plan, Inc. All rights reserved. Descriptions contained within MVP's Medical Policies are not a guarantee of coverage. Each MVP Group or Subscriber Contract contains specific limitations, exclusions and requirements that may affect a Policy. If there is any discrepancy between your Group or Subscriber Contract and a Policy, your Group or Subscriber Contract shall in all cases govern.* |

***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 |

**MVP Health Care Medical Policy**

# Secukinumab

| | |
|---|---|
| **Type of Policy:** | **Drug/Medical Therapy** |
| **Prior Approval Date:** | **10/01/2023** |
| **Approval Date:** | **02/01/2024** |
| **Effective Date:** | **02/01/2024** |
| **Related Policies:** | **Apremilast** |
| | **Etanercept** |
| | **Infliximab** |
| | **Risankizumab** |
| | **Adalimumab** |
| | **Tofacitinib** |
| | **Upadacitinib** |
| | **Ustekinumab** |
| | **Ozanimod** |

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies.

**Drugs Requiring Prior Authorization under the pharmacy benefit**

Cosentyx prefilled syringes and pen (secukinumab)

**Drugs Requiring Prior Authorization under the medical benefit**

J3590 Cosentyx intravenous solution (secukinumab)

**Overview**

Secukinumab is a human IgG1 monoclonal antibody that selectively binds to the interleukin-17A (IL-17A) cytokine, inhibiting its interaction with the IL-17A receptor. It is FDA approved for several indication including ankylosing spondylitis, psoriasis and psoriatic arthritis. Secukinumab carries an increased risk of infection; members should be screened for immunologic and infectious disease prior to initiating therapy.

**Medicaid Variation:** Medications that are a pharmacy benefit are covered and billed to New York State Fee-For-Service (FFS) program. They are defined as medications that go through a retail or specialty pharmacy, including self-administered injectable products. Pharmacy medications are subject to FFS's clinical criteria including (but not limited to) coverage, quantity limit, step therapy, and prior authorization. Pharmacy benefit information can be found here: https://www.emedny.org/info/fullform.pdf

**Indications/Criteria**

**A. For all indications, the following criteria must be met in addition to the specific diagnosis criteria below.**

- Prescription drugs covered under the pharmacy benefit must be self-administered. If office administration is being requested for SQ administration documentation must be provided identifying why the member or caregiver is unable to administer the medication
- Medical drugs covered under the medical benefit will require documentation identifying why the member or caregiver cannot use SQ administration
- Must be ordered by or with consult from an appropriate specialist: rheumatologist/immunologist/dermatologist
- Must be prescribed for an FDA approved indication and route of administration must be FDA approved for indication

**B. Ankylosing Spondylitis & Non-Radiographic Axial Spondylarthritis**

Secukinumab may be considered for coverage for Ankylosing Spondylitis and Non-Radiographic Axial Spondylarthritis when:

- Chart notes documenting a failure of at least one NSAIDS at maximum tolerated dose unless the member has contraindications to NSAID therapy such as cardiovascular disease, peptic ulcer disease or renal disease **AND**
- Documented significant clinical symptoms such as fatigue, spinal pain, arthralgia, inflammation of joints and tendons, morning stiffness duration and therapy **AND**
- Insufficient response to at least one local corticosteroid injection in patients with symptomatic peripheral arthritis **AND**

- Members **with pure axial manifestations** do not have to have a trial of nonbiologic disease modifying anti-rheumatic drugs (DMARDs)

**Initial approval** will be for 6 months

**Extension requests** will be approved for up to 12 months if the member has a continued benefit to therapy. Extension requests where the Secukinumab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

**C. Psoriasis**

Secukinumab may be considered for coverage for Psoriasis when:

- The medication is ordered by or in consultation with a dermatologist
- A diagnosis of moderate to severe chronic plaque psoriasis and one of the following:
    - Crucial body areas (e.g. hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected OR
    - At least 10% of the body surface area (BSA) is affected OR
    - At least 3% of the body surface area (BSA) is affected AND the member meets any of the following criteria:
        - Member has had an inadequate response or intolerance to either phototherapy (e.g. UVB, PUVA) OR
        - Member has had an inadequate response or intolerance to pharmacologic treatment with methotrexate, cyclosporine, or acitretin

**Initial approval** for **6 months**

**Extension requests** will be approved for 12 months if the member has a continued benefit to therapy. Extension requests where Secukinumab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

**D. Psoriatic Arthritis**

Secukinumab may be considered for coverage for Psoriatic Arthritis when:

- Member has a diagnosis of moderate to severe psoriatic arthritis as indicated by three or more tender joints AND three or more swollen joints on two separate occasions at least one month apart
- Chart notes documenting a failure of at least one NSAIDS at maximum tolerated dose unless the member has contraindications to NSAID therapy such as cardiovascular disease, peptic ulcer disease or renal disease **AND**Chart notes documenting a failure to respond to an adequate trial of at least one of the following nonbiologic disease modifying anti-rheumatic drugs (DMARDs): leflunomide, sulfasalazine, or methotrexate.
  - Members with **pure axial manifestations** do not have to have a trial of nonbiologic disease modifying anti-rheumatic drugs (DMARDs)
  - If a trial of methotrexate is not appropriate due to alcohol use and both leflunomide and sulfasalazine are not clinically appropriate, chart notes must be provided indicating that the patient has been counseled on the need to abstain from alcohol use while taking methotrexate and is unwilling to abstain from alcohol use.

**Initial approval** will be for 6 months

**Extensions requests** will be approved **up to 12 months** if the member has a continued benefit to therapy. Extension requests where the Secukinumab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

**E. Enthesitis- related arthritis**

Secukinumab may be considered for coverage for enthesitis-related arthritis when:

- Failure of at least one NSAID at maximum tolerated dose unless the member has contraindications to NSAID therapy such as cardiovascular disease, peptic ulcer disease or renal disease

**Initial approval** will be for 6 months

**Extensions requests** will be approved **up to 12 months** if the member has a continued benefit to therapy. Extension requests where the Secukinumab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

**F. Hidradenitis Suppurativa**

Secukinumab may be considered for coverage for Hidradenitis Suppurativa when:

- Member has a documented diagnosis of moderate to severe disease (Hurley State II or III)

**Initial approval** will be for 6 months.

**Extension requests** will be approved for up to 12 months if the member has a continued benefit to therapy with documentation of at least 50% improvement in clinical signs/symptoms. Extension requests where secukinumab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

## Exclusions

The use of Secukinumab will not be covered for the following situations:

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling. Secukinumab in combination with other biologics is excluded from coverage
- Combination therapy that is not supported by guidelines

## References


1. Clinical Pharmacology
2. Cosentyx (secukinumab) injection. Prescribing Information. East Hanover, NJ. Novartis Pharmaceuticals Corporation. January 2018.
3. Ward Michael, Atul Deodhar et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. Arthritis and Rheumatology. Vol 71 (No. 10). October 2019, pp 1599-1613. Available at: https://www.rheumatology.org/Portals/0/Files/AxialSpA-Guideline-2019.pdf
4. Ringold, Sarah; Angeles-Han Sheila et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Treatment Approaches for Non-Systemic Polyarthritis, Sacroilitis and Enthesitis. American College of Rheumatology. Vol 71 (No 6). June 2019, pp 717-734.
5. Ward MM, Deodhar A, Gensler LS, et al. 2019 update of the American college of rheumatology/spondylitis association of America/spondyloarthritis research and treatment network recommendations for the treatment of ankylosing spondylitis and nonradiographic axial spondyloarthritis. Arthritis Rheumatol. 2019;71(10):1599-1613. doi:10.1002/art.41042

6. Ali Aikhan, Christropher Sayed, et al. North American clinical management guidelines for hidradenitis suppurativa: A publication from the United States and Canadian Hidradenitis Suppurative Foundations. JAAD. 2019; 81(1):91-101.doi.org/10.1016/j.jaad.2019.02.068.

| 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 | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Authorization |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Medicare Gold Giveback | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D |
| 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).** | |
| *© 2024 MVP Health Plan, Inc. All rights reserved. Descriptions contained within MVP's Medical Policies are not a guarantee of coverage. Each MVP Group or Subscriber Contract contains specific limitations, exclusions and requirements that may affect a Policy. If there is any discrepancy between your Group or Subscriber Contract and a Policy, your Group or Subscriber Contract shall in all cases govern.* | |

***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 |

**MVP Health Care Medical Policy**

**Medicare Part B: Secukinumab**

| | |
|---|---|
| **Type of Policy:** | **Drug/Medical Therapy** |
| **Prior Approval Date:** | **N/A** |
| **Approval Date:** | **02/01/2024** |
| **Effective Date:** | **04/01/2024** |

**Related Policies: Infliximab, Risankizumab, Ustekinumab, Golimumab, Tocilizumab, Certolizumab**

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies for drugs that may be covered under the Part D benefit.

## Drugs Requiring Prior Authorization under the medical benefit

J3590 Cosentyx intravenous solution (secukinumab)

## Overview/Summary of Evidence

Secukinumab is a human IgG1 monoclonal antibody that selectively binds to the interleukin-17A (IL-17A) cytokine, inhibiting its interaction with the IL-17A receptor. It is FDA approved for several indications including ankylosing spondylitis, psoriasis and psoriatic arthritis. Secukinumab carries an increased risk of infection; members should be screened for immunologic and infectious disease prior to initiating therapy.

## Indications/Criteria

A. For all indications, Secukinumab IV may be considered for **medical** coverage when:

- Prescribed for an FDA approved indication **AND**
- Ordered by or with consult from an appropriate specialist: rheumatologist/immunologist/dermatologist **AND**

- Member has coverage under Medicare Part B and meets the criteria below for a provider administered drug identified in this policy

**B. Ankylosing Spondylitis & Non-Radiographic Axial Spondylarthritis**

Secukinumab may be considered for coverage for Ankylosing Spondylitis and Non-Radiographic Axial Spondylarthritis when:

- Chart notes documenting a failure of at least one NSAIDS at maximum tolerated dose unless the member has contraindications to NSAID therapy such as cardiovascular disease, peptic ulcer disease or renal disease **AND**
- Documented significant clinical symptoms such as fatigue, spinal pain, arthralgia, inflammation of joints and tendons, morning stiffness duration and therapy **AND**
- Insufficient response to at least one local corticosteroid injection in patients with symptomatic peripheral arthritis **AND**
- Members **with pure axial manifestations** do not have to have a trial of nonbiologic disease modifying anti-rheumatic drugs (DMARDs)

**Initial approval** will be for 6 months

**Extension requests** will be approved for up to 12 months if the member has a continued benefit to therapy. Extension requests where the Secukinumab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

**C. Psoriatic Arthritis**

Secukinumab may be considered for coverage for Psoriatic Arthritis when:

- Member has a diagnosis of moderate to severe psoriatic arthritis as indicated by three or more tender joints AND three or more swollen joints on two separate occasions at least one month apart
- Chart notes documenting a failure of at least one NSAIDS at maximum tolerated dose unless the member has contraindications to NSAID therapy such as cardiovascular disease, peptic ulcer disease or renal disease **AND**Chart notes documenting a failure to respond to an adequate trial of at least one of the following nonbiologic disease modifying anti-rheumatic drugs (DMARDs): leflunomide, sulfasalazine, or methotrexate.
    - Members with **pure axial manifestations** do not have to have a trial of nonbiologic disease modifying anti-rheumatic drugs (DMARDs)

- If a trial of methotrexate is not appropriate due to alcohol use and both leflunomide and sulfasalazine are not clinically appropriate, chart notes must be provided indicating that the patient has been counseled on the need to abstain from alcohol use while taking methotrexate and is unwilling to abstain from alcohol use.

**Initial approval** will be for 6 months

**Extensions requests** will be approved **up to 12 months** if the member has a continued benefit to therapy. Extension requests where the Secukinumab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

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## Exclusions

The use of Secukinumab will not be covered for the following situations:

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling.
- Secukinumab in combination with other biologics is excluded from coverage
- Combination therapy that is not supported by guidelines

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## References

1. Clinical Pharmacology. Secukinumab. Revised 11/02/2023. Accessed 01/04/2024.
2. Cosentyx (secukinumab) injection. Prescribing Information. East Hanover, NJ. Novartis Pharmaceuticals Corporation. January 2018. Revised November 2023.
3. Ward Michael, Atul Deodhar et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. Arthritis and Rheumatology. Vol 71 (No. 10). October 2019, pp 1599-1613. Available at: https://www.rheumatology.org/Portals/0/Files/AxialSpA-Guideline-2019.pdf
4. Ringold, Sarah; Angeles-Han Sheila et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Treatment Approaches for

Non-Systemic Polyarthritis, Sacroilitis and Enthesitis. American College of Rheumatology. Vol 71 (No 6). June 2019, pp 717-734.

5. Ward MM, Deodhar A, Gensler LS, et al. 2019 update of the American college of rheumatology/spondylitis association of America/spondyloarthritis research and treatment network recommendations for the treatment of ankylosing spondylitis and nonradiographic axial spondyloarthritis. Arthritis Rheumatol. 2019;71(10):1599-1613. doi:10.1002/art.41042

**MVP Health Care Medical Policy**

**Select Chelating Agents**

**Type of Policy:** **Drug Therapy**
**Prior Approval Date:** **10/01/2023**
**Approval Date:** **12/01/2024**
**Effective Date:** **02/01/2025**

**Related Policies:** N/A

**Drugs Requiring Prior Authorization under the pharmacy benefit**
Cuprimine (penicillamine oral capsule)
Syprine (trientine oral capsule)
Cuvrior (trientine tetrahydrochloride oral tablet)
penicillamine capsules

Refer to the Medicare Part D formulary for drugs that may be covered under the Part D benefit.

**Overview**

Penicillamine is a chelating agent recommended for the removal of excess copper in members with Wilson's disease. Penicillamine also is used in cystinuria to reduce excess cystine excretion and for the treatment of rheumatoid arthritis in members that have failed to respond to conventional therapy.

Trientine is a copper chelator that differs from D-penicillamine by a lack of sulfhydryl groups and chelated copper by forming a stable complex with its four constituent nitrogens.

**Indications/Criteria**

Cuprimine may be considered for coverage when all the following criteria are met:

- Member has a diagnosis of one of the following:

    - Wilson's disease
    - Cystinuria
    - Rheumatoid arthritis
- Member has a documented failure, contraindication or intolerable adverse reaction causing discontinuation of therapy to **Depen**® (penicillamine tablets) 250mg
- For brand name Cuprimine capsules, must have a documented failure of generic Cuprimine capsules (penicillamine).

Syprine and generic Syprine (trientine capsules) may be considered for coverage when all the following are met:

- Member has a diagnosis of Wilson's disease
- Member has a documented contraindication or intolerable adverse reaction causing discontinuation of **Depen**® (penicillamine tablets) 250mg

Cuvrior may be considered for coverage when all the following are met:

- Member has a diagnosis of stable Wilson's disease
- Member is de-coppered
- Member is tolerant to **Depen**® (penicillamine tablets) 250mg
- Provider attestation that member will discontinue penicillamine prior to starting Cuvrior therapy

**Coverage** will be for a period of 12 months.

**Requests for continuation of therapy** must be accompanied by current chart notes identifying continued benefit. Prescription history must show compliance, as defined by a medication possession ratio of at least 80%.

**Exclusions**

- Indication, age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling Syprine for the treatment of biliary cirrhosis, cystinuria, or rheumatoid arthritis

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**References**

1. Cuprimine (penicillamine) capsules. Prescribing Information. Bridgewater, NJ: Baush Health US, LLC. 10/2020.
2. Depen (penicillamine) tablets. Prescribing Information. Canonsburg, PA: Meda Pharmaceuticals Inc. Revised 07/2023
3. Syprine (trientine) capsules. Prescribing Information. Bridgewater, NJ: Baush Health US, LLC. 09/2020.
4. Cuvrior (trientine) tablets. Prescribing Information. Chicago, IL: Orphalan SA. 04/2022

| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Complete Wellness | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| USA Care PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

**Select Injectables for Asthma**

**Type of Policy:** **Drug Therapy**
**Prior Approval Date:** **06/01/2024**
**Approval Date:** **10/01/2024**
**Effective Date:** **01/01/2025**
**Related Policies:** **Xolair**
**Dupixent**

**Drug Requiring Prior Authorization (covered under the medical benefit)**
J2182 Nucala® (Injection, mepolizumab, 1mg)
J2786 Cinqair® (Injection, reslizumab,1mg)
J0517 Fasenra® (Injection, benralizumab,1mg)
J2356 Tezspire (Injection, tezepelumab-ekko, 1mg)

**Drugs Requiring Prior Authorization (covered under the pharmacy benefit)**
Nucala (mepolizumab) autoinjector and prefilled syringe
Fasenra (benralizumab) autoinjector
Tezspire (tezepelumab-ekko) pre-filled pen

Refer to the MVP website for the Medicare Part D formulary for drugs that may covered under the Part D benefit.

**Overview**
Asthma is a chronic inflammatory disease of the airways. Asthma affects between 1-18% of the population. Nucala, Cinqair, and Fasenra are interleukin-5 antagonist monoclonal antibodies indicated for add-on maintenance treatment of patients with severe asthma with an eosinophilic phenotype. Nucala is also indicated for adult patients with eosinophilic granulomatosis with polyangiitis (EGPA).

Tezspire is a thymic stromal lymphopoietin (TSLP) blocker, human monoclonal antibody indicated for the add-on maintenance treatment of adult and pediatric patients aged 12 years and older with severe asthma.

**Indications/Criteria:**

Prescription drugs covered under the pharmacy benefit must be self-administered. Self-administered products such as Nucala prefilled syringe and autoinjector cannot be approved under the medical benefit.

**Medicaid Variation:** Medications that are a pharmacy benefit are covered and billed to New York State Fee-For-Service (FFS) program. They are defined as medications that go through a retail or specialty pharmacy, including self administered injectable products. Pharmacy medications are subject to FFS's clinical criteria including (but not limited to) coverage, quantity limit, step therapy, and prior authorization. Pharmacy benefit information can be found here: https://www.emedny.org/info/fullform.pdf. Initial approval duration will be for 6 months and continuation approval duration will be for 12 months for applicable medical benefit drugs.

**A. ASTHMA**

**Nucala, Cinqair, Tezspire and Fasenra:**

Nucala, Cinqair, Tezspire or Fasenra may be considered for coverage for asthma when the following drug specific criteria are met:

- For Tezspire
  - Member must have a documented diagnosis of severe asthma
- For Nucala and Fasenra:
  - Member must have a documented diagnosis of severe eosinophilic asthma with one of the following:
  - A peripheral blood eosinophil count of at least 150 cells/microliter **OR**
  - Member is dependent on systemic corticosteroids

- For Cinqair
    - A peripheral blood eosinophil count of at least 400 cells/microliter in the past 30 days **OR**
      Member is dependent on systemic corticosteroids

**Nucala, Cinqair, Tezspire or Fasenra may be considered for coverage for asthma when the following criteria is met in addition to the specific drug criteria above**

- Member must be followed by an allergist, immunologist or pulmonologist
- Documentation and prescription claim history must identify that the member is compliant with the use of a high-dose inhaled corticosteroid (ICS) and a long-acting beta$_2$-agonist (LABA)
- Member still experiencing poor as demonstrated by the following in the previous year:
    - Poor asthma control defined as limitations of physical activity or exacerbations affecting activities of daily living **AND**
    - Two or more asthma exacerbations requiring treatment with systemic corticosteroids **OR**
    - One or more asthma exacerbations requiring hospitalization or an emergency room visit
    -
- Be a non-smoker by history or have a successful smoking cessation for at least 6 weeks
- Documentation that other medical and environmental conditions known to exacerbate asthma have been evaluated and treated
- Provider administered medications under the medical benefit may be considered for coverage if the following is provided:
    - Rationale and documentation are provided identifying why the member or caregiver is unable to self-administer

**Initial approval** will be for 12 months.

**Continued authorization** for up to 3 years will be considered if there is a documented decrease in asthma symptoms and exacerbations.

**Medicaid Variation:** Initial approval duration will be for 6 months and continuation approval duration will be for 12 months for applicable medical benefit drugs.

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**B. Eosinophilic Granulomatosis with Polyangiitis**

Nucala will be considered for coverage for Eosinophilic Granulomatosis with Polyangiitis when all the following are met:

- Member has a documented diagnosis of Eosinophilic Granulomatosis with Polyangiitis (EGPA) for at least 6 months confirmed by presence of:
    - Asthma plus eosinophilia (>1.0x10^9/Liter and/or >10% of leucocytes) AND at least two of the following additional features of EGPA
        - A biopsy confirming eosinophilic vasculitis, or perivascular eosinophilic infiltration, or eosinophil-rich granulomatous inflammation
        - Neuropathy;
        - Pulmonary infiltrates;
        - Sino-nasal abnormality;
        - Cardiomyopathy;
        - Glomerulonephritis;
        - Alveolar hemorrhage;
        - Palpable purpura;
        - Anti neutrophil cytoplasmic anti-body (ANCA) positive.
- Documentation of relapsing or refractory disease defined as:
    - Failure with an adequate trial of corticosteroid therapy
- Documented failure with at least one adequate trial of immunosuppressive therapy (i.e. azathioprine, methotrexate, mycophenolate, cyclosporine).

Provider administered medications under the medical benefit (i.e Nucala IV)may be considered for coverage when:

- Rationale and documentation is provided identifying why the member or caregiver is unable to self-administer **OR**
- Member has coverage under Medicare Part B and meets the criteria for a provider administered drug identified in this policy

**Initial approval** will be for 12 months.

**Continued authorization** for up to 3 years will be considered if there is a documented decrease in symptoms and exacerbations.

Medicaid Variation: Initial approval duration will be for 6 months and continuation approval duration will be for 12 months for applicable medical benefit drugs.

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**C. Chronic Rhinosinusitis with Nasal Polyps**

Nucala will be considered for coverage for Chronic Rhinosinusitis nasal polyps when all the following are met:

- Confirmed diagnosis of nasal polyps. Chart notes must document diagnosis confirmation by examination, endoscopy or sinus computed tomography (CT) scan.
- Prescribed by or in consultation with an allergist, otolaryngologist or immunologist
- Documented trial and failure of three (3) months to at least one intranasal corticosteroid indicated to treat nasal polyps.
- Documented failure, contraindication, intolerance, or allergy to other therapy used in the management of nasal polyps such as nasal saline irrigations, or antileukotriene agents (montelukast, zafirlukast, zileuton).
- Documentation of prior oral corticosteroid therapy and/or sinus surgery
- Nucala will be add on maintenance in combination with an intranasal corticosteriod

**Initial approval** will be for 12 months.

**Continued authorization** must be accompanied by current chart notes identifying continued benefit. Extension of therapy for up to 3 years will be based upon a positive clinical response.

**Medicaid Variation:** Initial approval duration will be for 6 months and continuation approval duration will be for 12 months for applicable medical benefit drugs.

**D. Hypereosinophilic Syndrome**

Nucala will be considered for coverage of Hypereosinophilic Syndrome when all the following are met:

- Prescribed by or in consultation with an allergist or immunologistMember as a documented diagnosis of hypereosinophilic syndrome (HES) for ≥ 6 months without an identifiable non-hematologic secondary cause
- Documentation of baseline eosinophil count and previous HES flares

**Initial approval** will be for 12 months.

**Continued authorization** must be accompanied by current chart notes identifying continued benefit. Extension of therapy for up to 3 years will be based upon a positive clinical response including a decrease in HES flares as well as documentation of decreasing eosinophil count from baseline.

> **Medicaid Variation:** Initial approval duration will be for 6 months and continuation approval duration will be for 12 months for applicable medical benefit drugs.

**Exclusions**

- Nucala
    1. For hypereosinophilic syndrome (HES): members with non-hematologic secondary HES or FIP1L1-PDGFRα kinase positive HES
- Dosing, age, and/or frequency outside of the FDA approved package labeling
- Dual therapy with another monoclonal antibody that is not supported by current clinical guidelines
- Treatment of acute bronchospasm or status asthmaticus
- Cinqair given more frequently than every 4 weeks
- Use of Fasenra or Cinqair for the treatment of other eosinophilic conditions

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**References**


1. Ortega H, Liu MC, Pavord I, et al. Mepolizumab Treatment in Patients with Severe Eosinophilic Asthma. N Engl J Med 2014; 371:1198-1207
2. National Asthma Education and Prevention Program: Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma. October 2007. Available at: http://www.nhlbi.nih.gov/guidelines/asthma/asthsumm.pdf

3. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2016. Available from www.ginasthma.org
4. Nucala (mepolizumab) for injection. Prescribing Information. Philadelphia, PA. GlaxoSmith Kline LLC.March 2023.
5. Cinqair (reslizumab) injection. Prescribing Information. Frazer, PA. Teva Respiratory LLC.February 2020.
6. Wechsler ME, Akuthota P, et al. Mepolizumab or Placebo for Eosinophilic Granulomatosis with Polyangiitis. N Engl J Med. 2017 May 18;376(20):1921-1932.
7. Prescribing Information. Fasenra (benralizumab) subcutaneous injection Wilmington, DE. Astra Zeneca. February 2021
8. American Academy of Allergy, Asthma & Immunology. Nasal Polyps. Nasal Polyps |AAAAI Reviewed May 1, 2023. Accessed April 18, 2024.
9. Global Strategy for Asthma Management and Prevention. 2023 Update. GINA Main Report 2023 Front Cover (ginasthma.org) .GINA 2023 - Global Strategy for Asthma Management and Prevention (ginasthma.org)
10. Prescribing Information. Tezspire (Tezepelumab-ekko). Thousand Oaks, CA. AstraZeneca and Amgen. May 2023.

| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Medicare Gold Giveback | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |

| | |
|---|---|
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D |
| 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).** | |
| *© 2024 MVP Health Plan, Inc. All rights reserved. Descriptions contained within MVP's Medical Policies are not a guarantee of coverage. Each MVP Group or Subscriber Contract contains specific limitations, exclusions and requirements that may affect a Policy. If there is any discrepancy between your Group or Subscriber Contract and a Policy, your Group or Subscriber Contract shall in all cases govern.* | |

***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 |

**MVP Health Care Medical Policy**

**Medicare Part B: Select Injectables for Asthma**

**Type of Policy:** **Drug Therapy**
**Prior Approval Date:** **11/01/2023**
**Approval Date:** **06/01/2024**
**Effective Date:** **06/01/2024**
**Related Policies:** **Medicare Part B: Xolair**

**Drug Requiring Prior Authorization (covered under the medical benefit)**

J2182 Nucala® (Injection, mepolizumab, 1mg)
J2786 Cinqair® (Injection, reslizumab,1mg)
J0517 Fasenra® (Injection, benralizumab,1mg)

Refer to the MVP website for the Medicare Part D formulary for drugs that may covered under the Part D benefit.

**Overview/Summary of Evidence**

Asthma is a chronic inflammatory disease of the airways. Asthma affects between 1-18% of the population. Nucala, Cinqair, and Fasenra are interleukin-5 antagonist monoclonal antibodies indicated for add-on maintenance treatment of patients with severe asthma with an eosinophilic phenotype. Nucala is also indicated for adult patients with eosinophilic granulomatosis with polyangiitis (EGPA).

**Indications/Criteria:**

Medications identified in this policy that are self-administered fall under the Medicare Part D (pharmacy) benefit. Refer to the MVP website for the Medicare Part D formulary and prior authorization criteria for drugs that may covered under the Part D benefit.

## A. ASTHMA

**Nucala, Cinqair and Fasenra:**

Nucala, Cinqair or Fasenra may be considered for coverage for asthma when the following criteria are met:

- For Nucala and Fasenra
    - Member must have a documented diagnosis of severe eosinophilic asthma with one of the following:
    - A peripheral blood eosinophil count of at least 150 cells/microliter **OR**
    - Member is dependent on systemic corticosteroids
- For Cinqair:
    - Must have a peripheral blood eosinophil count of at least 400 cells/microliter in the past 30 days OR
    - Member is dependent on systemic corticosteroids

- Member must be followed by an allergist, immunologist or pulmonologist
- Documentation and prescription claim history must identify that the member is compliant with the use of a high-dose inhaled corticosteroid (ICS) and a long-acting beta$_2$-agonist (LABA)
- Member still experiencing poor asthma control and has had at least two asthma exacerbations in the previous year
    - Poor asthma controlled defined as limitations of physical activity or exacerbations affecting activities of daily living
    - Exacerbations must have required treatment with systemic corticosteroids, hospitalization, or an emergency room visit
- Be a non-smoker by history or have a successful smoking cessation for at least 6 weeks
- Documentation that other medical and environmental conditions known to exacerbate asthma have been evaluated and treated
- Provider administered medications under the medical benefit may be considered for coverage if the following is provided:
    - Rationale and documentation are provided identifying why the member or caregiver is unable to self-administer **OR**
    - Member has coverage under Medicare Part B and meets the criteria for a provider administered drug identified in this policy.

**Initial approval** will be for 6 months.

**Continued authorization** for up to 12 months will be considered if there is a documented decrease in asthma symptoms and exacerbations.

---

**B. Eosinophilic Granulomatosis with Polyangiitis**

Nucala will be considered for coverage for Eosinophilic Granulomatosis with Polyangiitis when all the following are met:

- Member has a documented diagnosis of Eosinophilic Granulomatosis with Polyangiitis (EGPA) for at least 6 months confirmed by presence of:
    - Asthma plus eosinophilia (>1.0x10^9/Liter and/or >10% of leucocytes) plus at least two of the following additional features of EGPA
        - a biopsy confirming eosinophilic vasculitis, or perivascular eosinophilic infiltration, or eosinophil-rich granulomatous inflammation
        - neuropathy
        - pulmonary infiltrates
        - sino-nasal abnormality
        - cardiomyopathy
        - glomerulonephritis
        - alveolar hemorrhage
        - palpable purpura
        - anti neutrophil cytoplasmic anti-body (ANCA) positive.
- Documentation of relapsing or refractory disease defined as:
    - Failure with an adequate trial of corticosteroid therapy
- Documented failure with at least one adequate trial of immunosuppressive therapy (i.e. azathioprine, methotrexate, mycophenolate, cyclosporine).

Provider administered medications under the medical benefit (i.e Nucala IV)may be considered for coverage when:

- Rationale and documentation is provided identifying why the member or caregiver is unable to self-administer **OR**
- Member has coverage under Medicare Part B and meets the criteria for a provider administered drug identified in this policy

**Initial approval** will be for 6 months.

**Continued authorization** for up to 12 months will be considered if there is a documented decrease in symptoms and exacerbations

## C. Chronic Rhinosinusitis with Nasal Polyps

Nucala will be considered for coverage for Chronic Rhinosinusitis nasal polyps when all the following are met:

- Confirmed diagnosis of nasal polyps. Chart notes must document diagnosis confirmation by examination, endoscopy or sinus computed tomography (CT) scan.
- Prescribed by or in consultation with an allergist, otolaryngologist or immunologist
- Documented trial and failure of three (3) months, to at least one intranasal corticosteroid indicated to treat nasal polyps.
- Documented failure, contraindication, intolerance, or allergy to other therapy used in the management of nasal polyps such as nasal saline irrigations, or antileukotriene agents (montelukast, zafirlukast, zileuton).
- Documentation of prior oral corticosteroid therapy and/or sinus surgery
- Nucala will be add on maintenance in combination with an intranasal corticosteriod

**Initial approval** will be for 6 months.

**Continued authorization** must be accompanied by current chart notes identifying continued benefit. Extension of therapy for up to one year will be based upon a positive clinical response.

## D. Hypereosinophilic Syndrome

Nucala will be considered for coverage of Hypereosinophilic Syndrome when all the following are met:

- Prescribed by or in consultation with an allergist or immunologist
- Member as a documented diagnosis of hypereosinophilic syndrome (HES) for ≥ 6 months without an identifiable non-hematologic secondary cause
- Documentation of baseline eosinophil count and previous HES flares

**Initial approval** will be for 6 months.

**Continued authorization** must be accompanied by current chart notes identifying continued benefit. Extension of therapy for up to one year will be based upon a positive clinical response including a decrease in HES flares as well as documentation of decreasing eosinophil count from baseline.

**Exclusions**

- Nucala
    1. For hypereosinophilic syndrome (HES): members with non-hematologic secondary HES or FIP1L1-PDGFRα kinase positive HES
- Dosing, age, and/or frequency outside of the FDA approved package labeling Dual therapy with another monoclonal antibody that is not supported by current clinical guidelines Treatment of acute bronchospasm or status asthmaticus
- Cinqair given more frequently than every 4 weeks
- Use of Fasenra or Cinqair for the treatment of other eosinophilic conditions

**References**


1. Ortega H, Liu MC, Pavord I, et al. Mepolizumab Treatment in Patients with Severe Eosinophilic Asthma. N Engl J Med 2014; 371:1198-1207
2. National Asthma Education and Prevention Program: Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma. October 2007. Available at: http://www.nhlbi.nih.gov/guidelines/asthma/asthsumm.pdf
3. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2016. Available from www.ginasthma.org
4. Nucala (mepolizumab) for injection. Prescribing Information. Philadelphia, PA. GlaxoSmith Kline LLC.March 2023.
5. Cinqair (reslizumab) injection. Prescribing Information. Frazer, PA. Teva Respiratory LLC.February 2020.
6. Wechsler ME, Akuthota P, et al. Mepolizumab or Placebo for Eosinophilic Granulomatosis with Polyangiitis. N Engl J Med. 2017 May 18;376(20):1921-1932.
7. Prescribing Information. Fasenra (benralizumab) subcutaneous injection Wilmington, DE. Astra Zeneca. February 2021.GINA 2023 - Global Strategy for Asthma Management and Prevention (ginasthma.org)

**MVP Health Care Medical Policy**

**Select Oral Antipsychotics**

| | |
|---|---|
| **Type of Policy:** | Drug Therapy |
| **Prior Approval Date:** | 11/01/2023 |
| **Approval Date:** | 11/01/2024 |
| **Effective Date:** | 01/01/2025 |
| **Related Policies:** | N/A |

***Drugs Requiring Prior Authorization**

Nuplazid (pimavanserin tartrate) oral tablets

Refer to the MVP website for the Medicare Part D formulary for drugs that may covered under the Part D benefit.

**Overview**

Nuplazid (pimavanserin) is an atypical antipsychotic indicated for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis (PDP). Nuplazid is **NOT approved for the treatment of patients with dementia-related psychosis.**

**Indications/Criteria**

Nuplazid may be considered for coverage when all of the following criteria are met:

1. Chart notes documenting a diagnosis of Parkinson's disease for at least one year and that hallucinations/delusions started post Parkinson's diagnosis (PD)
2. Provider attestation that external or secondary causes of PDP have been ruled out, nonessential offending agents have been discontinued, and anti-PD drugs with the greatest potential for psychosis induction has been evaluated for reduction or discontinuation.
3. Prescription claim history supports the diagnosis of Parkinson's disease

**Initial approval and continued therapy** will be for 12 months

- **Continued therapy** will require documented benefit and prescription history identifying compliance

## Exclusions

1. Indication, age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling
2. Treatment of dementia-related psychosis

## References


1. Nuplazid (pimavanserin).Prescribing Information. San Diego, CA: Acadia Pharmaceuticals; Approval 2016. Revised: 09/2023
2. ANNE D. HALLI-TIERNEY, MD, JACQUELYNN LUKER, MD, AND DANA G. CARROLL, PharmD: Parkinson Disease: American Family Physician. 12/01/2020
3. Dutta R. Psychosis in Parkinson's Disease and Current Management Trends- an Updated Review of Literature. Journal of Neuroscience Neurological Disorders. 07/2023


| 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 |
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| 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 | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| 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).** | |
| *© 2025 MVP Health Plan, Inc. All rights reserved. Descriptions contained within MVP's Medical Policies are not a guarantee of coverage. Each MVP Group or Subscriber Contract contains specific limitations, exclusions and requirements that may affect a Policy. If there is any discrepancy between your Group or Subscriber Contract and a Policy, your Group or Subscriber Contract shall in all cases govern.* | |

***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 |

**MVP Health Care Medical Policy**

**Skysona**

| | |
|---|---|
| **Type of Policy:** | **Drug/Medical Therapy** |
| **Prior Approval Date:** | |
| **Approval Date:** | **12/01/2024** |
| **Effective Date:** | **02/01/2025** |
| **Related Policies:** | **CAR-T Therapy** |

Refer to the MVP website for the Medicare Part D formulary for drugs that may covered under the Part D benefit.

Refer to the MVP website for the Medicare Part B policies for coverage criteria of drugs covered under the medical benefit.

## Drugs Requiring Prior Authorization under the medical benefit

J3590 Skysona (elivaldogene autotemcel)

## Overview

Skysona is one time an autologous hematopoietic stem cell (HSC)-based gene therapy that is prepared from the members HSCs through apheresis procedure. Skysona is indicated to slow the progression of neurologic dysfunction in boys 4-17 years of age with early, active cerebral adrenoleukodystrophy (CALD). Early, active CALD refers to asymptomatic or mildly symptomatic (neurologic function score, NFS ≤ 1) boys who have gadolinium enhancement on brain magnetic resonance imaging (MRI) and Loes scores of 0.5-9.

CALD is a rare, progressive, neurodegenerative disease that primarily affects young boys and causes irreversible, devastating neurologic decline, including major functional disabilities such as loss of communication, cortical blindness, requirement for tube feeding, total incontinence, wheelchair dependence, or complete loss of voluntary

movement. Nearly half of members who do not receive treatment die within five years of symptom onset. Prior to the approval of Skysona treatment, effective options were limited to allogeneic hematopoietic stem cell transplant (allo-HSCT), which is associated with the risk of serious potential complications including death, that can increase dramatically in members without a human leukocyte antigen (HLA) matched donor.

Skysona has been approved under accelerated approval based on a 24-month Major Functional Disability (MFD)-free survival. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

---

**Indications/Criteria**

Skysona may be considered for coverage when the following criteria are met:

- Documented diagnosis of early active cerebral adrenoleukodystrophy (CALD) and documentation of the following:
    - Neurologic function score (NFS)≤ 1
    - Current brain magnetic resonance imaging (MRI) with use of Gadolinium Enhancement (GdE +) demonstrating demyelinating lesions
    - Loes scores of 0.5-9 based on assessment of brain MRI
    - Elevated very long chain fatty acid (VLCFA) confirmed by laboratory documentation
- Confirmed mutations on the ABCD1 gene (not full deletion of the gene).
    - If applicable, provider attestation confirming that anti-retroviral therapy will stop at least one month prior to initiating medications for stem cell mobilization and for the expected duration for elimination of the medications and until all cycles of apheresis are complete. Anti-retroviral medications may interfere with manufacturing of the apheresed cells.
- Member's sex is male
- Member is 4 years to 17 years of age
- Documentation that the member has been screened for the following: hepatitis B virus (HBV), hepatitis C virus (HCV), human immunodeficiency virus 1 and 2 (HIV-1, HIV-2), human T-lymphotropic virus 1 and 2 (HTLV-1, HTLV-2).

    - Laboratory documentation indicates that the member is negative for HIV-1, HIV-2, HTLV-1, and HTLV-2

- Confirm that member has not received any vaccinations at least 6 weeks prior to the start of myeloablative conditioning
- Provider attestation that full myeloablative and lymphodepleting conditioning would be administered prior to infusion of Skysona
- Skysona must be administered at a qualified treatment center. Please see link for treatment centers below: SKYSONA™ (elivaldogene autotemcel) Qualified Treatment Center Locator

Skysona will be approved as **a one-time dose** and will not need to be continued for maintenance. Coverage is contingent on eligibility at the time of infusion.

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**Exclusions**

The use of Skysona will not be covered for the following situations:

- More than one treatment per lifetime
- Indication, age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling CALD secondary to head trauma
- Requests for replacement due to lost or damaged product will not be covered
- Active infection
- Member is positive for HIV-1, HIV-2, HTLV-1, and /or HTLV-2
- Full deletion of the ABCD1 gene (may result in rapid loss of efficacy due to immune response)

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**References**

1. Skysona (elivaldogene autotemcel). Prescribing Information. Somerville, MA. Bluebird Bio Inc. April 2024
2. Clinical Pharmacology. Skysona. Accessed October 3, 2022.
3. X-linked adrenoleukodystrophy - About the Disease - Genetic and Rare Diseases Information Center (nih.gov)
4. Clinical Pharmacology. Skysona. Accessed November 1, 2023.

5. Micromedex Healthcare Series. Skysona. Accessed November 1, 2023.

6. Eichler F, Duncan C, Musolino PL, et al. Hematopoietic Stem-Cell Gene Therapy for Cerebral Adrenoleukodystrophy. The New England journal of medicine. 2017;377(17):1630-1638. doi:https://doi.org/10.1056/NEJMoa1700554 Accessed November 1, 2023.

| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Complete Wellness | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| USA Care PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

**Medicare Part B: Skysona**

**Type of Policy:** **Drug/Medical Therapy**
**Prior Approval Date:** **1/01/2024**
**Approval Date:** **12/01/2024**
**Effective Date:** **02/01/2025**
**Related Policies:** **N/A**

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies.

**Drugs Requiring Prior Authorization under the medical benefit**

J3590 Skysona (elivaldogene autotemcel)

**Overview/Summary of Evidence**

**Please refer to relevant CMS LCDs/NCDs/Policy Articles for most up to date Medicare Part B guidance if available.**

Skysona is one time an autologous hematopoietic stem cell (HSC)-based gene therapy that is prepared from the members HSCs through apheresis procedure. Skysona is indicated to slow the progression of neurologic dysfunction in boys 4-17 years of age with early, active cerebral adrenoleukodystrophy (CALD). Early, active CALD refers to asymptomatic or mildly symptomatic (neurologic function score, NFS ≤ 1) boys who have gadolinium enhancement on brain magnetic resonance imaging (MRI) and Loes scores of 0.5-9.

CALD is a rare, progressive, neurodegenerative disease that primarily affects young boys and causes irreversible, devastating neurologic decline, including major functional disabilities such as loss of communication, cortical blindness, requirement for tube feeding, total incontinence, wheelchair dependence, or complete loss of voluntary movement. Nearly half of members who do not receive treatment die within five years

of symptom onset. Prior to the approval of Skysona treatment, effective options were limited to allogeneic hematopoietic stem cell transplant (allo-HSCT), which is associated with the risk of serious potential complications including death, that can increase dramatically in members without a human leukocyte antigen (HLA) matched donor.

Skysona has been approved under accelerated approval based on a 24-month Major Functional Disability (MFD)-free survival. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

---

**Indications/Criteria**

Skysona may be considered for coverage when the following criteria are met:

- Documented diagnosis of early active cerebral adrenoleukodystrophy (CALD) and documentation of the following:
    - Neurologic function score (NFS)≤ 1
    - Current magnetic brain resonance imaging (MRI) with use of Gadolinium Enhancement (GdE +) demonstrating demyelinating lesions
    - Loes scores of 0.5-9 based on assessment of brain MRI
    - Elevated very long chain fatty acid (VLCFA) confirmed by laboratory documentation
    - Confirmed mutations on the ABCD1 gene (not full deletion of the gene)
- If applicable, provider attestation confirming that anti-retroviral therapy will stop at least one month prior to initiating medications for stem cell mobilization and for the expected duration for elimination of the medications and until all cycles of apheresis are complete. Anti-retroviral medications may interfere with manufacturing of the apheresed cells.
- Member's sex is male
- Member is 4 years to 17 years of age
- Documentation that the member has been screened for the following: hepatitis B virus (HBV), hepatitis C virus (HCV), human immunodeficiency virus 1 and 2 (HIV-1, HIV-2), human T-lymphotropic virus 1 and 2 (HTLV-1, HTLV-2).

    - Laboratory documentation indicates that the member is negative for HIV-1, HIV-2, HTLV-1, and HTLV-2

- Confirm that member has not received any vaccinations at least 6 weeks prior to the start of myeloablative conditioning
- Provider attestation that full myeloablative and lymphodepleting conditioning would be administered prior to infusion of Skysona.
- Skysona must be administered at a qualified treatment center. Please see link for treatment centers below: SKYSONA™ (elivaldogene autotemcel) Qualified Treatment Center Locator

Skysona will be approved as **a one-time dose** and will not need to be continued for maintenance. Coverage is contingent on eligibility at the time of infusion.

---

**Exclusions**

The use of Skysona will not be covered for the following situations:

- More than one treatment per lifetime
- Indication, age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling CALD secondary to head trauma
- Requests for replacement due to lost or damaged product will not be covered
- Active infection
- Member is positive for HIV-1, HIV-2, HTLV-1, and /or HTLV-2
- Full deletion of the ABCD1 gene (may result in rapid loss of efficacy due to immune response)

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**References**

1. Skysona (elivaldogene autotemcel). Prescribing Information. Somerville, MA. Bluebird Bio Inc. April 2024.
2. Clinical Pharmacology. Skysona. Accessed October 3, 2022.
3. X-linked adrenoleukodystrophy - About the Disease - Genetic and Rare Diseases Information Center (nih.gov)

4. Clinical Pharmacology. Skysona. Accessed November 1, 2023.

5. Micromedex Healthcare Series. Skysona. Accessed November 1, 2023.

6. Eichler F, Duncan C, Musolino PL, et al. Hematopoietic Stem-Cell Gene Therapy for Cerebral Adrenoleukodystrophy. The New England journal of medicine. 2017;377(17):1630-1638. doi:https://doi.org/10.1056/NEJMoa1700554 Accessed November 1, 2023.

**MVP Health Care Medical Policy**

**Soliris (Eculizumab)**

| | |
|---|---|
| **Type of Policy:** | **Medical Therapy** |
| **Prior Approval Date:** | **10/01/2023** |
| **Approval Date:** | **10/01/2024** |
| **Effective Date:** | **05/01/2025** |
| **Related Policies:** | Orphan Drug(s) and Biologicals |

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies.

**Drugs Requiring Prior Authorization under the medical benefit**
J1300 Injection, eculizumab 300 mg/30 mL solution for injection (Soliris)
J1299 Injection, eculizumab, 2 mg

**Overview**
Eculozumab is a humanized monoclonal antibody, complement inhibitor indicated for the treatment of paroxysmal nocturnal hemoglobinuria (PNH), atypical hemolytic uremic syndrome (aHUS), anti-acetylcholine receptor antibody positive generalized myasthenia gravis, and anti-aquaporin-4 (AQP4) antibody positive neuromyelitis optica spectrum disorder (NMOSD).
Eculizumab can increase the risk of meningococcal infections. Immunization with meningococcal vaccines is required prior to eculizumab administration unless the risks of delaying treatment outweigh the risks of developing a meningococcal infection. Prescribers who treat members with eculizumab must enroll in the Soliris REMS program.

**Indications/Criteria**

**For all indications, the following criteria must be met in addition the specific diagnosis criteria below.**

a. Prescriber is enrolled in Soliris REMS program
b. Documentation member has been vaccinated against N. meningitidis at least 2 weeks before initiation of eculizumab therapy and vaccinations for S. pneumoniae and H. influenzae are administered in accordance with ACIP guidelines.
    i. If eculizumab must be initiated immediately and the meningococcal vaccination is administered less than 2 weeks before eculizumab initiation, documentation of a 2-week course of antibacterial drug prophylaxis is required.
c. Site of Care
    i. Per the MVP Health Care Pharmacy Management Programs policy, Soliris is subject to Site of Care requirements and must be obtained through a preferred home infusion vendor or contracted provider office. Prior Authorization and medical justification is required for Soliris obtained and administered in a non-preferred site of care (i.e. outpatient hospital setting).
    ii. MVP will allow 60 days after prior authorization approval for members to transfer to a preferred infusion site.
    iii. This requirement does not apply to MVP Medicare and Medicaid, CHP members

**A. Paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis**

a. Diagnosis confirmed by high sensitivity flow cytometry with a monocyte or granulocyte clone size ≥10% **OR**
    i. >50% of glycosylphosphatidylinositol-anchored proteins (GPI-AP) deficient polymorphonuclear cells **AND**
b. Documentation demonstrating evidence of hemolysis including LDH level ≤1.5 times the upper limit of normal (ULN) at baseline
c. Documentation of a minimum of 1 **PNH related** sign or symptom within the last 3 months (fatigue, abdominal pain, dyspnea, dysphagia, erectile dysfunction, anemia, hemoglobinuria, history of major adverse cardiovascular events, or history of packed RBC transfusion due to PNH)
d. Documentation of medical necessity including side effects or drug failure of an adequate trial of Ultomiris

**B. Atypical hemolytic uremic syndrome (aHUS) to prevent complement-mediated thrombotic microangiopathy**

a. Documentation of the absence of Shiga toxin (Shiga toxin Escherichia coli related hemolytic uremic syndrome (STEC-HUS) negative)
b. ADAMTS 13 activity level ≥ 5%
c. Documentation of baseline platelet count (≤ 150 × 109 /L)
d. Documentation demonstrating evidence of hemolysis including elevation of serum LDH and sCr above ULN or dialysis is required
e. Documentation of medical necessity including side effects or drug failure of an adequate trial of Ultomiris

**C. Anti-acetylcholine receptor antibody positive generalized myasthenia gravis (gMG) in adult members who are anti-acetylcholine receptor (AchR) antibody positive.**

a. Positive serologic test for anti-AChR antibodies
b. Myasthenia Gravis Foundation of America (MGFA) clinical classification II to IV
c. MG activities of daily living (MG-ADL) total score ≥6
d. Member has had an inadequate response to at least two non-steroidal immunosuppressive therapies (ISTs) listed below **OR** failed at least one IST listed below and required chronic plasmapheresis or plasma exchange or IVIG:
    i. azathioprine
    ii. cyclosporine
    iii. mycophenolate mofetil
    iv. tacrolimus
    v. methotrexate
    vi. cyclophosphamide
    vii. rituximab
e. Documentation of medical necessity including side effects or drug failure of an adequate trial of Ultomiris

**D. Anti-aquaporin-4 (AQP4) antibody positive neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive.**

a. Serology confirming diagnosis of anti-aquaporin-4 (AQP4) antibody positive NMOSD
b. Expanded Disability Status Scale (EDSS) score ≤ 7

**Initial approval** will be for 6 months

**Extension requests** will be approved for up to 12 months if the members meeting the following criteria per applicable indication:

**PNH**

No evidence of disease progression while on current regimen and documentation of positive response to therapy (reduction in blood transfusions, stabilization in hemoglobin concentrations, reduction of exacerbations, improved quality of life scores/fatigue, and/or normalization of LDH levels).

**aHUS**

No evidence of disease progression while on the current regimen and documentation of a positive response to therapy (e.g., normalization of lactate dehydrogenase (LDH) levels, platelet counts, improvement in renal function from baseline).

**gMG**

No evidence of disease progression while on the current regimen and documentation of a positive response to therapy (e.g., improvement in MG-ADL score, changes compared to baseline in Quantitative Myasthenia Gravis (QMG) total score).

**NMOSD**

No evidence of disease progression while on current regimen and documentation of a positive response to therapy (e.g., improvement in EDSS score, decreased hospitalizations, improvement in stability, reduced plasma exchange treatments).

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**Exclusions**

- For the treatment of members with Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS)
- Indication, age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling
- Members with unresolved Neisseria meningitidis infection
- Members who are not currently vaccinated against Neisseria meningitidis, unless the risks of delaying treatment outweigh the risks of developing a meningococcal infection

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## References


1. Soliris (eculizumab) package insert. Boston, MA: Alexion Pharmaceuticals, Inc.;2020 Nov.
2. Clinical Resource, Drugs With Prescribing, Dispensing, or REMS Requirements. Pharmacist's Letter/Pharmacy Technician's Letter/Prescriber's *Letter*. February 2023. [390223]
3. Parker CJ. Update on the diagnosis and management of paroxysmal nocturnal hemoglobinuria. Hematology Am Soc Hematol Educ Program. 2016;2016(1):208-216
4. Cancado RD et al. Consensus statement for diagnosis and treatment of paroxysmal nocturnal hemoglobinuria. Hematology, Transfusion, and Cell Therapy. 2021;43(3):341-348.
5. Sanders D, Wolfe G, Benatar M et al. International consensus guidance for management of myasthenia gravis. Neurology. 2021; 96 (3) 114-122.
6. Soliris (eculizumab) package insert. Boston, MA: Alexion Pharmaceuticals, Inc.;2024 June.
7. A study of ravulizumab (ALXN1210) Versus Eculizumab in Complement Inhibitor Treatment-Naïve Adult Participants With Paroxysmal Nocturnal Hemoglobinuria (PNH)- full text view - clinicaltrials.gov. (n.d.), Alexion Pharmaceuticals, Inc, 2024-05-14
8. Daria V. Babushok; When does a PNH clone have clinical significance?. Hematology Am Soc Hematol Educ Program 2021; 2021 (1): 143–152. doi: https://doi.org/10.1182/hematology.2021000245
9. Paroxysmal Nocturnal Hemoglobinuria - NORD (National Organization for Rare Disorders). (2015). NORD (National Organization for Rare Disorders); NORD. https://rarediseases.org/rare-diseases/paroxysmal-nocturnal-hemoglobinuria/, Last updated: 05/29/2024


| Member Product | Medical Management Requirements* |
|---|---|
| **New York Products** | Prior Auth |
| 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 | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Medicare Gold Giveback | Refer to the MVP website for the Medicare Part B and Part D policies. |

| | |
|---|---|
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D |
| 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 | Retrospective Review Required |

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

**MVP Health Care Medical Policy**

**Spesolimab**

| | |
|---|---|
| **Type of Policy:** | **Drug Therapy** |
| **Prior Approval Date:** | **04/01/2024** |
| **Approval Date:** | **04/01/2025** |
| **Effective Date:** | **06/01/2025** |
| **Related Policies:** | **N/A** |

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies.

**Drugs Requiring Prior Authorization under the medical benefit**

J1747 injection, spesolimab-sbzo, 1mg (Spevigo) vials for IV use

J1747 injection, spesolimab-sbzo, 1mg (Spevigo) pre-filled syringes for subcutaneous injection

**Overview**

Spesolimab is an interleukin-36 receptor (IL36R) antagonist indicated for the treatment of generalized pustular psoriasis (GPP) flares in adults and pediatric patients 12 years of age and older and weighing at least 40 kg. It is administered by intravenous infusion over 90 minutes and an additional infusion may be administered one week after the initial dose if symptoms persist or via subcutaneous injection. Members should be screened for immunologic and infectious disease prior to initiating therapy and avoid the use of live vaccines during treatment with spesolimab and for at least 16 weeks after treatment.

**Indications/Criteria**

**Generalized Pustular Psoriasis (GPP):**

Spesolimab may be considered for coverage when the following criteria are met:

- Member has a diagnosis of moderate to severe generalized pustular psoriasis **AND**
- Must be ordered by or with consult from a dermatologist or rheumatologist

**Spevigo for GPP Flare:**

May be considered for coverage when all of the following criteria are met:

- Criteria for **Generalized Pustular Psoriasis (GPP)** above are met **AND**
- Chart notes are provided documenting all of the following:
  - Current GPP flare
    - Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) score of at least 3-[GPPPGA scores range from 0 (clear) to 4 (severe)] **AND**
    - At least 5% of body surface area covered with erythema and presence of pustules **AND**
    - Current presence of fresh pustules (new or worsening)

**Initial IV Spevigo approval** for a **current flare** will be for **two doses within 3 months**

**Subsequent IV Spevigo approval** for a **new flare** will be considered when the following criteria is met:

- For a new flare, at least 12 weeks has passed since the last dose of IV Spevigo **AND**
- Medication is ordered by or with consult from a dermatologist or rheumatologist **AND**
- Chart notes are provided indicate previous use and clinical benefit from Spevigo
- **Subsequent approvals for a new flare will be for two doses within 3 months**

**Subcutaneous Use *After IV Spevigo* for Treatment of GPP Flare:**

- Criteria for **Spevigo for GPP Flare** above are met **AND**
- 4 weeks have passed since treatment with IV SPEVIGO
- **Initial approval** for subcutaneous Spevigo will be **every 4 weeks for 12 months**

**Subcutaneous Spevigo for Generalized pustular psoriasis (GPP) when *not experiencing a flare*:**

- Chart notes documenting the following:

- Criteria for **Generalized Pustular Psoriasis (GPP)** above are met **AND**
- Member is not currently experiencing a flare
  - History of at least 2 moderate to severe GPP flares **OR**
  - History of flare during concomitant therapy **AND**
  - Clear or almost clear skin

**Initial approval** will be dosed every **4 weeks for 12 months**

**Subsequent approvals for subcutaneous use** when not experiencing a flare:

- Documentation indicating an overall beneficial clinical response
  - Low disease activity
  - Reduction in flares
  - Improvement in clinical signs and symptoms
  - **Approve for 12 months**

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## Exclusions

The use of spesolimab will not be covered for the following situations:

- Indication, age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling
- Systemic and/or topical therapy used concomitantly with Spevigo

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## References


1. Spesolimab. Clinical Pharmacology. Revision date 12/17/2024. Accessed on 03/2025.
2. Spevigo (spesolimab-sbzo) injection, for subcutaneous or intravenous use. Prescribing Information. Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT. Revised 03/2024.
3. Bachelez H, Choon SE, Marrakchi S, et al. Trial of spesolimab for generalized pustular psoriasis. N Engl J Med. 2021;385(26):2431-2440. doi:10.1056/NEJMoa2111563.
4. Shah M, Al Aboud DM, Crane JS, et al. Pustular Psoriasis. [Updated 2023 Aug 8]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK537002/


| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Complete Wellness | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| USA Care PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | |

| | |
|---|---|
| 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).** | |
| *© 2025 MVP Health Plan, Inc. All rights reserved. Descriptions contained within MVP's Medical Policies are not a guarantee of coverage. Each MVP Group or Subscriber Contract contains specific limitations, exclusions and requirements that may affect a Policy. If there is any discrepancy between your Group or Subscriber Contract and a Policy, your Group or Subscriber Contract shall in all cases govern.* | |

***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 |

**MVP Health Care Medical Policy**

**Medicare Part B: Spesolimab**

| | |
|---|---|
| **Type of Policy:** | **Drug Therapy** |
| **Prior Approval Date:** | **04/01/2024** |
| **Approval Date:** | **04/01/2025** |
| **Effective Date:** | **06/01/2025** |

**Related Policies: N/A**

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies.

## Drugs Requiring Prior Authorization under the medical benefit

J1747 injection, spesolimab-sbzo, 1mg (Spevigo)

J1747 injection, spesolimab-sbzo, 1mg (Spevigo) pre-filled syringes for subcutaneous injection

## Overview/Summary of Evidence

Spesolimab is an interleukin-36 receptor (IL36R) antagonist indicated for the treatment of generalized pustular psoriasis (GPP) flares in adults and pediatric patients 12 years of age and older and weighing at least 40 kg. It is administered by intravenous infusion over 90 minutes and an additional infusion may be administered one week after the initial dose if symptoms persist or via subcutaneous injection. Members should be screened for immunologic and infectious disease prior to initiating therapy and avoid the use of live vaccines during treatment with spesolimab and for at least 16 weeks after treatment.

## Indications/Criteria

**Generalized Pustular Psoriasis (GPP):**

Spesolimab may be considered for coverage when the following criteria are met:

- Member has a diagnosis of moderate to severe generalized pustular psoriasis **AND**
- Must be ordered by or with consult from a dermatologist or rheumatologist

**Spevigo for GPP Flare:**

May be considered for coverage when all of the following criteria are met:

- Criteria for **Generalized Pustular Psoriasis (GPP)** above are met **AND**
- Chart notes are provided documenting all of the following:
  - Current GPP flare
    - Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) score of at least 3- [GPPPGA scores range from 0 (clear) to 4 (severe)] **AND**
    - At least 5% of body surface area covered with erythema and presence of pustules **AND**
    - Current presence of fresh pustules (new or worsening)

**Initial IV Spevigo approval** for a **current flare** will be for **two doses within 3 months**

**Subsequent IV Spevigo approval** for a **new flare** will be considered when the following criteria is met:

- For a new flare, at least 12 weeks has passed since the last dose of Spevigo **AND**
- Medication is ordered by or with consult from a dermatologist or rheumatologist **AND**
- Chart notes are provided indicate previous use and clinical benefit from Spevigo
- **Subsequent approvals for a new flare will be for two doses within 3 months**

**Subcutaneous Use *After IV Spevigo* for Treatment of GPP Flare:**

- Criteria for **Spevigo for GPP Flare** above are met **AND**
- 4 weeks have passed since treatment with IV SPEVIGO
- **Initial approval** for subcutaneous Spevigo will be **every 4 weeks for 12 months**

**Subcutaneous Spevigo for Generalized pustular psoriasis (GPP) when *not experiencing a flare*:**

- Chart notes documenting the following:
  - Criteria for **Generalized Pustular Psoriasis (GPP)** above are met **AND**
  - Member is not currently experiencing a flare
    - History of at least 2 moderate to severe GPP flares **OR**
    - History of flare during concomitant therapy **AND**
    - Clear or almost clear skin

**Initial approval** will be dosed every **4 weeks for 12 months**

**Subsequent approvals for subcutaneous use** when not experiencing a flare:

- Documentation indicating an overall beneficial clinical response
    - Low disease activity
    - Reduction in flares
    - Improvement in clinical signs and symptoms
    - **Approve for 12 months**

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## Exclusions

The use of spesolimab will not be covered for the following situations:

- Indication, age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling
- Systemic and/or topical therapy used concomitantly with Spevigo

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## References

1. Spesolimab. Clinical Pharmacology. Revision date 12/17/2024. Accessed on 03/2025.
2. Spevigo (spesolimab-sbzo) injection, for subcutaneous or intravenous use. Prescribing Information. Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT. Revised 03/2024.
3. Bachelez H, Choon SE, Marrakchi S, et al. Trial of spesolimab for generalized pustular psoriasis. N Engl J Med. 2021;385(26):2431-2440. doi:10.1056/NEJMoa2111563.
4. Shah M, Al Aboud DM, Crane JS, et al. Pustular Psoriasis. [Updated 2023 Aug 8]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK537002/

**MVP Health Care Medical Policy**

**Spinal Muscular Atrophy (SMA)**

| | |
|---|---|
| **Type of Policy:** | **Medical Therapy *(administered by the pharmacy department)*** |
| **Prior Approval Date:** | **11/01/2023** |
| **Approval Date:** | **11/01/2024** |
| **Effective Date:** | **01/01/2025** |
| **Related Policies:** | **NA** |

**Codes Requiring Prior Authorization (covered under the medical benefit)**
J2326 Spinraza® (Nusinersen)
J3399 Zolgensma (Onasemnogene abeparvovex-xioi)

**Drugs requiring Prior Authorization (covered under the pharmacy benefit)**
Evrysdi (Risdiplam)

Refer to the Medicare Part D formulary for drugs that may be covered under the Part D benefit.

**Overview**

Nusinersen (Spinraza) is an intrathecal injection that is FDA approved for the treatment of spinal muscular atrophy (SMA) in pediatric and adult patients. SMA is caused by a deletion or mutation of both copies *SMN1* gene that results in a mutated SMN protein. Nusinersen (Spinraza) is an antisense oligonucleotide that binds a specific sequence in the intron downstream of exon 7 of the *SMN2* mRNA transcript. This leads to an increased production of functional full length SMN protein. At the beginning of therapy, nusinersen is administered as a sequence of four loading doses; the first three doses are administered every 14 days and the fourth dose is administered 30 days after the third dose. The patient then receives a maintenance dose which is administered every 4 months.

Spinraza is considered an orphan drug by the FDA and received fast track designation for approval. SMA is an autosomal recessive disease that is caused by a mutation/deletion of the *SMN1* gene. This leads to progressive muscle weakness and muscle atrophy due to degeneration of spinal and lower bulbar motor neurons.

Zolgensma (Onasemnogene abeparvovex-xioi) is a one-time infusion gene therapy FDA approved for the treatment of Spinal Muscular Atrophy (SMA) in pediatric patients under 2 years old. SMA is an inherited neuromuscular disease that causes progressive loss of muscle function. It is caused by a deletion or mutation of both copies *SMN1* gene that results in a mutated SMN protein. Zolgensma (Onasemnogene abeparvovex-xioi) addresses the root cause of SMA by replacing the defective or missing SMN1 gene, thus halting gene progression and improving motor neuron function and survivalZolgensma (Onasemnogene abeparvovex-xioi) was granted breakthrough therapy and priority review by the FDA.

Evrysdi (risdiplam) is an oral medication that is FDA approved for the treatment of spinal muscular atrophy (SMA) in pediatric and adult patients. Risdiplam is designed to treat patients with mutations in chromosome 5q that lead to SMN protein deficiency. Risdiplam is a SMN2 splicing modifier that was shown to increase exon 7 inclusion in SMN2 mRNA. An increase in exon 7 inclusion leads to an increase in production of full length SMN proteins. Risdiplam is taken orally once daily via an oral syringe after a meal at approximately the same time each day. The recommended dosage is determined by age and body weight.

The FDA granted Evrysdi (risdiplam) orphan drug designation and fast track designation approval.

## Indications/Criteria

**Medicaid Variation:** Medications that are a pharmacy benefit are covered and billed to New York State Fee-For-Service (FFS) program. They are defined as medications that go through a retail or specialty pharmacy, including self administered injectable products. Pharmacy medications are subject to FFS's clinical criteria including (but not limited to) coverage, quantity limit, step therapy, and prior authorization. Pharmacy benefit information can be found here: https://www.emedny.org/info/fullform.pdf

**ASO Variation:** Refer to ASO benefit grid for drugs that may be covered

## A. SPINRAZA

Spinraza is FDA approved for:

- Intrathecal injection in pediatric and adult patients for the treatment of spinal muscular atrophy (SMA)

Spinraza will be considered for coverage when the following criteria is met:

- The member has a confirmed diagnosis of Type 1, 2, or 3 spinal muscular atrophy (SMA) **AND**
- Chart notes document genetic testing that indicates:
    - Homozygous deletion/mutation of *SMN1* on chromosome 5q **OR**
    - Compound Heterozygous mutation (e.g., deletion of SMN1 exon 7 [allele 1] and an intragenic mutation of SMN1 [allele 2])
      **AND**
    - Genetic testing reveals at least two *SMN2* copies
      **AND**
- Spinraza is prescribed by a neurologist or geneticist **AND**
- Members must have motor functioning exams performed at baseline using an exam appropriate for the member's age and functioning. Examples of the exams include:
    - Hammersmith Functional Motor Scale Expanded (HFMSE)
    - Hammersmith Infant Neurological Exam (HINE)
    - Upper Limb Module Test (ULM)
    - Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND)

**Initial approval** will be for 3 months, 4 doses to determine the efficacy of the treatment
**Extension requests** for Spinraza will be approved up to 12 months when the following criteria are met:

- The member must have met all criteria specified in the "initiating therapy" section above
  **AND**
- Chart notes are provided documenting the most recent results (must be obtained within one month prior to request) of one of the following scales and must demonstrate symptom improvement from baseline:
    - Hammersmith Functional Motor Scale Expanded (HFMSE)
    - Hammersmith Infant Neurological Exam (HINE)
    - Upper Limb Module Test (ULM)
    - Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND)

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## B. ZOLGENSMA

Zolgensma is FDA approved for:

- One-time infusion in patients younger than 2 years old for the treatment of spinal muscular atrophy (SMA)

Zolgensma will be considered for coverage when the following criteria is met:

- Member is < 2 years old
- The member must be diagnosed with SMA
- Chart notes document genetic testing that indicates:
    - Bi-allelic gene mutation of *SMN1* **AND**
    - At least two *SMN2* copies **AND**
- Zolgensma is prescribed by a neurologist or geneticist
- Members must have motor functioning exams performed at baseline using an exam appropriate for the member's age and functioning. Examples of the exams include:
    - Hammersmith Functional Motor Scale Expanded (HFMSE)
    - Hammersmith Infant Neurological Exam (HINE)
    - Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND
- Documentation of baseline anti-AAV9 antibody titers ≤1:50

Zolgensma will be approved as a **one-time dose** and will not need to be continued for maintenance

### C. EVRYSDI

Evrysdi is FDA approved for:

- Oral solution in pediatric and adult patients for the treatment of spinal muscular atrophy (SMA)

Evrysdi will be considered for coverage when the following criteria is met:

- The member has a confirmed diagnosis of Type 1, 2, or 3 spinal muscular atrophy (SMA) AND
- Chart notes document genetic testing that indicates:
    - Homozygous deletion/mutation of *SMN1* on chromosome 5q **OR**
    - Compound Heterozygous mutation (e.g., deletion of SMN1 exon 7 [allele 1] and an intragenic mutation of SMN1 [allele 2])
      **AND**
    - Genetic testing reveals at least two *SMN2* copies
      **AND**
- Evrysdi is prescribed by a neurologist or geneticist **AND**
- Members must have motor functioning exams performed at baseline using an exam appropriate for the member's age and functioning. Examples of the exams include:
    - Hammersmith Functional Motor Scale Expanded (HFMSE)

- Hammersmith Infant Neurological Exam (HINE)
- Upper Limb Module Test (ULM)
- Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND)
- 6-Minute Walk Test (6MWT)

**Initial approval** will be for a duration of 6 months. Coverage of lost, damaged, or mishandled product will not be covered.
Quantity is limited to the 3 bottles (240ml) per 30 days.

**Extension requests** for Evrysdi will be approved up to 12 months when the following criteria are met:

- The member must have met all criteria specified in the "initiating therapy" section above
  **AND**
- Medical records including the most recent results (must be obtained within one month prior to request) of one of the following scales and must demonstrate symptom improvement from baseline:
  - Hammersmith Functional Motor Scale Expanded (HFMSE)
  - Hammersmith Infant Neurological Exam (HINE)
  - Upper Limb Module Test (ULM)
  - Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND)
  - 6-Minute Walk Test (6MWT)
- Coverage of lost, damaged, or mishandled product will not be covered.
- Quantity is limited to the 3 bottles (240ml) per 30 days.

**Exclusions**

I. Spinraza (nusinersen) is not considered medically necessary and, therefore, is not covered when any of the following are true:
   - No documentation of genetic testing confirming SMA in the medical record
   - The member has SMA that is caused by a mutation other than a *SMN1* deletion/mutation on chromosome 5
   - Medical records indicate member has SMA type 4

- The member has respiratory insufficiency that requires invasive ventilation.
- The member has respiratory insufficiency that requires non-invasive ventilation for ≥16 hours per day
- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling

II. Zolgensma (Onasemnogene abeparvovex-xioi) is not considered medically necessary and, therefore, is not covered when any of the following are true:
- No documentation of genetic testing confirming SMA in the medical record
- The member has SMA that is caused by a mutation other than a *SMN1* deletion/mutation on chromosome 5
- The member has respiratory insufficiency that requires permanent ventilator dependence defined as respiratory assistance for ≥16 hours per day (including noninvasive ventilatory support) continuously for 14 or more days in the absence of an acute reversible illness
- The use of invasive ventilatory support (tracheotomy with positive pressure)
- Member with signs of aspiration based on a swallowing test and unwilling to use an alternative method to oral feeding.
- Advanced SMA (e.g., complete paralysis of limbs, permanent ventilator dependence) as this has not been evaluated
- Member with single base mutation in SMN2
- Combination therapy with Spinraza (nusinersen)
- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling

III. Evrysdi (risdiplam) is not considered medically necessary and, therefore, is not covered when any of the following are true:
- No documentation of genetic testing confirming SMA in the medical record
- The member has SMA that is caused by a mutation other than a SMN1 deletion/mutation on chromosome 5
- Medical records indicate patient has SMA type 4
- The member has respiratory insufficiency that requires invasive ventilation or tracheostomy
- The member has respiratory insufficiency that requires non-invasive ventilation for ≥16 hours per day
- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling
- Combination therapy with Spinraza (nusinersen)

## References


1. Spinraza (nusinersen) [prescribing information]. Cambridge, MA: Biogen; April 2024
2. FDA News Release. FDA approves first drug for spinal muscular atrophy. U.S. Food & Drug Administration. Retrieved from: https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm534611.htm
3. Ionis Pharmaceuticals, Inc. A Study to Assess the Efficacy and Safety of IONIS-SMN Rx in Patients with Later-Onset Spinal Muscular Atrophy. *ClinicalTrials.gov*. retrieved from: https://clinicaltrials.gov/ct2/show/study/NCT02292537
4. Ionis Pharmaceuticals, Inc. A Study to Assess the Efficacy and Safety of IONIS-SMN Rx in Infants with Spinal Muscular Atrophy. *Clinical Trials.gov*. retrieved from: https://clinicaltrials.gov/ct2/show/study/NCT02193074?term=ENDEAR&rank=4&view=record
5. Zolgensma (Onasemnogene abeparvovex-xioi) [prescribing information]. July 2024https://www.zolgensma.com/images/pdf/dosing-and-infusion-guide.pdf
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7. AveXis receives FDA approval for Zolgensma®, the first and only gene therapy for pediatric patients with spinal muscular atrophy (SMA) | Novartis [Internet]. Novartis. 2019 [cited 5 June 2019]. Available from: https://www.novartis.com/news/media-releases/avexis-receives-fda-approval-zolgensma-first-and-only-gene-therapy-pediatric-patients-spinal-muscular-atrophy-sma
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9. FDA News Release. FDA Approves Oral Treatment for Spinal Muscular Atrophy. U.S Food Drug Administration. Retrieved from https://www.fda.gov/news-events/press-announcements/fda-approves-oral-treatment-spinal-muscular-atrophy
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11. Hoffman-La Roche. Investigate Safety, Tolerability, PK, PD, and Efficacy of Risdiplam (RO7034067) in Infants with Type 1 Spinal Muscular Atrophy (FIREFISH). *ClinicalTrials.gov*. Retrieved from https://clinicaltrials.gov/ct2/show/NCT02913482

| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
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| 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 | 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 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

**Spravato® (Esketamine)**

**Type of Policy:** **Medical Therapy *(administered by the pharmacy department)***
**Prior Approval Date:** **10/01/2024**
**Approval Date:** **04/01/2025**
**Effective Date:** **06/01/2025**
**Related Policies:** **NA**

**Codes Requiring Prior Authorization covered under the medical benefit**
S0013, G2082, G2083 Spravato® (Esketamine) nasal spray 1 mg

**Overview**

Spravato (esketamine) is the S-enantiomer of ketamine. It is a non-selective, non-competitive antagonist of N-methyl-D-aspartate (NMDA) receptor, an ionotropic glutamate receptor, thus causing an increase in glutamate and activation of AMPA receptors. Activation of AMPA receptors have strengthened synapses in the frontal cortex, the part of the brain which is closely associated with mood and motivation. Spravato is only available through a **REMS program.**

Spravato (esketamine) is an intranasal spray that is indicated for

- Treatment-resistant depression (TRD) in adults as monotherapy or in conjunction with an oral antidepressant
- Depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior in conjunction with an oral antidepressant

**Medicare Variation:**

Refer to the MVP website for the Medicare Part B policies for coverage criteria of drugs covered under the medical benefit.

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies.

Classified as Confidential

**Indications/Criteria**

**A. <u>Treatment Resistant Depression (TRD)</u>**

Spravato may be considered for coverage of Treatment Resistant Depression as either monotherapy or in conjunction with an oral antidepressant when the following criteria are met:

- Member has a diagnosis of Major Depressive Disorder (MDD) based on DSM-5-TR criteria
- Chart notes indicate the following:
    - Failure of at least 2 antidepressants from two different antidepressant medication classes at the maximally tolerated FDA-approved dose for a minimum of 8 weeks each.
        - If an 8 week trial with two oral antidepressants used at therapeutic dosages, is inappropriate, clinical rationale must be documented in the medical record and will be considered on a case by case basis **AND**
    - Inadequate response to antidepressant in the current depressive episode.
        - Claims history must demonstrate compliance with an antidepressant in the current depressive episode.
- Spravato must be prescribed **AND** administered by a certified provider who is able to properly monitor patient after administration at a **REMS certified clinic.**
    - Treatment center finder:
        - SPRAVATO® Treatment Center Locator | SPRAVATO® (esketamine) Nasal Spray
- Documentation indicates the member has been assessed using an appropriate diagnostic instrument such as the Patient Health Questionnaire-9 (PHQ-9) or Montgomery-Asberg Depression Rating Scale (MADRS) at baseline prior to dose administration and after each week prior to dose administration

- **Initial approval for TRD indication will be for 8 weeks**. MADRS or PHQ-9 Patient Health Questionnaire-9 score at week 4 (after induction phase) and most current MADRS or PHQ-9 score must be submitted with the initial extension request.

- **Extension requests will be approved for TRD up to 3 months if all the following are met:**

- Member has a diagnosis of Major Depressive Disorder (MDD) based on DSM-5-TR criteria
- Spravato continues to be prescribed AND administered by a certified provider
- Chart notes include current PHQ-9 (Patient Health Questionnaire-9) or MADRS score and must demonstrate score and symptom improvement from baseline.

**B. <u>Major Depressive Disorder with suicidal ideation</u>**

Spravato may be considered for coverage for Major Depressive Disorder with suicidal ideation when the following criteria are met:

- Member has a diagnosis of Major Depressive Disorder (MDD) based on DSM-5-TR criteria
- Chart notes documenting the member has experienced acute suicidal ideation or behavior and the member is receiving standard of care (including hospitalization if clinically warranted).
- Spravato must be prescribed **AND** administered by a certified provider who is able to properly monitor patient after administration at a **REMS certified clinic.**
    - Treatment center finder:
        - SPRAVATO® Treatment Center Locator | SPRAVATO® (esketamine) Nasal Spray
- Documentation indicates the member has been assessed using an appropriate diagnostic instrument such as Patient Health Questionnaire-9 (PHQ-9) or Montgomery-Asberg Depression Rating Scale (MADRS) at baseline prior to dose administration and after each week prior to dose administration
- **Initial approval for MDD with acute suicidal ideation or behavior indication** will be for 4 weeks.
- **Extension requests will be approved up to 3 months** and must include documentation of continued benefit to therapy and provider evaluation to determine need for continued treatment.

Classified as Confidential

**Medicaid Variation**

- Prescribers must attest that they have obtained a baseline score using a validated clinical assessment tool for depression (e.g., HAMD17, QIDS-C16C, MADRS, PHQ-9).
- Medical records must support a trial of at least two oral antidepressants prior to esketamine nasal spray (Spravato) when used for Treatment Resistant Depression.

**Initial approval for TRD indication** will be for 8 weeks and requires the prescriber to attest that esketamine nasal spray (Spravato) has resulted in an improvement of depressive symptoms (from baseline) using the same baseline clinical assessment tool for depression (e.g., HAMD17, QIDS-C16C, MADRS, PHQ-9).

**Extension requests for TRD** will be approved for up to 6 months and require the prescriber to attest that esketamine nasal spray (Spravato) has resulted in an improvement of depressive symptoms (from baseline) using the same baseline clinical assessment tool for depression (e.g., HAMD17, QIDS-C16C, MADRS, PHQ-9).

**Initial approval for MDD with acute suicidal ideation or behavior indication** will be for 4 weeks. **Continuation requests** will be approved up to 3 months and require evidence of therapeutic benefit with evaluation to determine need for continued treatment.

**Exclusions**

Spravato (esketamine) is not considered medically necessary and therefore is not covered when any of the following are true:

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling Prescribed for anesthetic use
- Pregnant or planning to become pregnant
- Severe hepatic impairment (Child-Pugh class C)
- History of aneurysm (e.g., aneurysmal vascular disease including thoracic and abdominal aorta, intracranial, and peripheral arterial vessels), arteriovenous malformation
- A history of intracranial bleeding (intracerebral hemorrhage).
- Homicidal ideation, substance/alcohol use disorder in the past year, autism spectrum disorder, recent cannabis use, prior DSM-5-TR diagnosis of psychotic disorder, MDD with psychotic features, bipolar or related disorders, current OCD,

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intellectual disability, borderline personality disorder, antisocial personality disorder, histrionic personality disorder, or narcissistic personality disorder.

**References**


1. Spravato (esketamine) [prescribing information]. Jannesen Pharmaceuticals Lakewood, NJ 2019. Updated 10/2023
2. FDA New Release. FDA approves new nasal spray medication for treatment-resistant depression; available only at a certified doctor's office or clinic Available from: https://www.fda.gov/news-events/press-announcements/fda-approves-new-nasal-spray-medication-treatment-resistant-depression-available-only-certified
3. Johnson & Johnson Press Release. Esketamine Receives Breakthrough Therapy Designation from U.S. Food and Drug Administration for Major Depressive Disorder with Imminent Risk for Suicide. Available at: https://www.jnj.com/media-center/press-releases/esketamine-recieves-breakthrough-therapy-designation-from-us-food-and-drug-administration-for-major-depressive-disorder-with-imminent-risk-of-suicide. Accessed June 2019
4. E Wajs, L Aluisio, R Morrison, EJ Daly, R Lane, P Lim, R Holder, G Sanacora, AH Young, S Kasper, AH Sulaiman, C Li, J Paik, H Manji, D Hough, WC Drevets, JB Singh. Long-Term Safety of Esketamine Nasal Spray Plus an Oral Antidepressant in Patients with Treatment-Resistant Depression: Phase 3, Open Label Safety and Efficacy Study (SUSTAIN-2).
5. National Institute of Mental Health. Sequenced Treatment Alternatives to Relieve Depression (STAR*D) Study. Available at: https://www.nimh.nih.gov/funding/clinical-research/practical/stard
6. American Psychiatric Association. Practice Guidelines for the Treatment of Patients with Major Depressive Disorder: Third Edition. October 2010. Available at: https://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/mdd.pdf
7. Contraindications/precautions. Clinical Pharmacology. September 2021.
8. Dosage and administration of SPRAVATO. (n.d.). Janssenscience.com. Updated May 14, 2024, from https://www.janssenscience.com/products/spravato/medical-content/dosage-and-administration-of-spravato
9. New York State Department of Health. Practitioner Administered Drug Update: New York State Medicaid Fee-for-Service Policy Guidance for Spravato. August 2022 Vol 38 No.9. Link available: Policy Guidance for Spravato.


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| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Complete Wellness | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
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| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D |
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| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D |
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| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D |
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| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D |
| USA Care PPO | Refer to the MVP website for the Medicare Part B and Part D |
| 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 | Refer to the MVP website for the Medicare Part B and Part D |
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| 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).** | |
| *© 2025 MVP Health Plan, Inc. All rights reserved. Descriptions contained within MVP's Medical Policies are not a guarantee of coverage. Each MVP Group or Subscriber Contract contains specific limitations, exclusions and requirements that may affect a Policy. If there is any discrepancy between your Group or Subscriber Contract and a Policy, your Group or Subscriber Contract shall in all cases govern.* | |

***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 |

**MVP Health Care Medical Policy**

**Medicare Part B: Spravato® (Esketamine)**

**Type of Policy:** **Medical Therapy**
**Prior Approval Date:** **11/01/2024**
**Approval Date:** **04/01/2025**
**Effective Date:** **06/01/2025**
**Related Policies:** **NA**

**Codes Requiring Prior Authorization covered under the medical benefit**
S0013 Spravato® (Esketamine) nasal spray 1 mg

**Please refer to relevant CMS LCDs/NCDs/Policy Articles for most up to date Medicare Part B guidance if available**

**Overview/Summary of Evidence**

Spravato (esketamine) is the S-enantiomer of ketamine. It is a non-selective, non-competitive antagonist of N-methyl-D-aspartate (NMDA) receptor, an ionotropic glutamate receptor, thus causing an increase in glutamate and activation of AMPA receptors. Activation of AMPA receptors have strengthened synapses in the frontal cortex, the part of the brain which is closely associated with mood and motivation.
Spravato is only available through a **REMS program.**
Spravato (esketamine) is an intranasal spray that is indicated for

- Treatment-resistant depression (TRD) in adults as monotherapy or in conjunction with an oral antidepressant
- Depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior in conjunction with an oral antidepressant

**Indications/Criteria**

**A. <u>Treatment Resistant Depression (TRD)</u>**

Spravato may be considered for coverage of Treatment Resistant Depression as either monotherapy or in conjunction with an oral antidepressant when the following criteria are met:

- Member has a diagnosis of Major Depressive Disorder (MDD) based on DSM-5-TR criteria
- Chart notes indicate the following:
    - Failure of at least 2 antidepressants from two different antidepressant medication classes at the maximally tolerated FDA-approved dose for a minimum of 8 weeks each.
        - If an 8 week trial with two oral antidepressants used at therapeutic dosages, is inappropriate, clinical rationale must be documented in the medical record and will be considered on a case by case basis **AND**
    - Inadequate response to antidepressant in the current depressive episode.
        - Claims history must demonstrate compliance with an antidepressant in the current depressive episode.
- Spravato must be prescribed **AND** administered by a certified provider who is able to properly monitor patient after administration at a **REMS certified clinic.**
    - Treatment center finder:
        - SPRAVATO® Treatment Center Locator | SPRAVATO® (esketamine) Nasal Spray
- Documentation indicates the member has been assessed using an appropriate diagnostic instrument such as the Patient Health Questionnaire-9 (PHQ-9) or Montgomery-Asberg Depression Rating Scale (MADRS) at baseline prior to dose administration and after each week prior to dose administration

- **Initial approval for TRD indication will be for 8 weeks**. MADRS or PHQ-9 Patient Health Questionnaire-9 score at week 4 (after induction phase) and most current MADRS or PHQ-9 score must be submitted with the initial extension request.

- **Extension requests will be approved for TRD up to 3 months if all the following are met:**
    - Member has a diagnosis of Major Depressive Disorder (MDD) based on DSM-5-TR criteria

- Spravato continues to be prescribed AND administered by a certified provider
- Chart notes include current PHQ-9 (Patient Health Questionnaire-9) or MADRS score and must demonstrate score and symptom improvement from baseline.

**B. <u>Major Depressive Disorder with suicidal ideation</u>**

Spravato may be considered for coverage for Major Depressive Disorder with suicidal ideation when the following criteria are met:

- Member has a diagnosis of Major Depressive Disorder (MDD) based on DSM-5-TR criteria
- Chart notes documenting the member has experienced acute suicidal ideation or behavior and the member is receiving standard of care (including hospitalization if clinically warranted).
- Spravato must be prescribed **AND** administered by a certified provider who is able to properly monitor patient after administration at a **REMS certified clinic.**
    - Treatment center finder:
        - SPRAVATO® Treatment Center Locator | SPRAVATO® (esketamine) Nasal Spray
- Documentation indicates the member has been assessed using an appropriate diagnostic instrument such as Patient Health Questionnaire-9 (PHQ-9) or Montgomery-Asberg Depression Rating Scale (MADRS) at baseline prior to dose administration and after each week prior to dose administration
- **Initial approval for MDD with acute suicidal ideation or behavior indication** will be for 4 weeks.
- **Extension requests will be approved up to 3 months** and must include documentation of continued benefit to therapy and provider evaluation to determine need for continued treatment.

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**Exclusions**

Spravato (esketamine) is not considered medically necessary and therefore is not covered when any of the following are true:

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling
- Prescribed for anesthetic use
- Pregnant or planning to become pregnant
- Severe hepatic impairment (Child-Pugh class C)
- History of aneurysm (e.g., aneurysmal vascular disease including thoracic and abdominal aorta, intracranial, and peripheral arterial vessels), arteriovenous malformation
- A history of intracranial bleeding (intracerebral hemorrhage).
- Homicidal ideation, substance/alcohol use disorder in the past year, autism spectrum disorder, recent cannabis use, prior DSM-5 diagnosis of psychotic disorder, MDD with psychotic features, bipolar or related disorders, current OCD, intellectual disability, borderline personality disorder, antisocial personality disorder, histrionic personality disorder, or narcissistic personality disorder.

**References**


1. Spravato (esketamine) [prescribing information]. Jannesen Pharmaceuticals Lakewood, NJ 2019. Updated 10/2023
2. FDA New Release. FDA approves new nasal spray medication for treatment-resistant depression; available only at a certified doctor's office or clinic Available from: https://www.fda.gov/news-events/press-announcements/fda-approves-new-nasal-spray-medication-treatment-resistant-depression-available-only-certified
3. Johnson & Johnson Press Release. Esketamine Receives Breakthrough Therapy Designation from U.S. Food and Drug Administration for Major Depressive Disorder with Imminent Risk for Suicide. Available at: https://www.jnj.com/media-center/press-releases/esketamine-recieves-breakthrough-therapy-designation-from-us-food-and-drug-administration-for-major-depressive-disorder-with-imminent-risk-of-suicide. Accessed June 2019
4. E Wajs, L Aluisio, R Morrison, EJ Daly, R Lane, P Lim, R Holder, G Sanacora, AH Young, S Kasper, AH Sulaiman, C Li, J Paik, H Manji, D Hough, WC Drevets, JB Singh. Long-Term Safety of Esketamine Nasal Spray Plus an Oral Antidepressant in Patients with Treatment-Resistant Depression: Phase 3, Open Label Safety and Efficacy Study (SUSTAIN-2).


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5. National Institute of Mental Health. Sequenced Treatment Alternatives to Relieve Depression (STAR*D) Study. Available at: https://www.nimh.nih.gov/funding/clinical-research/practical/stard
6. American Psychiatric Association. Practice Guidelines for the Treatment of Patients with Major Depressive Disorder: Third Edition. October 2010. Available at: https://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/mdd.pdf
7. Contraindications/precautions. Clinical Pharmacology. September 2021.
8. Dosage and administration of SPRAVATO. (n.d.). Janssenscience.com. Updated May 14, 2024, from https://www.janssenscience.com/products/spravato/medical-content/dosage-and-administration-of-spravato

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**MVP Health Care Medical Policy**

**Syfovre**

| | |
|---|---|
| **Type of Policy:** | **Medical Therapy** |
| **Prior Approval Date:** | **02/01/2024** |
| **Approval Date:** | **04/01/2025** |
| **Effective Date:** | **06/01/2025** |

**Related Policies:** **Orphan Drug(s) and Biologicals**

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies.

Refer to the MVP website for the Medicare Part B policies for coverage criteria of drugs covered under the medical benefit.

## Drugs Requiring Prior Authorization under the medical benefit

J2781 Syfovre (pegcetacoplan) solution for injection

## Overview

Syfovre (pegcetacoplan) solution for intravitreal injection is a parenteral complement (C3) inhibitor. It is FDA approved for the treatment of geographic atrophy (GA) secondary to the dry advanced form of age-related macular degeneration (AMD). GA is an irreversible eye disease.

## Indications/Criteria

### Geographic atrophy (GA) secondary to age-related macular degeneration (AMD)

Syfovre may be considered for coverage when:

- Prescribed and administered by an ophthalmologist

- Chart notes confirming the diagnosis of GA secondary to AMD
- Best-corrected visual acuity (BCVA) ≥24 letters using Early Treatment Diabetic Retinopathy Study (ETDRS) charts OR approximate Snellen equivalent of 20/320

Initial approval will be for 6 months.

Subsequent approvals will be for up to 1 year duration and require documentation of clinical benefit.

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## Exclusions

The use of Syfovre will not be covered for the following situations:

- Members with ocular or periocular infections
- Members with active intraocular inflammation
- Age, dosage, and/or frequency outside of the FDA approved package labeling
- GA secondary to a condition other than AMD such as Stargardt disease in either eye

## References


1. Syfovre (pegcetacoplan). Clinical Pharmacology. Revised February 24, 2023. Accessed June 5, 2023.
2. Syfovre (pegcetacoplan). Prescribing Information. Apellis Pharmaceuticals, Inc. Waltham, MA. Revised 12/2024. PI_SYFOVRE.pdf (apellis.com).
3. Apellis. (2023, April). *SyfovreTM (Pegcetacoplan Injection)*. Syfovre. https://syfovreecp.com/
4. Prevent Blindness (n.d.). *Eye Diseases & Conditions*. Retrieved June 5, 2023, from https://preventblindness.org/geographic-atrophy/


| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Complete Wellness | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |

| | |
|---|---|
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| USA Care PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

**Medicare Part B: Syfovre**

| | |
|---|---|
| **Type of Policy:** | **Medical Therapy** |
| **Prior Approval Date:** | **02/01/2024** |
| **Approval Date:** | **04/01/2025** |
| **Effective Date:** | **06/01/2025** |
| **Related Policies:** | **Orphan Drug(s) and Biologicals** |

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies.

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## Drugs Requiring Prior Authorization under the medical benefit

J2781 Syfovre (pegcetacoplan) solution for injection

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## Overview

Syfovre (pegcetacoplan) solution for intravitreal injection is a parenteral complement (C3) inhibitor. It is FDA approved for the treatment of geographic atrophy (GA) secondary to the dry advanced form of age-related macular degeneration (AMD). GA is an irreversible eye disease.

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## Indications/Criteria

### Geographic atrophy (GA) secondary to age-related macular degeneration (AMD)

Syfovre may be considered for coverage when:

- Prescribed and administered by an ophthalmologist
- Chart notes confirming the diagnosis of GA secondary to AMD
- Best-corrected visual acuity (BCVA) ≥24 letters using Early Treatment Diabetic Retinopathy Study (ETDRS) charts OR approximate Snellen equivalent of 20/320

Initial approval will be for 6 months.

Subsequent approvals will be for up to 1 year duration and require documentation of clinical benefit.

---

**Exclusions**

The use of Syfovre will not be covered for the following situations:

- Members with ocular or periocular infections
- Members with active intraocular inflammation
- Age, dosage, and/or frequency outside of the FDA approved package labeling
- GA secondary to a condition other than AMD such as Stargardt disease in either eye

**References**

1. Syfovre (pegcetacoplan). Clinical Pharmacology. Revised February 24, 2023. Accessed June 5, 2023.
2. Syfovre (pegcetacoplan). Prescribing Information. Apellis Pharmaceuticals, Inc. Waltham, MA. Revised 12/2024. PI_SYFOVRE.pdf (apellis.com).
3. Apellis. (2023, April). *SyfovreTM (Pegcetacoplan Injection)*. Syfovre. https://syfovreecp.com/
4. Prevent Blindness (n.d.). *Eye Diseases & Conditions*. Retrieved June 5, 2023, from https://preventblindness.org/geographic-atrophy/

**MVP Health Care Medical Policy**

**TECELRA® (afamitresgene autoleucel)**

| | |
|---|---|
| **Type of Policy:** | Drug/Medical Therapy (administered by the pharmacy department) |
| **Prior Approval Date:** | N/A |
| **Approval Date:** | 12/01/2024 |
| **Effective Date:** | 02/01/2025 |
| **Related Polices:** | Experimental or Investigational Procedures, Drugs and Treatments, Clinical Trials |

## Drugs Requiring Prior Authorization under the Medical Benefit

Q2057 TECELRA® (afamitresgene autoleucel) suspension, for intravenous infusion

Refer to the MVP Medicare website for the Medicare Part D Formulary and Part D policies for drugs that may be covered under the Part D benefit.

Refer to the MVP website for the Medicare Part B policies for coverage criteria of drugs covered under the medical benefit.

## Overview

Tecelra is a melanoma-associated antigen A4 (MAGE-A4)-directed genetically modified autologous T cell immunotherapy consisting of CD4 and CD8 positive T cells transduced with a self-inactivating lentiviral vector (LV) to express an affinity-enhanced TCR specific for human MAGE-A4 on the cell surface. MAGE-A4 is an intracellular cancer-testis antigen that has restricted expression in normal tissues and is expressed in synovial sarcoma.

Tecelra is prepared from the patient's peripheral blood mononuclear cells (PBMCs), which are obtained via a standard leukapheresis procedure. The PBMCs are enriched for T cells and are then transduced with a replication-incompetent lentiviral vector (LV)

containing the MAGE-A4 TCR transgene. The transduced T cells are expanded, washed, formulated into a suspension, and cryopreserved.

This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

Tecelra has a black box warning for Cytokine Release Syndrome (CRS).

## Indications/Criteria

Tecelra may be considered for coverage when all of the following are met:

- 18 years of age or older
- Prescribed by or in consultation with an oncologist
- Diagnosis of unresectable or metastatic synovial sarcoma
- Member is positive for HLA-A*02:01P, -A*02:02P, -A*02:03P, or -A*02:06P*
- Documentation that the tumor expresses the MAGE-A4 antigen as determined by FDA-approved or cleared companion diagnostic devices
- Documentation that the member has received prior systemic chemotherapy therapy
- Glomerular filtration rate (GFR) ≥ 60 mL/min
- Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1
- Provider attestation of all the following:
    - To verify pregnancy status of biological females with reproductive potential prior to starting treatment
    - That the member will receive lymphodepleting chemotherapy with fludarabine for 4 days and cyclophosphamide for 3 days
    - That the member will be monitored daily at the healthcare facility for at least 7 days for signs and symptoms of cytokine release syndrome (CRS).
- Hospital administering Tecelra must be appropriately certified to do so. Please see link for treatment centers below: Tecelra Authorized Treatment Centers

Tecelra will be approved as a **one-time dose** within 6 months. Requests for replacement due to lost or damaged product will not be covered. Coverage is contingent on eligibility at the time of infusion.

## Exclusions

- Indication, age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling.
- Repeat Administration
- Adults who are heterozygous or homozygous for HLA-A*02:05P

- Pregnancy
- Members on systemic corticosteroids for at least 14 days prior to leukapheresis and lymphodepletion
- Prophylactic systemic corticosteroids
- Recipients of allogeneic hematopoietic stem cell transplants
- Active infections or active inflammatory disorders

## References

1. TECELRA® (afamitresgene autoleucel) suspension, for intravenous infusion. Package Insert. Adaptimmune, LLC. Philadelphia, PA. Revised 08/2024.
2. AFAMITRESGENE AUTOLEUCEL [Contained in: Tecelra]. In: Micromedex [database on the Internet]. Greenwood Village (CO): IBM Corporation; Last Revised 8/21/2024. Available from: www.micromedexsolutions.com. Subscription required to view.

| Member Product | Medical Management Requirements* |
|---|---|
| **New York Products** | |
| HMO | Prior Auth |
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| MVP EPO HDHP | Prior Auth |
| MVP PPO | Prior Auth |
| MVP PPO HDHP | Prior Auth |
| Student Health Plans | Prior Auth |
| ASO | See SPD |
| **Vermont Products** | |

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|---|---|
| POS in Plan | Prior Auth |
| POS OOP | Prior Auth |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
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| MVP VT HDHP HMO | Prior Auth |
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| 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).** | |

*© 2025 MVP Health Plan, Inc. All rights reserved. Descriptions contained within MVP's Medical Policies are not a guarantee of coverage. Each MVP Group or Subscriber Contract contains specific limitations, exclusions and requirements that may affect a Policy. If there is any discrepancy between your Group or Subscriber Contract and a Policy, your Group or Subscriber Contract shall in all cases govern.*

***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 |

**MVP Health Care Medical Policy**

**Medicare Part B: TECELRA® (afamitresgene autoleucel)**

| | |
|---|---|
| **Type of Policy:** | Drug/Medical Therapy (administered by the pharmacy department) |
| **Prior Approval Date:** | N/A |
| **Approval Date:** | 12/01/2024 |
| **Effective Date:** | 02/01/2025 |
| **Related Polices:** | Experimental or Investigational Procedures, Drugs and Treatments, Clinical Trials |

## Drugs Requiring Prior Authorization Under the Medical Benefit

Q2057 TECELRA® (afamitresgene autoleucel) suspension, for intravenous infusion

Refer to the MVP Medicare website for the Medicare Part D Formulary and Part D policies for drugs that may be covered under the Part D benefit.

Refer to the MVP website for the Medicare Part B policies for coverage criteria of drugs covered under the medical benefit.

**Please refer to relevant CMS LCDs/NCDs/Policy Articles for most up to date Medicare Part B guidance if available.**

## Overview

Tecelra is a melanoma-associated antigen A4 (MAGE-A4)-directed genetically modified autologous T cell immunotherapy consisting of CD4 and CD8 positive T cells transduced with a self-inactivating lentiviral vector (LV) to express an affinity-enhanced TCR specific for human MAGE-A4 on the cell surface. MAGE-A4 is an intracellular cancer-testis antigen that has restricted expression in normal tissues and is expressed in synovial sarcoma.

Tecelra is prepared from the patient's peripheral blood mononuclear cells (PBMCs), which are obtained via a standard leukapheresis procedure. The PBMCs are enriched for T cells and are then transduced with a replication-incompetent lentiviral vector (LV) containing the MAGE-A4 TCR transgene. The transduced T cells are expanded, washed, formulated into a suspension, and cryopreserved.

This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

Tecelra has a black box warning for Cytokine Release Syndrome (CRS).

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**Indications/Criteria**

Tecelra may be considered for coverage when all of the following are met:

- 18 years of age or older
- Prescribed by or in consultation with an oncologist
- Diagnosis of unresectable or metastatic synovial sarcoma
- Member is positive for HLA-A*02:01P, -A*02:02P, -A*02:03P, or -A*02:06P*
- Documentation that the tumor expresses the MAGE-A4 antigen as determined by FDA-approved or cleared companion diagnostic devices
- Documentation that the member has received prior systemic chemotherapy therapy
- Glomerular filtration rate (GFR) ≥ 60 mL/min
- Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1
- Provider attestation
    - To verify pregnancy status of biological females with reproductive potential prior to starting treatment
    - That the member will receive lymphodepleting chemotherapy with fludarabine for 4 days and cyclophosphamide for 3 days
    - That the member will be monitored daily at the healthcare facility for at least 7 days for signs and symptoms of cytokine release syndrome (CRS)
- Hospital administering Tecelra must be appropriately certified to do so. Please see link for treatment centers below: Tecelra Authorized Treatment Centers

Tecelra will be approved as a **one-time dose** within 6 months. Requests for replacement due to lost or damaged product will not be covered. Coverage is contingent on eligibility at the time of infusion.

## Exclusions

- Indication, age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling.
- Repeat Administration
- Adults who are heterozygous or homozygous for HLA-A*02:05P
- Pregnancy
- Members on systemic corticosteroids for at least 14 days prior to leukapheresis and lymphodepletion
- Prophylactic systemic corticosteroids
- Recipients of allogeneic hematopoietic stem cell transplants
- Active infections or active inflammatory disorders

## References

1. TECELRA® (afamitresgene autoleucel) suspension, for intravenous infusion. Package Insert. Adaptimmune, LLC. Philadelphia, PA. Revised 08/2024.
2. AFAMITRESGENE AUTOLEUCEL [Contained in: Tecelra]. In: Micromedex [database on the Internet]. Greenwood Village (CO): IBM Corporation; Last Revised 8/21/2024. Available from: www.micromedexsolutions.com. Subscription required to view.

**MVP Health Care Medical Policy**

# Tepezza (teprotumumab-trbw)

| | |
|---|---|
| **Type of Policy:** | **Drug Therapy** |
| **Prior Approval Date:** | **10/01/2023** |
| **Approval Date:** | **02/01/2025** |
| **Effective Date:** | **04/01/2025** |
| **Related Policies:** | **N/A** |

**Drugs Requiring Prior Authorization under the medical benefit**

J3241 TEPEZZA (teprotumumab-trbw) injection, 500 mg powder vials for solution.

## Medicare Variation

Refer to the MVP website for the Medicare Part D formulary for drugs that may be covered under Part D benefit.

## Overview

TEPEZZA (teprotumumab-trbw) is a fully human monoclonal antibody IV infusion indicated for the treatment of thyroid eye disease (TED). Thyroid eye disease, also known as Grave's ophthalmopathy, is an inflammatory condition primarily impacting the extraocular muscles (the muscles that move the eye) and the orbit (bone cavity in the skull that holds the eyeball). The disease course transitions from an active progressive period characterized by inflammation to a stable and fibrotic (inactive) period. Diagnosis is made based on clinical signs and symptoms including feeling irritation/grittiness in the eyes, red or inflamed conjunctiva, excessive tearing or dry eyes, eyelid swelling, light sensitivity, diplopia (double vision), and proptosis (bulging or displacement of the eyes). The pathogenesis of thyroid eye disease is incompletely understood at this time which has resulted in inconsistently effective treatment of the disease and uncertain modification of the disease outcome itself. Such treatments have included high-dose corticosteroids and radiotherapy of the eye. In many patients with thyroid eye disease, radiotherapy and glucocorticoids result in dose-limiting adverse effects and minimal

improvement in proptosis. Unlike these other methods of treating thyroid eye disease, TEPEZZA is an insulin-like growth factor 1 receptor (IGF-1R) antagonist, blocking its activation and signaling therefore working to attenuate the underlying autoimmune processes involved in ophthalmopathy. IGF-1R has roles in the body in development, metabolism, and immune processes and strong evidence has implicated the IGF-1R in the pathogenesis of TED. In multiple placebo-controlled randomized control trials, TEPEZZZA improved both diplopia and proptosis in patients with active moderate-severe thyroid eye disease at 24 weeks. It also improves the signs and symptoms of Thyroid Eye Disease including eye pain, redness, and swelling.

---

**Indications/Criteria**

TEPEZZA may be considered for coverage when the following criteria are met:

- Member is at least 18 years of age
- Documented diagnosis of Graves' eye disease, also called Graves' Ophthalmopathy or Thyroid Eye disease
- Member must be euthyroid or with mild hypothyroidism or hyperthyroidism, defined as free thyroxine (T4) and free triiodothyronine (T3) levels less than 50% above or below the normal limits for the testing laboratory
- Must be prescribed by, or in consultation with, a specialist in ophthalmology, endocrinology, oculoplastic surgery, or neuro-ophthalmology
- For female patients, healthcare provider has documented the member is not pregnant and that highly effective contraceptive methods have been implemented prior to, during, and for 6 months after treatment has been discussed with the patient.
- For members with pre-existing diabetes, documentation that diabetes is under appropriate glycemic control due to increased risk of hyperglycemia.
- Site of Care
    - Per the MVP Health Care Pharmacy Management Programs policy, Tepezza is subject to Site of Care requirements and must be obtained through a preferred home infusion vendor. Prior Authorization and medical justification is required for Tepezza obtained and administered in other outpatient settings such as a provider's office or hospital facility.
    - MVP will allow 60 days after prior authorization approval for members to transfer to a preferred infusion site.

- This requirement does not apply to MVP Medicare and Medicaid members

**Initial Approval** for 24 weeks (8 infusions administered every 3 weeks).

**Continuation** of TEPEZZA beyond 8 infusions is and will be reviewed on a case-by-case basis.

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## Exclusions

- Prior surgical treatment for Thyroid Eye Disease
- Age, dose, frequency of dosing and/or duration of therapy outside of FDA approved labeling.

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## References


1. Tepezza injection [prescribing information]. Lake Forest, IL: Horizon Therapeutics;July 2023..
2. Smith TJ, Kahaly GL, Ezra DG, et al. Teprotumumab for Thyroid-Associated Ophthalmopathy [internet]. NEJM; 2017 [cited 2021 Aug 23]. Available from: https://www.nejm.org/doi/10.1056/NEJMoa1614949
3. Douglas R, Kahaly GL, Patel A, et al. Teprotumumab for the Treatment of Active Thyroid Eye Disease [internet]. NEJM; 2020 [cited 2021 Aug 24]. Available from: https://www.nejm.org/doi/10.1056/NEJMoa1910434
4. TEPEZZA (teprotumumab-trbw) [prescribing information] Horizon Therapeutics; Revised: 12/2022.


| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Complete Wellness | Refer to the MVP website for the Medicare Part B and Part D |

| | |
|---|---|
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| USA Care PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

# Medicare Part B: Tepezza (teprotumumab-trbw)

| | |
|---|---|
| **Type of Policy:** | **Drug Therapy** |
| **Prior Approval Date:** | **NA** |
| **Approval Date:** | **02/01/2025** |
| **Effective Date:** | **02/01/2025** |
| **Related Policies:** | **N/A** |

**Drugs Requiring Prior Authorization under the medical benefit**

J3241 TEPEZZA (teprotumumab-trbw) injection, 500 mg powder vials for solution.

Refer to the MVP website for the Medicare Part D formulary for drugs that may be covered under Part D benefit.

## Overview

TEPEZZA (teprotumumab-trbw) is a fully human monoclonal antibody IV infusion indicated for the treatment of thyroid eye disease (TED). Thyroid eye disease, also known as Grave's ophthalmopathy, is an inflammatory condition primarily impacting the extraocular muscles (the muscles that move the eye) and the orbit (bone cavity in the skull that holds the eyeball). The disease course transitions from an active progressive period characterized by inflammation to a stable and fibrotic (inactive) period. Diagnosis is made based on clinical signs and symptoms including feeling irritation/grittiness in the eyes, red or inflamed conjunctiva, excessive tearing or dry eyes, eyelid swelling, light sensitivity, diplopia (double vision), and proptosis (bulging or displacement of the eyes). The pathogenesis of thyroid eye disease is incompletely understood at this time which has resulted in inconsistently effective treatment of the disease and uncertain modification of the disease outcome itself. Such treatments have included high-dose corticosteroids and radiotherapy of the eye. In many patients with thyroid eye disease, radiotherapy and glucocorticoids result in dose-limiting adverse effects and minimal improvement in proptosis. Unlike these other methods of treating thyroid eye disease,

TEPEZZA is an insulin-like growth factor 1 receptor (IGF-1R) antagonist, blocking its activation and signaling therefore working to attenuate the underlying autoimmune processes involved in ophthalmopathy. IGF-1R has roles in the body in development, metabolism, and immune processes and strong evidence has implicated the IGF-1R in the pathogenesis of TED. In multiple placebo-controlled randomized control trials, TEPEZZZA improved both diplopia and proptosis in patients with active moderate-severe thyroid eye disease at 24 weeks. It also improves the signs and symptoms of Thyroid Eye Disease including eye pain, redness, and swelling.

---

**Indications/Criteria**

TEPEZZA may be considered for coverage when the following criteria are met:

- Member is at least 18 years of age
- Documented diagnosis of Graves' eye disease, also called Graves' Ophthalmopathy or Thyroid Eye disease
- Member must be euthyroid or with mild hypothyroidism or hyperthyroidism, defined as free thyroxine (T4) and free triiodothyronine (T3) levels less than 50% above or below the normal limits for the testing laboratory
- Must be prescribed by, or in consultation with, a specialist in ophthalmology, endocrinology, oculoplastic surgery, or neuro-ophthalmology
- For female patients, healthcare provider has documented the member is not pregnant and that highly effective contraceptive methods have been implemented prior to, during, and for 6 months after treatment has been discussed with the member.
- For members with pre-existing diabetes, documentation that diabetes is under appropriate glycemic control due to increased risk of hyperglycemia.

**Initial Approval** for 24 weeks (8 infusions administered every 3 weeks).

**Continuation** of TEPEZZA beyond 8 infusions is and will be reviewed on a case-by-case basis.

---

**Exclusions**

- Prior surgical treatment for Thyroid Eye Disease

- Age, dose, frequency of dosing and/or duration of therapy outside of FDA approved labeling.

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## References


1. Tepezza injection [prescribing information]. Lake Forest, IL: Horizon Therapeutics;July 2023..
2. Smith TJ, Kahaly GL, Ezra DG, et al. Teprotumumab for Thyroid-Associated Ophthalmopathy [internet]. NEJM; 2017 [cited 2021 Aug 23]. Available from: https://www.nejm.org/doi/10.1056/NEJMoa1614949
3. Douglas R, Kahaly GL, Patel A, et al. Teprotumumab for the Treatment of Active Thyroid Eye Disease [internet]. NEJM; 2020 [cited 2021 Aug 24]. Available from: https://www.nejm.org/doi/10.1056/NEJMoa1910434
4. TEPEZZA (teprotumumab-trbw) [prescribing information] Horizon Therapeutics; Revised: 12/2022.


| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Complete Wellness | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
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| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
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| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| USA Care PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

# Teplizumab-mzwv

| | |
|---|---|
| **Type of Policy:** | **Drug Therapy** |
| **Prior Approval Date:** | **02/01/2024** |
| **Approval Date:** | **02/01/2025** |
| **Effective Date:** | **04/01/2025** |
| **Related Policies:** | |

## Drugs Requiring Prior Authorization under the medical benefit

J9381 Tzield (teplizumab-mzwv)

## Overview

Tzield is an IV administered anti-CD3 antibody, designed to bind to certain immune system cells, moderate the body's immune response, and delay progression to stage 3 type 1 diabetes (T1D) in adults and pediatric patients 8 years of age and older with stage 2 T1D. T1D is an autoimmune disease resulting from inability to make insulin and requiring insulin replacement.

## Indications/Criteria

Teplizumab may be considered for coverage when the following criteria is met:

- Prescribed by, or in consultation with an endocrinologist
- Diagnosis of stage 2 type 1 diabetes with documentation of the **ALL** following:
    - At least TWO positive pancreatic islet cell autoantibodies (Glutamic acid decarboxylase 65 autoantibody, Insulin autoantibody, Insulinoma-associated antigen 2 autoantibody, Zinc transporter 8 autoantibody, or Islet cell autoantibody) confirmed within the past 6 months
    - Evidence of dysglycemia without overt hyperglycemia using an oral glucose tolerance test.
        - Dysglycemia defined as a fasting glucose level of 110 to 125mg/dL, a 2-hour postprandial plasma glucose level of at least 140 mg/dL and less than 200mg/dL or an intervening postprandial glucose

level at 30, 60, or 90 minutes of greater than 200mg/dL on two occasions within the past 60 days.

- Confirmation that member does not have type 2 diabetes
- Documentation of complete blood count confirming member has hemoglobin greater than 10 g/dL, lymphocyte count greater than 1,000 lymphocytes/mcL, platelet count greater than 150,000 platelets/mcL, and absolute neutrophil count greater than 1,500 neutrophils/mcL.
- Documentation that member does not have alanine aminotransferase (ALT) or aspartate aminotransferase (AST) concentrations greater than 2 times the upper limit of normal (ULN) or bilirubin concentration greater than 1.5 times the ULN.
- Member is 8 years of age or older

**Initial approval** will be for 14 consecutive infusions within two months. Additional courses and requests for replacement due to lost or damaged product will not be covered.

## Exclusions

The use of teplizumab will not be covered for the following situations:

- Dosing, age, and/or frequency outside of the FDA approved package labeling
- Diagnosis of type 2 diabetes
- In patients with active serious infection or chronic infection, other than localized skin infections, or in patients with laboratory or clinical evidence of acute infection with Epstein-Barr virus (EBV) or cytomegalovirus (CMV).

## References

1. Tzield (teplizumab-mzwv) injection package insert. Red Bank, NJ: Provention Bio, Inc.; 12/2023.

| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Complete Wellness | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D |

| | |
|---|---|
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D |
| USA Care PPO | Refer to the MVP website for the Medicare Part B and Part D |
| 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 | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

**Medicare Part B: Teplizumab-mzwv**

| | |
|---|---|
| **Type of Policy:** | **Drug Therapy** |
| **Prior Approval Date:** | **02/01/2024** |
| **Approval Date:** | **02/01/2025** |
| **Effective Date:** | **04/01/2025** |
| **Related Policies:** | **N/A** |

## Drugs Requiring Prior Authorization under the medical benefit

**J9381** Tzield (teplizumab-mzwv)

## Overview/Summary of Evidence

Tzield is an IV administered anti-CD3 antibody, designed to bind to certain immune system cells, moderate the body's immune response, and delay progression to stage 3 type 1 diabetes (T1D) in adults and pediatric patients 8 years of age and older with stage 2 T1D. T1D is an autoimmune disease resulting from inability to make insulin and requiring insulin replacement.

## Indications/Criteria

Teplizumab may be considered for coverage when the following criteria is met:

- Prescribed by, or in consultation with an endocrinologist
- Diagnosis of stage 2 type 1 diabetes with documentation of the **ALL** following:
    - At least TWO positive pancreatic islet cell autoantibodies (Glutamic acid decarboxylase 65 autoantibody, Insulin autoantibody, Insulinoma-associated antigen 2 autoantibody, Zinc transporter 8 autoantibody, or Islet cell autoantibody) confirmed within the past 6 months
    - Evidence of dysglycemia without overt hyperglycemia using an oral glucose tolerance test. Dysglycemia defined as a fasting glucose level of

110 to 125mg/dL, a 2-hour postprandial plasma glucose level of at least 140 mg/dL and less than 200mg/dL or an intervening postprandial glucose level at 30, 60, or 90 minutes of greater than 200mg/dL on two occasions within the past 60 days.

- Confirmation that member does not have type 2 diabetes
- Documentation of complete blood count confirming member has hemoglobin greater than 10 g/dL, lymphocyte count greater than 1,000 lymphocytes/mcL, platelet count greater than 150,000 platelets/mcL, and absolute neutrophil count greater than 1,500 neutrophils/mcL.
- Documentation that member does not have alanine aminotransferase (ALT) or aspartate aminotransferase (AST) concentrations greater than 2 times the upper limit of normal (ULN) or bilirubin concentration greater than 1.5 times the ULN.
- Member is 8 years of age or older

**Initial approval** will be for 14 consecutive infusions within two months. Additional courses and requests for replacement due to lost or damaged product will not be covered.

---

**Exclusions**

The use of teplizumab will not be covered for the following situations:

- Dosing, age, and/or frequency outside of the FDA approved package labeling
- Diagnosis of type 2 diabetes
- In patients with active serious infection or chronic infection, other than localized skin infections, or in patients with laboratory or clinical evidence of acute infection with Epstein-Barr virus (EBV) or cytomegalovirus (CMV).

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**References**

1. Tzield (teplizumab-mzwv) injection package insert. Red Bank, NJ: Provention Bio, Inc.; 12/2023.

**MVP Health Care Medical Policy**

**Tocilizumab**

| | |
|---|---|
| **Type of Policy:** | **Medical Therapy** |
| **Prior Approval Date:** | **03/01/2023** |
| **Approval Date:** | **02/01/2024** |
| **Effective Date:** | **04/01/2024** |
| **Related Policies:** | **Apremilast, Adalimumab , Infliximab, Risankizumab, Secukinumab, Tofacitinib, Upadacitinib, Ustekinumab, Ozanimod, Abatacept, Golimumab, Certolizumab** |

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies.

Refer to the MVP website for the Medicare Part B policies for coverage criteria of drugs covered under the medical benefit.

**Drugs Requiring Prior Authorization under the pharmacy benefit**

Actemra SQ is non-preferred under the pharmacy benefit

**Drugs Requiring Prior Authorization under the medical benefit**

J3262 tocilizumab, 1mg injection (Actemra injection)

**Overview**

Tocilizumab is a humanized interleukin-6 (IL-6) receptor-inhibiting monoclonal antibody produced in mammalian (Chinese hamster ovary) cells. It is FDA approved to treat moderate to severe rheumatoid arthritis (RA), polyarticular and systemic juvenile idiopathic arthritis (pJIA and sJIA), giant cell arteritis (GCA or temporal arteritis), systemic sclerosis-associated interstitial lung disease (SSc-ILD), and cytokine release syndrome

(CRS). Members should be screened for immunologic and infectious disease prior to initiating therapy.

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**Indications/Criteria**

**Medicaid Variation:** Medications that are a pharmacy benefit are covered and billed to New York State Fee-For-Service (FFS) program. They are defined as medications that go through a retail or specialty pharmacy, including self administered injectable products. Pharmacy medications are subject to FFS's clinical criteria including (but not limited to) coverage, quantity limit, step therapy, and prior authorization. Pharmacy benefit information can be found here: https://www.emedny.org/info/fullform.pdf

A. For all indications, Tocilizumab SQ (Actemra) is non-formulary and will only be considered for **pharmacy** coverage when:
    - Documented failure, contraindication or ineffective response to all preferred/formulary therapies for the specific indication.

B. For all indications, Tocilizumab IV (Actemra) may be considered for **medical** coverage when:
    - Must be prescribed for an FDA approved indication **AND**
    - Must be ordered by or with consult from a rheumatologist/immunologist **AND**
    - Documentation identifies failure of **preferred** self-administered biologic therapies to treat the condition **AND**
    - Rationale and documentation is provided identifying why member or caregiver is unable to self-administer **AND**
    - Site of Care
        - Per the MVP Health Care Pharmacy Management Programs policy, Tocilizumab IV is subject to Site of Care requirements and must be obtained through a preferred home infusion vendor. Prior Authorization and medical justification is required for Tocilizumab IV obtained and administered in other outpatient settings such as a provider's office or hospital facility.
        - MVP will allow 60 days after prior authorization approval for members to transfer to a preferred infusion site.
        - This requirement does not apply to MVP Medicare and Medicaid members

C. **Giant Cell Arteritis**

Tocilizumab may be considered for coverage for Giant Cell Arteritis when the above criteria is met **AND**:

- Treatment must be directed by or in consultation with a Rheumatologist or Immunologist
- Member has received high-dose glucocorticoids (prednisone 40mg to 60mg) but is unable to taper without disease flare **OR**
- The member has a contraindication to the use of glucocorticoids

**Initial approval** for **6 months**.

**Extension requests** will be approved for 12 months if the member has a continued benefit to therapy **AND** there is medical necessity for use of the IV formulation instead of a self-administered formulation.
**Extension requests** where Tocilizumab IV (Actemra) did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

D. **Juvenile Idiopathic Arthritis**

Tocilizumab to treat Juvenile idiopathic arthritis will be reviewed on a case-by-case basis using the American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis.

**Initial approval** for **6 months**.

**Extension requests** will be approved for 12 months if the member has a continued benefit to therapy **AND** there is medical necessity for use of the IV formulation instead of a self-administered formulation.
**Extension requests** where Tocilizumab IV (Actemra) did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

E. **Rheumatoid Arthritis**

Tocilizumab may be considered for coverage for Rheumatoid Arthritis when the above criteria is met **AND**:

- Documentation identifies failure of nonbiologic disease modifying anti-rheumatic drugs (DMARDs) and NSAIDs if indicated; **AND**Rationale and documentation are provided identifying why member or caregiver is unable to self-administer

**Initial approval** for **6 months**.

**Extension requests** will be approved for 12 months if the member has a continued benefit to therapy **AND** there is medical necessity for use of the IV formulation instead of a self-administered formulation.
**Extension requests** where Tocilizumab IV (Actemra) did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

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## Exclusions

The use of Tocilizumab will not be covered for the following situations:

- Dosing, age, and/or frequency outside of the FDA approved package labeling
- Combination therapy that is not supported by current clinical guidelines

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## References


1. Clinical Pharmacology. Tocilizumab (Actemra). Revised 12/22/2022. Accessed 01/04/2023
2. Fraenkel et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care & Research Vol. 73, No. 7, July 2021, pp 924–939 DOI 10.1002/acr.24596. Available at: 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis (contentstack.io).
3. Actemra (tocilizumab) injection, for intravenous or subcutaneous use. Genentech, Inc. San Francisco, CA. Revised December 2022.
4. 2021 American College of Rheumatology Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Oligoarthritis, Temporomandibular Joint Arthritis, and Systemic Juvenile Idiopathic Arthritis. Arthritis and Rheumatology. Vol 74 No. 4 April 2022, pp553-569. Available at: https://www.rheumatology.org/Portals/0/Files/ACR-JIA%20Guideline-Oligo-TMJ-sJIA-EarlyView.pdf


| Member Product | Medical Management Requirements* |
|---|---|
| **New York Products** | Prior Auth |
| 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 | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Medicare Gold Giveback | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D |
| 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).** | |
| *© 2024 MVP Health Plan, Inc. All rights reserved. Descriptions contained within MVP's Medical Policies are not a guarantee of coverage. Each MVP Group or Subscriber Contract contains specific limitations, exclusions and requirements that may affect a Policy. If there is any discrepancy between your Group or Subscriber Contract and a Policy, your Group or Subscriber Contract shall in all cases govern.* | |

***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 |

**MVP Health Care Medical Policy**

**Medicare Part B: Tocilizumab**

| | |
|---|---|
| **Type of Policy:** | **Medical Therapy** |
| **Prior Approval Date:** | **11/01/2023** |
| **Approval Date:** | **02/01/2024** |
| **Effective Date:** | **04/01/2024** |
| **Related Policies:** | **Abatacept, Certolizumab, Golimumab, Infliximab, Risankizumab, Ustekinumab** |

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies for drugs that may be covered under the Part D benefit.

## Drugs Requiring Prior Authorization under the medical benefit

J3262 tocilizumab, 1mg injection (Actemra injection)

## Overview/Summary of Evidence

Tocilizumab is a humanized interleukin-6 (IL-6) receptor-inhibiting monoclonal antibody produced in mammalian (Chinese hamster ovary) cells. It is FDA approved to treat moderate to severe rheumatoid arthritis (RA), polyarticular and systemic juvenile idiopathic arthritis (pJIA and sJIA), giant cell arteritis (GCA or temporal arteritis), systemic sclerosis-associated interstitial lung disease (SSc-ILD), and cytokine release syndrome (CRS). Members should be screened for immunologic and infectious disease prior to initiating therapy.

## Indications/Criteria

A. For all indications, Tocilizumab IV (Actemra) may be considered for **medical** coverage when:
   - Must be prescribed for an FDA approved indication **AND**
   - Must be ordered by or with consult from a rheumatologist/immunologist **AND**
   - Member has coverage under Medicare Part B and meets the criteria below for a provider administered drug identified in this policy

B. **Giant Cell Arteritis**

   Tocilizumab may be considered for coverage for Giant Cell Arteritis when the above criteria is met **AND**:
   - Treatment must be directed by or in consultation with a Rheumatologist or Immunologist
   - Member has received high-dose glucocorticoids (prednisone 40mg to 60mg) but is unable to taper without disease flare **OR**
   - The member has a contraindication to the use of glucocorticoids

**Initial approval** for **6 months**.

**Extension requests** will be approved for 12 months if the member has a continued benefit to therapy
**Extension requests** where Tocilizumab IV (Actemra) did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

C. **Juvenile Idiopathic Arthritis**

   Tocilizumab to treat Juvenile idiopathic arthritis will be reviewed on a case-by-case basis using the American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis.

**Initial approval** for **6 months**.

**Extension requests** will be approved for 12 months if the member has a continued benefit to therapy **AND** there is medical necessity for use of the IV formulation instead of a self-administered formulation.
**Extension requests** where Tocilizumab IV (Actemra) did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

D. **Rheumatoid Arthritis**

Tocilizumab may be considered for coverage for Rheumatoid Arthritis when the above criteria is met **AND**:

Documentation identifies failure of nonbiologic disease modifying anti-rheumatic drugs (DMARDs) and NSAIDs if indicated

**Initial approval** for **6 months**.

**Extension requests** will be approved for 12 months if the member has a continued benefit to therapy.
**Extension requests** where Tocilizumab IV (Actemra) did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

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**Exclusions**

The use of Tocilizumab will not be covered for the following situations:

- Dosing, age, and/or frequency outside of the FDA approved package labeling
- Combination therapy that is not supported by current clinical guidelines

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**References**

1. Clinical Pharmacology. Tocilizumab (Actemra). Revised 12/22/2022. Accessed 01/04/2023
2. Fraenkel et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care & Research Vol. 73, No. 7, July 2021, pp 924–939 DOI 10.1002/acr.24596. Available at: 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis (contentstack.io).
3. Actemra (tocilizumab) injection, for intravenous or subcutaneous use. Genentech, Inc. San Francisco, CA. Revised December 2022.
4. 2021 American College of Rheumatology Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Oligoarthritis, Temporomandibular Joint Arthritis, and Systemic Juvenile Idiopathic Arthritis. Arthritis and Rheumatology. Vol 74 No. 4 April 2022, pp553-569. Available at: https://www.rheumatology.org/Portals/0/Files/ACR-JIA%20Guideline-Oligo-TMJ-sJIA-EarlyView.pdf

**MVP Health Care Medical Policy**

**Tofacitinib**

**Type of Policy:** **Drug Therapy**
**Prior Approval Date:** **10/01/2023**
**Approval Date:** **10/01/2024**
**Effective Date:** **01/01/2025**
**Related Policies:** **Adalimumab**
**Apremilast**
**Etanercept**
**Infliximab**
**Risankizumab**
**Secukinumab**
**Upadacitinib**
**Ustekinumab**
**Zeposia**

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies.

## Drugs Requiring Prior Authorization under the pharmacy benefit

Xeljanz/XR (tofacitinib) tablet

Xeljanz (tofacitinib) 1mg/mL oral solution

## Overview

Tofacitinib (Xeljanz/XR) is an oral Janus Kinase (JAK) inhibitor and considered a targeted synthetic disease-modifying antirheumatic drug (tsDMARD).

Tofacitinib is indicated for the treatment of adult members with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers, the treatment of adult members with active psoriatic arthritis (PsA) who have had an inadequate response or intolerance to one or more TNF blockers, the treatment of adult members with active ankylosing spondylitis (AS) who have had an inadequate response or intolerance to one or more TNF blockers, and the treatment of adult members with moderately to severely active ulcerative colitis (UC) who have had an inadequate response or intolerance to one or more TNF blockers.

Xeljanz/Xeljanz Oral Solution is indicated for the treatment of active polyarticular course juvenile idiopathic arthritis (pcJIA) in members 2 years of age and older who have had an inadequate response or intolerance to one or more TNF blockers.

Members should be screened for immunologic and infectious disease prior to initiating therapy.

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**Indications/Criteria**

**Medicaid Variation:** Medications that are a pharmacy benefit are covered and billed to New York State Fee-For-Service (FFS) program. They are defined as medications that go through a retail or specialty pharmacy, including self administered injectable products. Pharmacy medications are subject to FFS's clinical criteria including (but not limited to) coverage, quantity limit, step therapy, and prior authorization. Pharmacy benefit information can be found here: https://www.emedny.org/info/fullform.pdf

**A. For all indications, the following criteria must be met in addition to the specific diagnosis criteria below.**

- Prescription drugs covered under the pharmacy benefit must be self-administered. If office administration is being requested documentation must be provided identifying why the member or caregiver is unable to administer the medication.
- Must be ordered by or with consult from a rheumatologist, immunologist, dermatologist, gastroenterologist, or colorectal surgeon

- Must be prescribed for an FDA approved indication

**B. Rheumatoid Arthritis (RA)**

Tofacitinib may be considered for coverage when the following criteria is met:

- Member has a diagnosis of moderate to severe active adult RA as defined by persistent or recurrent symptoms with documented synovitis and morning stiffness of significant duration to inhibit activities of daily living
- Chart notes are provided documenting a failure to respond to a three-month trial of methotrexate at a maximally tolerated dose.
    - Failure is demonstrated by documentation of provider assessment without improvement in joint counts and/or physical symptoms and inflammatory markers while on therapy.
    - If the member has a contraindication or significant intolerance to methotrexate
        - Chart notes documenting a failure to respond to at least one other nonbiologic DMARD at a maximally tolerated dose for at least 3 months AND documentation confirming why methotrexate cannot be used is required. If a trial of methotrexate is not appropriate due to alcohol use, chart notes must be provided indicating that the patient has been counseled on the need to abstain from alcohol use while taking methotrexate and is unwilling to abstain from alcohol use.
        - Tofacitinib may be used without prior DMARD trial if the member has an acute, aggressive, very rapidly progressive intense inflammatory symmetrical arthritis disease as defined by their rheumatologist
- Chart notes are provided documenting an inadequate response or intolerance to one tumor necrosis factor (TNF) inhibitor
    - Documentation must be provided if TNF inhibitor therapy is not considered medically appropriate

**Initial approval** will be for **12 months**.

**Extensions requests** will be approved **up to 3 years** if the member has a continued benefit to therapy. Extension requests where the tofacitinib did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

**C. Psoriatic Arthritis (PsA)**

Tofacitinib may be considered for coverage when the following criteria is met:

- Member has a diagnosis of moderate to severe PsA as indicated by three or more tender joints AND three or more swollen joints on two separate occasions at least one month apart.
- Chart notes documenting failure of at least one NSAID at maximum tolerated dose unless the member has contraindications to NSAID therapy such as cardiovascular disease, peptic ulcer disease or renal disease **AND**
- Chart notes documenting a failure to respond to an adequate trial of at least one of the following nonbiologic disease modifying anti-rheumatic drugs (DMARDs): leflunomide, sulfasalazine, or methotrexate.
    - **Members with pure axial manifestations** do not have to have a trial of nonbiologic disease modifying anti-rheumatic drugs (DMARDs)
    - If a trial of methotrexate is not appropriate due to alcohol use and both leflunomide and sulfasalazine are not clinically appropriate, chart notes must be provided indicating that the member has been counseled on the need to abstain from alcohol use while taking methotrexate and is unwilling to abstain from alcohol use.
- Chart notes are provided documenting an inadequate response or intolerance to one tumor necrosis factor (TNF) inhibitor
    - Documentation must be provided if TNF inhibitor therapy is not considered medically appropriate

**Initial approval** will be for **12 months**.

**Extensions requests** will be approved **up to 3 years** if the member has a continued benefit to therapy. Extension requests where the tofacitinib did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

### D. Ankylosing Spondylitis (AS)

Tofacitinib may be considered for coverage when the following criteria is met:

- Member has a diagnosis of moderate to severe AS
- Chart notes documenting a failure of at least one NSAID at maximum tolerated dose **AND**
- Chart notes are provided documenting significant clinical symptoms such as fatigue, spinal pain, arthralgia, inflammation of joints and tendons, morning stiffness duration and therapy **AND**
- Chart notes are provided documenting an insufficient response to at least one local corticosteroid injection in members with symptomatic peripheral arthritis **AND**

- **For members with persistent peripheral arthritis:** Failure of sulfasalazine or methotrexate at maximum tolerated dose
- **Members with pure axial manifestations** do not have to have a trial of nonbiologic disease modifying anti-rheumatic drugs (DMARDs)
- Chart notes are provided documenting an inadequate response or intolerance to one tumor necrosis factor (TNF) inhibitor
    - Documentation must be provided if TNF inhibitor therapy is not considered medically appropriate

**Initial approval** will be for **12 months**.

**Extensions requests** will be approved **up to 3 years** if the member has a continued benefit to therapy. Extension requests where the tofacitinib did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

### E. Ulcerative Colitis (UC)

Tofacitinib may be considered for coverage when the following criteria is met:

- A diagnosis of moderate to severe Ulcerative Colitis
- Chart notes are provided documenting an inadequate response, intolerance, or contraindication to conventional therapy for maintenance of remission (i.e.:, anti-inflammatory aminosalicylates [e.g., mesalamine (5-ASA), sulfasalazine], 6-mercaptopurine, and azathioprine)
    - If conventional therapy is not considered medically appropriate, documentation must be provided
- Chart notes are provided documenting an inadequate response or intolerance to one tumor necrosis factor (TNF) inhibitor
    - Documentation must be provided if TNF inhibitor therapy is not considered medically appropriate

**Initial approval** will be for **12 months**.

**Extensions requests** will be approved **up to 3 years** if the member has a continued benefit to therapy. Extension requests where the tofacitinib did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

### F. Polyarticular Juvenile Idiopathic Arthritis (JIA)

Tofacitinib may be considered for coverage when the following criteria is met:

- Requests will be reviewed on a case-by-case basis using the American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis
- Chart notes are provided documenting an inadequate response or intolerance to one tumor necrosis factor (TNF) inhibitor

- Documentation must be provided if TNF inhibitor therapy is not considered medically appropriate

**Initial approval** will be for **12 months**.

**Extensions requests** will be approved **up to 3 years** if the member has a continued benefit to therapy. Extension requests where the tofacitinib did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

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**Exclusions**

The use of tofacitinib will not be covered for the following situations:

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling
- Combination therapy that is not supported by current guidelines
- Should not be used for members at high risk for infections or who have active infections including chronic or localized infections
- Avoid using tofacitinib in members that may be at increased risk of thrombosis and thromboembolism; use with caution in those with thromboembolic disease
- Known malignancy or risk factors in developing malignancy
- Lymphocyte count less than 500 cells/$mm^3$, ANC less than 1000
- Hemoglobin less than 8.0 g/dL
- Liver function tests greater than 3 times upper limit of normal
- Administration of live vaccine 6 weeks prior to start of tofacitinib

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**References**

1. Xeljanz™ (tofacitinib) tablets. Prescribing Information. New York, NY: Pfizer Labs. Revised May 2024.

2. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis

3. ACG Clinical Guidline: Ulcerative Colitis in Adults. The American Journal of Gastroenterology: March 2019 - Volume 114 - Issue 3 - p 384-413 doi: 10.14309/ajg.0000000000000152. Accessed: ACG Clinical Guideline: Ulcerative Colitis in Adults : Official journal of the American College of Gastroenterology | ACG (lww.com)

4. Ward Michael, Atul Deodhar et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondylosrthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. Arthritis and Rheumatology. Vol 71 (No. 10). October 2019, pp 1599-1613. Available at: https://www.rheumatology.org/Portals/0/Files/AxialSpA-Guideline-2019.pdf

5. 2021 American College of Rheumatology Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Oligoarthritis, Temporomandibular Joint Arthritis, and Systemic Juvenile Idiopathic Arthritis. Arthritis and Rheumatology. Vol 74 No. 4 April 2022, pp553-569. Available at: https://www.rheumatology.org/Portals/0/Files/ACR-JIA%20Guideline-Oligo-TMJ-sJIA-EarlyView.pdf

6. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. *Journal of Psoriasis and Psoriatic Arthritis*. 2019;4(1):31-58. doi:10.1177/2475530318812244

7. Ringold S, Weiss PF, et al. 2013 Update of the 2011 American College of Rheumatology Recommendations for the Treatment of Juvenile Idiopathic Arthritis. Arthritis Rheum. 2013;65:2499-2512

| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Medicare Gold Giveback | Refer to the MVP website for the Medicare Part B and Part D policies. |

| | |
|---|---|
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D |
| 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).** | |
| *© 2024 MVP Health Plan, Inc. All rights reserved. Descriptions contained within MVP's Medical Policies are not a guarantee of coverage. Each MVP Group or Subscriber Contract contains specific limitations, exclusions and requirements that may affect a Policy. If there is any discrepancy between your Group or Subscriber Contract and a Policy, your Group or Subscriber Contract shall in all cases govern.* | |

***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 |

**MVP Health Care Medical Policy**

**Tofersen**

**Type of Policy:** Medical therapy (administered by the pharmacy department)

**Prior Approval Date:** NA

**Approval Date:** 10/01/2024

**Effective Date:** 01/01/2025

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies.

## Drugs Requiring Prior Authorization under the medical benefit

J1304 Qalsody (tofersen)

## Overview

Tofersen is an intrathecal, antisense oligonucleotide indicated for the treatment of amyotrophic lateral sclerosis (ALS) in adults who have a mutation in the superoxide dismutase 1 (SOD1) gene. Tofersen approval was based on a reduction in plasma neurofilament light chain (NfL) and continued approval may be contingent upon verification of clinical benefit.

## Indications/Criteria

### A. Amyotrophic Lateral Sclerosis (ALS)

Qalsody may be considered for coverage when all of the following criteria are met:

- Member has a confirmed diagnosis of ALS

- Member has a confirmed mutation in the superoxide dismutase 1 (SOD1) gene
- Qalsody is prescribed by or in consultation with a neurologist
- Member has a forced vital capacity (FVC) or slow vital capacity (SVC) greater than or equal to 45% of predicted value for gender, height and age
- Member does not have invasive ventilation or a tracheostomy.

**Initial approval** will be for 6 months

**Extension requests** will be approved for up to one year if the member has had a documented clinical benefit from therapy with Qalsody and invasive ventilation or tracheostomy is not required.
Extension requests where Qalsody did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

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## Exclusions

The use of Qalsody will not be covered for the following situations:

- Dosing, age, and/or frequency outside of the FDA approved package labeling

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## References


1. Qalsody [package insert]. Cambridge, MA. Biogen INC. Revised April 2023.
2. Biogen. January 20, 2021 to July 16, 2021. An Efficacy, Safety, Tolerability, Pharmacokinetics and Pharmacodynamics Study of BIIB067 (Tofersen) in Adults With Inherited Amyotrophic Lateral Sclerosis (ALS) (VALOR (Part C)). NCT02623699. Study Details | An Efficacy, Safety, Tolerability, Pharmacokinetics and Pharmacodynamics Study of BIIB067 (Tofersen) in Adults With Inherited Amyotrophic Lateral Sclerosis (ALS) | ClinicalTrials.gov
3. ALS Association. Therapies Targeting ALS- Linked Genetic Mutations. Accessed July 24, 2024. Therapies Targeting ALS-Linked Genetic Mutations | The ALS Association
4. Roggenbuck, J., Eubank, B.H., et al. Evidence-based consensus guidelines for ALS genetic testing and counseling. Annals of Clinical and Translational Neurology. Vol 10: Issue 11.

November 2023; pages 2074-2091. Evidence-based consensus guidelines for ALS genetic testing and counseling - Roggenbuck - 2023 - Annals of Clinical and Translational Neurology - Wiley Online Library

| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Medicare Gold Giveback | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

# Transgender Hormone Policy (Commercial/Exchange/Child Health Plus)

**Type of Policy:** Drug Therapy
**Prior Approval Date:** 02/01/2023
**Approval Date:** 02/01/2024
**Effective Date:** 04/01/2024
**Related Policies:**

Gender Dysphoria Treatment (Commercial and Medicare)
Gender Dysphoria Treatment (Medicaid and HARP)
Transgender Hormone Policy (Medicaid/HARP)
Experimental or Investigational Procedures, Behavioral Health Services, Drugs and Treatments, Off-Label use of FDA Approved Drugs, and Clinical Trials

## Drugs Requiring Prior Authorization

Conjugated estrogens
Estradiol
Injectable Testosterone formulations
Topical Testosterone formulations

## Drugs subject to Retrospective Review

The following gonadotropin-releasing hormone agents (pubertal suppressants)

- Lupron Depot

## Overview

Gender dysphoria is defined as a marked difference between the individual's expressed/experienced gender and the gender others would assign them, continuing for at least six months. Gender dysphoria is manifested in a variety of ways, including strong desires to be

treated as another gender or to be rid of one's sex characteristics, or a strong conviction that one has feelings and reactions typical of another gender.[2]

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**Indications/Criteria**

MVP health Care recognizes that gender dysphoria affects people of all genders, and is not limited to people with binary gender identities. Coverage of medically necessary services is allowed for binary and non-binary gender identities. Testosterone (injectable and topical), conjugated estrogens or estradiol may be considered medically necessary when the following criteria are met:

- Patient is at least 16 years old
    - Requests for coverage of cross-sex hormones for members less than 16 years old will be reviewed on case-by-case basis.
- Diagnosis of gender dysphoria
- Must be used for a Food and Drug Administration (FDA) approved indication, or use supported in at least one of the Official Compendia as defined in federal law under the Social Security Act section 1927 (g)(1)(B)(i), (k)(2)
- For patients that have undergone gender reassignment surgery, post-transition care will be covered

Approvals will be for a period of one year.

Gonadotropin-releasing hormone agents (pubertal suppressants) are subject to retro-review and will be approved if all the following criteria are met:

- Patient has a diagnosis of gender dysphoria;
- Patient has experienced puberty to at least Tanner stage 2, and pubertal changes have resulted in an increase in gender dysphoria;
- Patient does not suffer from psychiatric comorbidity that interferes with a diagnostic work-up or treatment
- Patient has adequate psychological and social support during treatment
- Patient 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.

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## Exclusions

- Hormone products that do not meet MVP Experimental and Investigational Policy will not be covered

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**References**

1. New York State Department of Health. Medicaid Update. Volume 31. March 2015
2. "Gender Dysphoria." American Psychiatric Association, 2013. Web. http://www.dsm5.org/documents/gender%20dysphoria%20fact%20sheet.pdf. Accessed July 7, 2015.
3. New York State Department of Health. Medicaid Update. Volume 33. January 2017
4. New York State Department of Health. Criteria Standards for the Authorization and Utilization Management of Hormone Therapy and Surgery for the Treatment of Gender Dysphoria. July 2018
5. New York State Office of Mental Health. Memorandum. March 18, 2020. Clinical Review Criteria for the Treatment of Gender Dysphoria (ny.gov)
6. New York State Department of Financial Services. Department of Financial Services Announces Final Regulation to Prevent Discrimination Against Transgender and Gender Non-Conforming Individuals. April 29, 2020. Press Release - April 29, 2020: Department of Financial Services Announces Final Regulation to Prevent Discrimination Against Transgender and Gender Non-Conforming Individuals | Department of Financial Services (ny.gov)
7. New York State Department of Financial Services. Insurance Circular Letter No. 13 (2020). June 28, 2020. Insurance Circular Letter No. 13 (2020): Discrimination Based on Sexual Orientation, Gender Identity or Expression, and Transgender Status and Coverage for Preventive Care and Screenings | Department of Financial Services (ny.gov)

| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Medicare Gold Giveback | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |

| | |
|---|---|
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D |
| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

# Transgender Hormone Policy (Medicaid/HARP)

**Type of Policy:** **Drug Therapy**
**Prior Approval Date:** **02/01/2024**
**Approval Date:** **02/01/2025**
**Effective Date:** **04/01/2025**
**Related Policies:**
Gender Reassignment Surgery (Medicaid and Harp)
Transgender Hormone Policy (Commercial/Exchange/Child Health Plus)
Experimental or Investigational Procedures, Behavioral Health Services, Drugs and Treatments, Off-Label use of FDA Approved Drugs, and Clinical Trials

**Drug subject to retrospective review**

The following fonadotropin-releasing hormone agents (pubertal suppressants)

- Lupron Depot

## Overview

Gender dysphoria is defined as a marked difference between the individual's expressed/experienced gender and the gender others would assign them, continuing for at least six months. Gender dysphoria is manifested in a variety of ways, including strong desires to be treated as the other gender or to be rid of one's sex characteristics, or a strong conviction that one has feelings and reactions typical of another gender.[2] Hormone therapy is necessary if it is appropriate to the enrollee's gender goals, recommended by the enrollee's treating provider, clinically appropriate for the type of surgery requested, not medically contraindicated, and the enrollee is otherwise able to take hormones.

## Indications/Criteria

MVP Health Care recognizes that gender dysphoria affects people of all genders, and is not limited to people with binary gender identities. Coverage of medically necessary services is allowed for binary and non-binary gender identities.

Medications that are a pharmacy benefit are covered and billed to New York State Fee-For-Service (FFS) program. They are defined as medications that go through a retail or specialty pharmacy, including self-administered injectable products. Pharmacy medications are subject to FFS's clinical criteria including (but not limited to) coverage, quantity limit, step therapy, and prior authorization. Pharmacy benefit information can be found here: https://www.emedny.org/info/fullform.pdf

Gonadotropin-releasing hormone agents (pubertal suppressants) are subject to retro-review and will be approved if all of the following criteria are met:

- Patient has a diagnosis of gender dysphoria;
- Patient has experienced puberty to at least Tanner stage 2, and pubertal changes have resulted in an increase in gender dysphoria;
- Patient does not suffer from psychiatric comorbidity that interferes with a diagnostic work-up or treatment
- Patient has adequate psychological and social support during treatment;
- Patient 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.

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**References**


1. New York State Department of Health. Medicaid Update. Volume 31. March 2015
2. "Gender Dysphoria." American Psychiatric Association, 2013. Web. http://www.dsm5.org/documents/gender%20dysphoria%20fact%20sheet.pdf. Accessed July 7, 2015.
3. New York State Department of Health. Medicaid Update. Volume 33. January 2017
4. New York State Department of Health. Criteria Standards for the Authorization and Utilization Management of Hormone Therapy and Surgery for the Treatment of Gender Dysphoria. July 2018
5. New York State Department of Health. Medicaid Update. Transgender Related Care and Services Pharmacy Coverage Update. Vol 36; Number 12. July 2020.

6. New York State Department of Health. Medicaid Update. Hormone Replacement Therapy for Treatment of Gender Dysphoria. October 2023 Vol 39- Number 15. New York State Medicaid Update.

| Member Product | Medical Management Requirements* |
|---|---|
| **New York Products** | |
| HMO | Refer to Transgender Hormone Policy (Commercial/Exchange/Child Health Plus) |
| PPO in Plan | Refer to Transgender Hormone Policy (Commercial/Exchange/Child Health Plus) |
| PPO OOP | Refer to Transgender Hormone Policy (Commercial/Exchange/Child Health Plus) |
| POS in Plan | Refer to Transgender Hormone Policy (Commercial/Exchange/Child Health Plus) |
| POS OOP | Refer to Transgender Hormone Policy (Commercial/Exchange/Child Health Plus) |
| Essential Plan | Refer to Transgender Hormone Policy (Commercial/Exchange/Child Health Plus) |
| MVP Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Refer to Transgender Hormone Policy (Commercial/Exchange/Child Health Plus) |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Complete Wellness | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| USA Care PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| Healthy NY | Refer to Transgender Hormone Policy (Commercial/Exchange/Child Health Plus) |
| MVP Premier | Refer to Transgender Hormone Policy (Commercial/Exchange/Child Health Plus) |
| MVP Premier Plus | Refer to Transgender Hormone Policy (Commercial/Exchange/Child Health Plus) |
| MVP Premier Plus HDHP | Refer to Transgender Hormone Policy (Commercial/Exchange/Child Health Plus) |
| MVP Secure | Refer to Transgender Hormone Policy (Commercial/Exchange/Child Health Plus) |
| MVP EPO | Refer to Transgender Hormone Policy (Commercial/Exchange/Child Health Plus) |

| | |
|---|---|
| MVP EPO HDHP | Refer to Transgender Hormone Policy (Commercial/Exchange/Child Health Plus) |
| MVP PPO | Refer to Transgender Hormone Policy (Commercial/Exchange/Child Health Plus) |
| MVP PPO HDHP | Refer to Transgender Hormone Policy (Commercial/Exchange/Child Health Plus) |
| Student Health Plans | Refer to Transgender Hormone Policy (Commercial/Exchange/Child Health Plus) |
| ASO | See SPD |
| **Vermont Products** | |
| POS in Plan | Refer to Transgender Hormone Policy (Commercial/Exchange/Child Health Plus) |
| POS OOP | Refer to Transgender Hormone Policy (Commercial/Exchange/Child Health Plus) |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP VT HMO | Refer to Transgender Hormone Policy (Commercial/Exchange/Child Health Plus) |
| MVP VT Plus HMO | Refer to Transgender Hormone Policy (Commercial/Exchange/Child Health Plus) |
| MVP VT HDHP HMO | Refer to Transgender Hormone Policy (Commercial/Exchange/Child Health Plus) |
| MVP VT Plus HDHP HMO | Refer to Transgender Hormone Policy (Commercial/Exchange/Child Health Plus) |
| MVP Secure | Refer to Transgender Hormone Policy (Commercial/Exchange/Child Health Plus) |
| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

**Transthyretin-Mediated Amyloidosis Therapy**

**Type of Policy:** **Drug Therapy**
**Prior Approval Date:** **08/01/2023**
**Approval Date:** **08/01/2024**
**Effective Date:** **10/01/2024**
**Related Policies:** **NA**

**Drug(s) Requiring Prior Authorization (covered under the medical benefit)**
J0222- Onpattro™ (patisiran), injection 0.1 mg
J0225- Amvuttra (vutrisiran), 25mg/0.5mL prefilled syringe for injection

**Drug(s) Requiring Prior Authorization (covered under the pharmacy benefit)**
Tegsedi™ (inotersen), 284mg/1.5mL prefilled syringe for injection
Vyndamax (tafamidis), 61mg oral capsule
Vyndaqel (tafamidis meglumine), 20mg oral capsule

Refer to the MVP website for the Medicare Part D formulary for drugs that may be covered under the Part D benefit.

**Overview**
Hereditary transthyretin amyloidosis (hATTR) is an inherited disease that often affects the liver, nerves, heart and kidneys. It is characterized by the deposit of an abnormal protein called amyloid in multiple organs of the body where it should not be, which causes disruption of organ tissue structure and function. The amyloid buildup most frequently occurs in the peripheral nervous system, which can result in a loss of sensation, pain, or immobility in the arms, legs, hands and feet.

**Indications**
Onpattro™ is indicated for the treatment of the polyneuropathy in hereditary transthyretin-mediated amyloidosis in adults. The active substance in Onpattro is a 'small interfering RNA' (siRNA), a very short piece of synthetic genetic material that has been designed to attach to and block the genetic material of the cell responsible for

producing transthyretin. This reduces production of defective transthyretin, thereby reducing the formation of amyloids and relieving the symptoms of hATTR amyloidosis.

Amvuttra is indicated for the treatment of the polyneuropathy in hereditary transthyretin-mediated amyloidosis in adults. The active substance in Amvuttra is a 'small interfering RNA' (siRNA), a very short piece of synthetic genetic material that has been designed to attach to and block the genetic material of the cell responsible for producing transthyretin. This reduces production of defective transthyretin, thereby reducing the formation of amyloids and relieving the symptoms of hATTR amyloidosis.

Tegsedi™ is indicated for treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults. Tegsedi™ is an 'antisense oligonucleotide', a very short piece of synthetic genetic material that has been designed to attach to and block the genetic material of the cell responsible for producing transthyretin. This reduces production of transthyretin, and the formation of amyloids, relieving the symptoms of hATTR amyloidosis.

Vyndaqel and Vyndamax are indicated for the treatment of wild type or hereditary transthyretin amyloid cardiomyopathy in adults to reduce cardiovascular mortality and cardiovascular-related hospitalization. Wild type amyloidosis does not involve genetic mutation- wild type occurs usually in older population when the normal TTR protein becomes unstable and begins to form amyloid fibrils. Hereditary amyloidosis is an inherited mutation in the DNA making the TTR protein unstable and form amyloid fibrils. It works as a selective transthyretin (TTR) stabilizer. Transthyretin amyloid cardiomyopathy is caused by the accumulations of transthyretin amyloid fibrils, which consist of TTR monomers. Tafamidis works by binding to sites on TTR and slowing monomer dissociation. Please note that Vyndaqel and Vyndamax are not equivalents on a mg-per-mg basis.

## Policy Criteria

**Medicaid Variation:** Medications that are a pharmacy benefit are covered and billed to New York State Fee-For-Service (FFS) program. They are defined as medications that go through a retail or specialty pharmacy, including self administered injectable products. Pharmacy medications are subject to FFS's clinical criteria including (but not limited to) coverage, quantity limit, step therapy, and prior authorization. Pharmacy benefit information can be found here: https://www.emedny.org/info/fullform.pdf

**A. Onpattro** will be considered medically necessary for the treatment of the polyneuropathy of hATTR amyloidosis in adults who meet the following criteria:

- Member has documented transthyretin (TTR) mutation as confirmed through genetic testing AND symptomatic polyneuropathy (i.e. weakness, sensory loss, decreased motor strength, decreased gait speed) characterized by ONE of the following:
    - Baseline polyneuropathy disability (PND) score < IIIb (see reference table)
    - Baseline FAP (familial amyloid polyneuropathy) Stage 1 or 2 (see reference table)
- Biopsy is positive for amyloid deposits or medical justification is provided as to why treatment should be initiated despite a negative biopsy or no biopsy
- Prescribed by a neurologist, immunologist, or physician who specializes in the treatment of amyloidosis
- Site of Care
    - Per the MVP Health Care Pharmacy Management Programs policy, Onpattro is subject to Site of Care requirements and must be obtained through a preferred home infusion vendor. Prior Authorization and medical justification is required for Onpattro obtained and administered in other outpatient settings such as a provider's office or hospital facility.
    - MVP will allow 60 days after prior authorization approval for members to transfer to a preferred infusion site.
    - This requirement does not apply to MVP Medicare and Medicaid members

**Initial approval will be for 6 months, continuation requests up to 6 months.**

Continuation of therapy will be considered medically necessary with documentation of disease stability or improvement in symptoms (e.g., decrease in neuropathic pain, improved motor function, quality of life assessment, and/or serum TTR levels)

**B. Amvuttra** will be considered medically necessary for the treatment of the polyneuropathy of hATTR amyloidosis in adults who have **previously failed or have a contraindication to Onpattro**, AND who meet the following criteria:

- Member has documented transthyretin (TTR) mutation as confirmed through genetic testing AND symptomatic polyneuropathy (i.e. weakness, sensory loss,

decreased motor strength, decreased gait speed) characterized by ONE of the following:
    - Baseline polyneuropathy disability (PND) score < IIIb (see reference table)
    - Baseline FAP (familial amyloid polyneuropathy) Stage 1 or 2 (see reference table)
- Biopsy is positive for amyloid deposits or medical justification is provided as to why treatment should be initiated despite a negative biopsy or no biopsy
- Baseline documentation of disease status must be submitted if applicable such as 10-meter walk test, quality of life assessment, nutritional health assessment or modified body mass index (mBMI), and ability to perform activities of daily living
- Prescribed by a neurologist, immunologist, or physician who specializes in the treatment of amyloidosis
- Site of Care
    - Per the MVP Health Care Pharmacy Management Programs policy, Amvuttra is subject to Site of Care requirements and must be obtained through a preferred home infusion vendor. Prior Authorization and medical justification is required for Amvuttra obtained and administered in other outpatient settings such as a provider's office or hospital facility.
    - MVP will allow 60 days after prior authorization approval for members to transfer to a preferred infusion site.
    - This requirement does not apply to MVP Medicare and Medicaid members

**Initial approval will be for 6 months, continuation requests up to 6 months.**

Continuation of therapy will be considered medically necessary with documentation of disease stability or improvement in symptoms (e.g., decrease in neuropathic pain, improved motor function, improved gait speed, improved quality of life assessment, improved ability to perform activities of daily living, increased mBMI, and/or serum TTR levels)

**C. Tegsedi** will be considered medically necessary for the treatment of the polyneuropathy of hATTR amyloidosis in adults who meet the following criteria:

- Member has documented transthyretin (TTR) mutation as confirmed through genetic testing AND symptomatic polyneuropathy ((i.e. weakness, sensory loss, decreased motor strength, decreased gait speed) characterized by ONE of the following:
    - Baseline polyneuropathy disability (PND) score < IIIb (see reference table)

    - Baseline FAP (familial amyloid polyneuropathy) Stage 1 or 2 (see reference table)
- Biopsy is positive for amyloid deposits or medical justification is provided as to why treatment should be initiated despite a negative biopsy or no biopsy
- Member has a platelet count > 100 x $10^9$/L
- Prescribed by a neurologist, immunologist, or physician who specializes in the treatment of amyloidosis
- If member has a history of liver transplant, a provider attestation is required that indicates ALT, AST and total bilirubin will be monitored monthly

**Initial approval will be for 6 months, continuation requests up to 6 months.**

Continuation of therapy will be considered medically necessary with documentation of disease stability or improvement in symptoms (e.g., decrease in neuropathic pain, improved motor function, quality of life assessment, and/or serum TTR levels).

- If member has a history of liver transplant, a provider attestation is required that indicates ALT, AST and total bilirubin are being monitored monthly

**Polyneuropathy Disability Score (PND) Reference Table**

- Stage 0: No impairment
- Stage I: Sensory disturbances but preserved walking capability
- Stage II: Impaired walking capability but ability to walk without a stick or crutches
- Stage IIIa: Walking only with the help of one stick or crutch
- Stage IIIb: Walking with the help of two sticks or crutches
- Stage IV: Confined to a wheelchair or bedridden

**Familial Amyloid Polyneuropathy (FAP) Stage Reference Table**

- Stage 0: No symptoms of sensory or motor neuropathy
- Stage 1: Unimpaired ambulation; mostly mild sensory, autonomic, or motor neuropathy in lower limbs
- Stage 2: Requires assistance with ambulation; mostly moderate impairment progression in lower limbs, upper limbs, and trunk

- Stage 3: Confined to wheelchair or bedridden; severe sensory, autonomic, and motor involvement of all limbs

**D. Vyndaqel** and **Vyndamax** will be considered medically necessary for the treatment of the cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) in adults who meet all of the following criteria:

- Chart notes documenting a diagnosis of wild type or hereditary transthyretin-mediated amyloidosis cardiomyopathy AND baseline disease severity
- Chart notes documenting member has New York Heart Association (NYHA) functional class I to III heart failure
- Documentation of the presence of TTR genotype confirmed by genetic testing for hereditary transthyretin-mediated amyloidosis
- Biopsy is positive for amyloid deposits or medical justification is provided as to why treatment should be initiated despite a negative biopsy or no biopsy

**Initial approval will be for 6 months, continuation requests up to 6 months.**

**Continuation of therapy** will be considered medically necessary with documentation of disease stability or improvement in symptoms (e.g., quality of life assessment, decrease cardiac related hospitalizations)

**Exclusions**

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling Tafamidis therapy in members with NYHA class IV heart failure or severely impaired renal function (eGFR < 25 mL/min/1.73 $m^2$ BSA)
- Treatment with Onpattro or Tegsedi for members without the presence of a polyneuropathy symptoms associated with hATTR amyloidosis
- Treatment with Onpattro or Tegsedi when member has form of amyloidosis that is not due to a genetic mutation in the TTR gene
- Tegsedi therapy in members with a history of acute glomerulonephritis caused by Tegsedi
- Concurrent use of Tegsedi with Amvuttra, Onpattro, or tafamidis
- Concurrent use of Vyndaqel and Vyndamax

**References**


1. ONPATTRO (patisiran) [package insert]. Cambridge, MA: Alnylam Pharmaceuticals, Inc; 2018.
2. Coutinho P, Martins da Silva A, Lopes Lima J, Resende Barbosa A. (1980) Forty years of experience with type I amyloid neuropathy. Review of 483 cases. In: Glenner G., Costa P., de Freitas A., editors. (eds), Amyloid and Amyloidosis. Amsterdam: Execerpta Medica, pp. 88–98
3. Yamamoto S, Wilczek H, Nowak G, et al. Liver transplantation for familial amyloidotic polyneuropathy (FAP): a single-center experience over 16 years. Am J Transplant. 2007 Nov;7(11):2597-604.
4. Adams D, Suhr OB, Dyck PJ, et al. Trial design and rationale for APOLLO, a Phase 3, placebo-controlled study of patisiran in patients with hereditary ATTR amyloidosis with polyneuropathy. BMC Neurol. 2017 Sep 11;17(1):181.
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8. Tegsedi Prescribing Information. Boston, MA: Akcea Therapeutics, Inc.; October 2018.
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11. Amvuttra Prescribing Information. Cambridge, MA: Alnylam Pharmaceuticals, Inc; June 2022.
12. Vultrisiran. Clinical Pharmacology [Internet]. Tampa (FL): Elsevier. c2022- [cited 2022 June 17]. Available from: http://www.clinicalpharmacology.com
13. ONPATTRO (patisiran) [handout/package insert]. Cambridge, MA: Alnylam Pharmaceuticals, Inc; 1/2023.

14. Amvuttra Prescribing Information. Cambridge, MA: Alnylam Pharmaceuticals, Inc; 2/2023
15. Tegsedi Prescribing Information. Watham, MA: Akcea Therapeutics, Inc.; 5/2021.
16. Vyndaqel and Vyndamax Prescribing Information. New York, NY: Division of Pfizer, Inc.; 10/2023

| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Medicare Gold Giveback | Refer to the MVP website for the Medicare Part B and Part D policies. |
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| 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 | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D |
| 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 | See SPD |
| ASO | |
| **♦ 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).** | |
| *© 2024 MVP Health Plan, Inc. All rights reserved. Descriptions contained within MVP's Medical Policies are not a guarantee of coverage. Each MVP Group or Subscriber Contract contains specific limitations, exclusions and requirements that may affect a Policy. If there is any discrepancy between your Group or Subscriber Contract and a Policy, your Group or Subscriber Contract shall in all cases govern.* | |

***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 |

**MVP Health Care Medical Policy**

**Medicare Part B:**
**Transthyretin-Mediated Amyloidosis Therapy**

**Type of Policy:** **Drug Therapy**
**Prior Approval Date:** **11/01/2023**
**Approval Date:** **08/01/2024**
**Effective Date:** **10/01/2024**
**Related Policies:** **N/A**

Refer to the MVP website for the Medicare Part D formulary for drugs that may be covered under the Part D benefit.

**Drug(s) Requiring Prior Authorization (covered under the medical benefit)**

J0222- Onpattro™ (patisiran), injection 0.1 mg

J0225 Amvuttra (vutrisiran), 25mg/0.5mL prefilled syringe for injection

**Overview/Summary of Evidence**

Hereditary transthyretin amyloidosis (hATTR) is an inherited disease that often affects the liver, nerves, heart and kidneys. It is characterized by the deposit of an abnormal protein called amyloid in multiple organs of the body where it should not be, which causes disruption of organ tissue structure and function. The amyloid buildup most frequently occurs in the peripheral nervous system, which can result in a loss of sensation, pain, or immobility in the arms, legs, hands and feet.

**Indications**

Onpattro™ is indicated for the treatment of the polyneuropathy in hereditary transthyretin-mediated amyloidosis in adults. The active substance in Onpattro is a 'small interfering RNA' (siRNA), a very short piece of synthetic genetic material that has been designed to attach to and block the genetic material of the cell responsible for producing transthyretin. This reduces production of defective transthyretin, thereby reducing the formation of amyloids and relieving the symptoms of hATTR amyloidosis.

Amvuttra is indicated for the treatment of the polyneuropathy in hereditary transthyretin-mediated amyloidosis in adults. The active substance in Amvuttra is a 'small interfering RNA' (siRNA), a very short piece of synthetic genetic material that has been designed to attach to and block the genetic material of the cell responsible for producing transthyretin. This reduces production of defective transthyretin, thereby reducing the formation of amyloids and relieving the symptoms of hATTR amyloidosis.

Tegsedi™ is indicated for treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults. Tegsedi™ is an 'antisense oligonucleotide', a very short piece of synthetic genetic material that has been designed to attach to and block the genetic material of the cell responsible for producing transthyretin. This reduces production of transthyretin, and the formation of amyloids, relieving the symptoms of hATTR amyloidosis.

Vyndaqel and Vyndamax are indicated for the treatment of wild type or hereditary transthyretin amyloid cardiomyopathy in adults to reduce cardiovascular mortality and cardiovascular-related hospitalization. Wild type amyloidosis does not involve genetic mutation- wild type occurs usually in older population when the normal TTR protein becomes unstable and begins to form amyloid fibrils. Hereditary amyloidosis is an inherited mutation in the DNA making the TTR protein unstable and form amyloid fibrils. It works as a selective transthyretin (TTR) stabilizer. Transthyretin amyloid cardiomyopathy is caused by the accumulations of transthyretin amyloid fibrils, which consist of TTR monomers. Tafamidis works by binding to sites on TTR and slowing monomer dissociation. Please note that Vyndaqel and Vyndamax are not equivalents on a mg-per-mg basis.

## Policy Criteria

**A. Onpattro** will be considered medically necessary for the treatment of the polyneuropathy of hATTR amyloidosis in adults who meet the following criteria:

- Member has documented transthyretin (TTR) mutation as confirmed through genetic testing AND symptomatic polyneuropathy (i.e. weakness, sensory loss, decreased motor strength, decreased gait speed) characterized by ONE of the following:
    - Baseline polyneuropathy disability (PND) score < IIIb (see reference table)
    - Baseline FAP (familial amyloid polyneuropathy) Stage 1 or 2 (see reference table)
- Biopsy is positive for amyloid deposits or medical justification is provided as to why treatment should be initiated despite a negative biopsy or no biopsy

- Prescribed by a neurologist, immunologist, or physician who specializes in the treatment of amyloidosis

**Initial approval will be for 6 months, continuation requests up to 6 months.**

Continuation of therapy will be considered medically necessary with documentation of disease stability or improvement in symptoms (e.g., decrease in neuropathic pain, improved motor function, quality of life assessment, and/or serum TTR levels)

**B. Amvuttra** will be considered medically necessary for the treatment of the polyneuropathy of hATTR amyloidosis in adults who have **previously failed or have a contraindication to Onpattro**, AND who meet the following criteria:

- Member has documented transthyretin (TTR) mutation as confirmed through genetic testing AND symptomatic polyneuropathy (i.e. weakness, sensory loss, decreased motor strength, decreased gait speed) characterized by ONE of the following:
    - Baseline polyneuropathy disability (PND) score < IIIb (see reference table)
    - Baseline FAP (familial amyloid polyneuropathy) Stage 1 or 2 (see reference table)
- Biopsy is positive for amyloid deposits or medical justification is provided as to why treatment should be initiated despite a negative biopsy or no biopsy
- Baseline documentation of disease status must be submitted if applicable such as 10-meter walk test, quality of life assessment, nutritional health assessment or modified body mass index (mBMI), and ability to perform activities of daily living
- Prescribed by a neurologist, immunologist, or physician who specializes in the treatment of amyloidosis

**Initial approval will be for 6 months, continuation requests up to 6 months.**

Continuation of therapy will be considered medically necessary with documentation of disease stability or improvement in symptoms (e.g., decrease in neuropathic pain, improved motor function, improved gait speed, improved quality of life assessment, improved ability to perform activities of daily living, increased mBMI, and/or serum TTR levels

**Polyneuropathy Disability Score (PND) Reference Table**

- **Stage 0: No impairment**
- **Stage I: Sensory disturbances but preserved walking capability**
- **Stage II: Impaired walking capability but ability to walk without a stick or crutches**
- **Stage IIIa: Walking only with the help of one stick or crutch**
- **Stage IIIb: Walking with the help of two sticks or crutches**
- **Stage IV: Confined to a wheelchair or bedridden**

**Familial Amyloid Polyneuropathy (FAP) Stage Reference Table**

- **Stage 0: No symptoms of sensory or motor neuropathy**
- **Stage 1: Unimpaired ambulation; mostly mild sensory, autonomic, or motor neuropathy in lower limbs**
- **Stage 2: Requires assistance with ambulation; mostly moderate impairment progression in lower limbs, upper limbs, and trunk**
- **Stage 3: Confined to wheelchair or bedridden; severe sensory, autonomic, and motor involvement of all limbs**

**Exclusions**

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling Concurrent use with Tegsedi
- Treatment with Onpattro for members without the presence of a polyneuropathy symptoms associated with hATTR amyloidosis
- Treatment with Onpattro when member has form of amyloidosis that is not due to a genetic mutation in the TTR gene

**References**

1. ONPATTRO (patisiran) [package insert]. Cambridge, MA: Alnylam Pharmaceuticals, Inc; 2018.
2. Coutinho P, Martins da Silva A, Lopes Lima J, Resende Barbosa A. (1980) Forty years of experience with type I amyloid neuropathy. Review of 483 cases. In: Glenner G., Costa P., de Freitas A., editors. (eds), Amyloid and Amyloidosis. Amsterdam: Execerpta Medica, pp. 88–98

3. Yamamoto S, Wilczek H, Nowak G, et al. Liver transplantation for familial amyloidotic polyneuropathy (FAP): a single-center experience over 16 years. Am J Transplant. 2007 Nov;7(11):2597-604.
4. Adams D, Suhr OB, Dyck PJ, et al. Trial design and rationale for APOLLO, a Phase 3, placebo-controlled study of patisiran in patients with hereditary ATTR amyloidosis with polyneuropathy. BMC Neurol. 2017 Sep 11;17(1):181.
5. Adams D, Gonzalez-Duarte A, O'Riordan WD, et al. Patisiran, an RNAi Therapeutic, for Hereditary Transthyretin Amyloidosis. N Engl J Med. 2018 Jul 5;379(1):11-21
6. Alnylam Pharmaceuticals. The Study of an Investigational Drug, Patisiran (ALN-TTR02), for the Treatment of Transthyretin (TTR)-Mediated Amyloidosis in Patients Who Have Already Been Treated With ALN-TTR02 (Patisiran). In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000- [cited 2018 April 12]. Available from: https://clinicaltrials.gov/ct2/show/NCT02510261. NLM Identifier: NCT02510261.
7. Institute for Clinical and Economic Review: Draft Evidence Report - Inotersen and Patisiran for Hereditary Transthyretin Amyloidosis: Effectiveness and Value. July 20, 2018.
8. Tegsedi Prescribing Information. Boston, MA: Akcea Therapeutics, Inc.; October 2018.
9. Benson MD, Waddington-Cruz M, Berk JL, et al. Inotersen treatment for patients wth hereditary transthyretin amyloidosis. N Engl J Med 2018;379:22-31. DOI: 10.1056/NEJMoa1716793.
10. Tafamidis. Clinical Pharmacology [Internet]. Tampa (FL): Elsevier. c2021- [cited 2021 June 25]. Available from: http://www.clinicalpharmacology.com
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12. Vultrisiran. Clinical Pharmacology [Internet]. Tampa (FL): Elsevier. c2022- [cited 2022 June 17]. Available from: http://www.clinicalpharmacology.com
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15. Tegsedi Prescribing Information. Watham, MA: Akcea Therapeutics, Inc.; 5/2021.
16. Vyndaqel and Vyndamax Prescribing Information. New York, NY: Division of Pfizer, Inc.; 10/2023

**MVP Health Care Medical Policy**

**Ultomiris (ravulizumab-cwvz)**

| | |
|---|---|
| **Type of Policy:** | **Drug/Medical Therapy** |
| **Prior Approval Date:** | **10/01/2023** |
| **Approval Date:** | **10/01/2024** |
| **Effective Date:** | **01/01/2025** |
| **Related Policies:** | Orphan Drug(s) and Biologicals |

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies.

**Drugs Requiring Prior Authorization under the medical benefit**

J1303 IV Injection, ravulizumab 300 mg/3 mL solution in a single-dose vial (Ultomiris)

J1303 IV Injection, ravulizumab 1,100 mg/11 mL solution in a single-dose vial (Ultomiris)

**Overview**

Ravulizumab is a long-acting humanized monoclonal antibody complement inhibitor indicated for the treatment of myasthenia gravis (anti-anticholinergic receptor antibody positive), hemolytic uremia syndrome (atypical), paroxysmal nocturnal hemoglobinuria, and anti-aquaporin-4 (AQP4) antibody positive neuromyelitis optica spectrum disorder (NMOSD). Ravulizumab can increase the risk of meningococcal infections. Immunization with meningococcal vaccines is required prior to ravulizumab administration unless the risks of delaying treatment outweigh the risks of developing a meningococcal infection. Prescribers who treat members with ravulizumab must enroll in the Ultomiris REMS program.

**Indications/Criteria**

**For all indications, the following criteria must be met in addition the specific diagnosis criteria below:**

a. Prescriber is enrolled in Ultomiris REMS program
b. Documentation member has been vaccinated against N. meningitidis at least 2 weeks before initiation of ravilizumab therapy and vaccinations for S. pneumoniae and H. influenzae are administered in accordance with ACIP guidelines

i. If ravulizumab must be initiated immediately and the meningococcal vaccination is administered less than 2 weeks before ravulizumab initiation, documentation of a 2-week course of antibacterial drug prophylaxis is required

c. Site of Care

i. Per the MVP Health Care Pharmacy Management Programs policy, Ultomiris is subject to Site of Care requirements and must be obtained through a preferred home infusion vendor. Prior Authorization and medical justification is required for Ultomiris and administered in other outpatient settings such as a provider's office or hospital facility.

ii. MVP will allow 60 days after prior authorization approval for members to transfer to a preferred infusion site.

iii. This requirement does not apply to MVP Medicare and Medicaid members

**A. Paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis**

a. Diagnosis confirmed by high sensitivity flow cytometry with a monocyte or granulocyte clone size ≥5% **OR**
   i. >50% of glycosylphosphatidylinositol-anchored proteins (GPI-AP) deficient polymorphonuclear cells **AND**
b. Documentation demonstrating evidence of hemolysis including LDH level ≤1.5 times the upper limit of normal (ULN) at baseline **AND**
c. Documentation of a minimum of 1 **PNH related** sign or symptom within the last 3 months (fatigue, abdominal pain, dyspnea, dysphagia, erectile dysfunction, anemia, hemoglobinuria, history of major adverse cardiovascular events, or history of packed RBC transfusion due to PNH)

**B. Atypical hemolytic uremic syndrome (aHUS) to prevent complement-mediated thrombotic microangiopathy**

a. Documentation of the absence of Shiga toxin (Shiga toxin Escherichia coli related hemolytic uremic syndrome (STEC-HUS) negative)
b. ADAMTS 13 activity level ≥ 5%
c. Documentation of baseline platelet count (≤ 150 × 109 /L)
d. Documentation demonstrating evidence of hemolysis including elevation of serum LDH and sCr above ULN or dialysis is required

**C. Anti-acetylcholine receptor antibody positive generalized myasthenia gravis (gMG) in adult members who are anti-acetylcholine receptor (AchR) antibody positive**

a. Positive serologic test for anti-AChR antibodies

b. Myasthenia Gravis Foundation of America (MGFA) clinical classification II to IV
c. MG activities of daily living (MG-ADL) total score ≥6
d. Member has had an inadequate response to at least two non-steroidal immunosuppressive therapies (ISTs) listed below **OR** failed at least one IST listed below and required chronic plasmapheresis or plasma exchange or IVIG:
    i. azathioprine
    ii. cyclosporine
    iii. mycophenolate mofetil
    iv. tacrolimus
    v. methotrexate
    vi. cyclophosphamide
    vii. rituximab

**D. Anti-aquaporin-4 (AQP4) antibody positive neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive.**
a. Serology confirming diagnosis of anti-aquaporin-4 (AQP4) antibody positive NMOSD
b. Expanded Disability Status Scale (EDSS) score ≤ 7

**Initial approval will be for 6 months**

**Extension requests** will be approved for up to 12 months if the members meeting the following criteria per applicable indication:

**PNH**
No evidence of disease progression while on current regimen and documentation of positive response to therapy (reduction in blood transfusions, stabilization in hemoglobin concentrations, reduction of exacerbations, improved quality of life scores/fatigue, and/or normalization of LDH levels)

**aHUS**
No evidence of disease progression while on the current regimen and documentation of a positive response to therapy (e.g., normalization of LDH levels, platelet counts, improvement in renal function from baseline)

**gMG**
No evidence of disease progression while on the current regimen and documentation of a positive response to therapy (e.g., improvement in MG-ADL score, changes compared to baseline in Quantitative Myasthenia Gravis (QMG) total score)

**NMOSD**
No evidence of disease progression while on current regimen and documentation of a positive response to therapy (e.g., improvement in EDSS score, decreased hospitalizations, improvement in stability, reduced plasma exchange treatments)

**Exclusions**

- For the treatment of members with Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS).
- Indication, age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling
- Members with unresolved Neisseria meningitidis infection
- Members who are **not** currently vaccinated against Neisseria meningitidis, unless the risks of delaying treatment outweigh the risks of developing a meningococcal infection

**References**


1. Ultomiris (ravulizumab-cwzv) package insert. Boston, MA: Alexion Pharmaceuticals, Inc.;2020 July.
2. Cancado RD. Consensus statement for diagnosis and treatment of paroxysmal nocturnal hemoglobinuria. Hematology, Transfusion, and Cell Therapy. 2021;43(3):341-348.
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4. Parker CJ. Update on the diagnosis and management of paroxysmal nocturnal hemoglobinuria. Hematology Am Soc Hematol Educ Program. 2016;2016(1):208-216
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8. A study of ravulizumab (ALXN1210) Versus Eculizumab in Complement Inhibitor Treatment-Naïve Adult Participants With Paroxysmal Nocturnal Hemoglobinuria (PNH)-full text view - clinicaltrials.gov. (n.d.), Alexion Pharmaceuticals, Inc, 2024-05-14
9. Daria V. Babushok; When does a PNH clone have clinical significance?. Hematology Am Soc Hematol Educ Program 2021; 2021 (1): 143–152. doi: https://doi.org/10.1182/hematology.2021000245
10. Paroxysmal Nocturnal Hemoglobinuria - NORD (National Organization for Rare Disorders). (2015). NORD (National Organization for Rare Disorders); NORD. https://rarediseases.org/rare-diseases/paroxysmal-nocturnal-hemoglobinuria/, Last updated: 05/29/2024

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| **New York Products** | |
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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** | |
| POS in Plan | Prior Auth |
| POS OOP | Prior Auth |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D |
| 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).** | |
| *© 2024 MVP Health Plan, Inc. All rights reserved. Descriptions contained within MVP's Medical Policies are not a guarantee of coverage. Each MVP Group or Subscriber Contract contains specific limitations, exclusions and requirements that may affect a Policy. If there is any discrepancy between your Group or Subscriber Contract and a Policy, your Group or Subscriber Contract shall in all cases govern.* | |

***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 |

**MVP Health Care Medical Policy**

# Upadacitinib

**Type of Policy:** Drug Therapy
**Prior Approval Date:** 10/01/2023
**Approval Date:** 10/01/2024
**Effective Date:** 01/01/2025
**Related Policies:** Adalimumab
Apremilast
Etanercept
Infliximab
Risankizumab
Secukinumab
Tofacitinib
Upadacitinib
Ustekinumab
Ozanimod

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies.

## Drugs Requiring Prior Authorization under the pharmacy benefit

Rinvoq (upadacitinib)

## Overview

Upadacitinib is an oral Janus kinase (JAK) inhibitor and is considered a targeted synthetic disease-modifying antirheumatic drug (tsDMARD).

Upadacitinib is indicated for adults with moderately to severely active rheumatoid arthritis (RA), active psoriatic arthritis, active ankylosing spondylitis (AS), moderately to severely active ulcerative colitis (UC) who have had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) inhibitors, Crohn's disease and non-radiographic axial spondyloarthritis. It is also indicated for the treatment of adults and pediatric members 12 years and older with refractory, moderate to severe atopic dermatitis whose disease is not adequately controlled with other systemic medications (including biologics) or when use of those therapies is not advisable.

Caution may be necessary when co-administered with certain drugs that inhibit or induce certain CYP isoenzymes. Use with potent CYP3A4 inducers may result in loss of or reduced clinical response to upadacitinib.

Providers should perform screening for tuberculosis (TB) according to the local practice.

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**Indications/Criteria**

**Medicaid Variation:** Medications that are a pharmacy benefit are covered and billed to New York State Fee-For-Service (FFS) program. They are defined as medications that go through a retail or specialty pharmacy, including self-administered injectable products. Pharmacy medications are subject to FFS's clinical criteria including (but not limited to) coverage, quantity limit, step therapy, and prior authorization. Pharmacy benefit information can be found here: https://www.emedny.org/info/fullform.pdf

**A. For all indications, the following criteria must be met in addition to the specific diagnosis criteria below.**

a. Must be prescribed for an FDA approved indication

b. Must be ordered by or with consult from an appropriate specialist: rheumatologist, immunologist, dermatologist, gastroenterologist or colorectal surgeon

**B. Ankylosing Spondylitis (AS):**

Upadacitinib may be considered for coverage for Ankylosing Spondylitis when the following criteria is met:

- Member has a diagnosis of moderate to severe AS
- Chart notes are provided documenting failure of at least one non-steroidal anti-inflammatory drug (NSAID) at maximum tolerated dose unless the member has contraindications to NSAID therapy such as cardiovascular disease, peptic ulcer disease or renal disease **AND**
- Chart notes are provided documenting significant clinical symptoms such as fatigue, spinal pain, arthralgia, inflammation of joints and tendons, and/or morning stiffness **AND**
- Chart notes are provided documenting an insufficient response to at least one local corticosteroid injection in members with symptomatic peripheral arthritis **AND**
- Chart notes are provided documenting an inadequate response or intolerance to one tumor necrosis factor (TNF) inhibitor
    - Documentation must be provided if TNF inhibitor therapy is not considered medically appropriate

**Initial approval** will be for 12 months

**Extension requests** will be approved for up to 3 years if the member has a continued benefit to therapy. Extension requests where the upadacitinib did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

**C. Atopic Dermatitis:**

Upadacitinib may be considered for coverage for Atopic Dermatitis when the following criteria is met:

- Member is diagnosed with refractory moderate-to-severe atopic dermatitis (widespread areas of dry skin, severe limitation of everyday activities, nightly loss of sleep) **AND**
- Must have at least 10% BSA involvement at baseline **AND**
- Chart notes provided confirm symptom control has not been achieved with **one** of the following after an adequate trial:
    - Medium high or very-high potency topical corticosteroids

- Topical calcineurin inhibitors (i.e. tacrolimus ointment, pimecrolimus cream)
- Topical PDE-4 inhibitor (e.g. Eucrisa)
- Documentation that disease is not adequately controlled with other systemic medications, including biologics, or when use of those therapies is not advisable.

**Initial approval** will be for 12 months

**Extension requests** will be approved for up to 3 years if the member has a continued benefit to therapy. Extension requests where the upadacitinib did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

**D. Psoriatic Arthritis (PsA):**

Upadacitinib may be considered for coverage for PsA when the following criteria is met:

- Member has a diagnosis of moderate to severe psoriatic arthritis as indicated by three or more tender joints AND three or more swollen joints on two separate occasions at least one month apart **AND**
- Chart notes are provided documenting failure of at least one NSAID at maximum tolerated dose unless the member has contraindications to NSAID therapy such as cardiovascular disease, peptic ulcer disease or renal disease **AND**
- Chart notes are provided documenting failure to an adequate trial of at least one of the following nonbiologic disease modifying anti-rheumatic drugs (DMARDs): leflunomide, sulfasalazine, or methotrexate.
  - **Members with pure axial manifestations** do not have to have a trial of nonbiologic disease modifying anti-rheumatic drugs (DMARDs)
  - If a trial of methotrexate is not appropriate due to alcohol use and both leflunomide and sulfasalazine are not clinically appropriate, chart notes must be provided indicating that the member has been counseled on the need to abstain from alcohol use while taking methotrexate and is unwilling to abstain from alcohol use.

**AND**

- Chart notes are provided documenting an inadequate response or intolerance to one tumor necrosis factor (TNF) inhibitor
    - Documentation must be provided if TNF inhibitor therapy is not considered medically appropriate

**Initial approval** will be for 12 months

**Extension requests** will be approved for up to 3 years if the member has a continued benefit to therapy. Extension requests where the upadacitinib did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

**E. Rheumatoid Arthritis (RA):**

Upadacitinib may be considered for coverage for Rheumatoid Arthritis when the following criteria is met:

- Member is diagnosed with moderate to severe active adult rheumatoid arthritis as defined by persistent or recurrent symptoms with documented synovitis and morning stiffness of significant duration to inhibit activities of daily living **AND**
- Chart notes are provided documenting a failure to respond to a three-month trial of methotrexate at a maximally tolerated dose.
    - Failure is demonstrated by documentation of provider assessment without improvement in joint counts and/or physical symptoms and inflammatory markers while on therapy.
    - If the member has a contraindication or significant intolerance to methotrexate
        - Chart notes documenting a failure to respond to at least one other nonbiologic DMARDs at a maximally tolerated dose for at least 3 months AND documentation confirming why methotrexate cannot be used is required. If a trial of methotrexate is not appropriate due to alcohol use, chart notes must be provided indicating that the patient has been counseled on the need to abstain from alcohol use while taking methotrexate and is unwilling to abstain from alcohol use.

        - Upadacitinib may be used without prior DMARD trial if the member has an acute, aggressive, very rapidly progressive intense inflammatory symmetrical arthritis disease as defined by their rheumatologist
- Chart notes are provided documenting an inadequate response or intolerance to one tumor necrosis factor (TNF) inhibitor
    - Documentation must be provided if TNF inhibitor therapy is not considered medically appropriate

**Initial approval** will be for 12 months

**Extension requests** will be approved up to 3 years if the member has a continued benefit to therapy. Extension requests where the upadacitinib did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

**F. Ulcerative Colitis:**

Upadacitinib may be considered for coverage for Ulcerative Colitis (UC) when the following criteria is met:

- Member is diagnosed with moderate to severe active ulcerative colitis
- Chart notes are provided identifying inadequate response, intolerance, or contraindication to conventional therapy for maintenance of remission (i.e.: anti-inflammatory aminosalicylates [e.g., mesalamine (5-ASA), sulfasalazine], 6-mercaptopurine, and azathioprine)
    - If conventional therapy is not considered medically appropriate, documentation must be provided
- Chart notes documenting an inadequate response or intolerance to one tumor necrosis factor (TNF) inhibitor
    - Documentation must be provided if TNF inhibitor therapy is not considered medically appropriate

**Initial approval** will be for 12 months

**Extension requests** will be approved up to 3 years if the member has a continued benefit to therapy. Extension requests where the upadacitinib did not

have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

## G. Non-Radiographic Axial Spondylarthritis (nr-axSpA)

Upadacitinib may be considered for coverage for Non-Radiographic Axial Spondylarthritis (nr-axSpA) when the following criteria is met:

- Member is diagnosed with Non-Radiographic Axial Spondylarthritis (nr-axSpA)
- Chart notes are provided documenting failure of at least one non-steroidal anti-inflammatory drug (NSAID) at maximum tolerated dose unless the member has contraindications to NSAID therapy such as cardiovascular disease, peptic ulcer disease or renal disease **AND**
- Failure of sulfasalazine or methotrexate at maximum tolerated dose
- Chart notes are provided documenting an inadequate response or intolerance to one tumor necrosis factor (TNF) inhibitor
    - Documentation must be provided if TNF inhibitor therapy is not considered medically appropriate

**Initial approval** will be for 12 months

**Extension requests** will be approved up to 3 years if the member has a continued benefit to therapy. Extension requests where the upadacitinib did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

## H. Crohn's Disease

Updacitinib may be considered for coverage for Crohn's Disease when the following criteria is met:

- Diagnosis of moderate to severe active Crohn's disease confirmed by endoscopy (or capsule endoscopy when appropriate)
- Documentation including the assessment of growth, nutrition, extraintestinal complications, therapy-induced complications and functional ability and any clinical signs and symptoms outlined in Crohn's Disease Activity Index (CDAI) such as frequent liquid stools >4/day, severity grade and frequency of abdominal pain, presence of an abdominal mass, general well-being, extra-intestinal symptoms (arthralgia, uveitis, erythema, stomatitis, abscess, fever >37.5 in the last

week), taking opiates or diphenoxylate/atropine for diarrhea, anemia, and weight loss >10%.

- Documentation identifying inadequate response to or an intolerance to conventional therapy (i.e.: corticosteroids, anti-inflammatory aminosalicylates [e.g., mesalamine (5-ASA), sulfasalazine], 6-mercaptopurine, and azathioprine)
- Chart notes are provided documenting an inadequate response or intolerance to one tumor necrosis factor (TNF) inhibitor
    - Documentation must be provided if TNF inhibitor therapy is not considered medically appropriate

**Initial approval** will be for 12 months.

**Extension requests** will be approved for up to 3 years if the member has a continued benefit to therapy. Extension requests where upadacitinib did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

**I. Polyarticular juvenile idiopathic arthritis**

- Upadacitinib may be considered for coverage for Polyarticular juvenile idiopathic arthritis on a case- by-case basis using the American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis and in accordance with the prescribing information.
- Upadacitinib is indicated for members who have had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) inhibitor.
- The request must include chart notes documenting an inadequate response or intolerance to one tumor necrosis factor (TNF) inhibitor OR documentation must be provided if TNF inhibitor therapy is not considered medically appropriate

**Initial approval** will be for 12 months.

**Extension requests** will be approved for up to 3 years if the member has a continued benefit to therapy. Extension requests where upadacitinib did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

## Exclusions

The use of Upadacitinib will not be covered for the following situations:

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling
- Combination therapy that is not supported by current guidelines
- Should not be used for members at high risk for infections or who have active infections including chronic or localized infections
- Avoid using upadacitinib in members that may be at increased risk of thrombosis and thromboembolism; use with caution in those with thromboembolic disease

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   FDA requires warnings about increased risk of serious heart-related events, cancer, blood clots, and death for JAK inhibitors that treat certain chronic inflammatory conditions. Retrieved Aug 25, 2022. Available at: https://www.fda.gov/drugs/drug-safety-and-availability/fda-requires-warnings-about-increased-risk-serious-heart-related-events-cancer-blood-clots-and-death?utm_medium=email&utm_source=govdelivery
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| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Medicare Gold Giveback | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |

| | |
|---|---|
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D |
| 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).** | |
| *© 2024 MVP Health Plan, Inc. All rights reserved. Descriptions contained within MVP's Medical Policies are not a guarantee of coverage. Each MVP Group or Subscriber Contract contains specific limitations, exclusions and requirements that may affect a Policy. If there is any discrepancy between your Group or Subscriber Contract and a Policy, your Group or Subscriber Contract shall in all cases govern.* | |

***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 |

**MVP Health Care Medical Policy**

**Ustekinumab**

| | |
|---|---|
| **Type of Policy:** | **Drug/Medical Therapy** |
| **Prior Approval Date:** | **12/01/2023** |
| **Approval Date:** | **10/01/2024** |
| **Effective Date:** | **01/01/2025** |
| **Related Policies:** | **Adalimumab** |
| | **Apremilast** |
| | **Etanercept** |
| | **Infliximab** |
| | **Risankizumab** |
| | **Secukinumab** |
| | **Tofacitinib** |
| | **Upadacitinib** |
| | **Zeposia** |

**Drugs Requiring Prior Authorization under the pharmacy benefit**

J3357 Stelara prefilled syringe (ustekinumab)

**Drugs Requiring Prior Authorization under the medical benefit**

J3358 Stelara (ustekinumab intravenous injection, 1mg)

**Overview**

Ustekinumab (Stelara®) is a human IgG1 monoclonal antibody that binds to the p40 protein used by both IL-12 and IL-23 cytokines.

Ustekinumab is indicated for moderate to severe plaque psoriasis in members 6 years or older who are candidates for phototherapy or systemic therapy, active psoriatic arthritis

(PsA) alone or in combination with methotrexate (MTX), moderately to severely active Crohn's disease (CD), and moderately to severely active ulcerative colitis (UC).

Members should be screened for immunologic and infectious disease prior to initiating therapy.

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**Medicare Variation**

- Refer to the Medicare Part D formulary for drugs that may be covered under the Part D benefit.

**Medicaid Variation:** Medications that are a pharmacy benefit are covered and billed to New York State Fee-For-Service (FFS) program. They are defined as medications that go through a retail or specialty pharmacy, including self-administered injectable products. Pharmacy medications are subject to FFS's clinical criteria including (but not limited to) coverage, quantity limit, step therapy, and prior authorization. Pharmacy benefit information can be found here: https://www.emedny.org/info/fullform.pdfInitial approval duration will be for 6 months, and continuation approval duration will be for 12 months for applicable medical benefit drugs.

**Indications/Criteria**

**A. For all indications, the following criteria must be met in addition to the specific diagnosis criteria below.**

- Prescription drugs covered under the pharmacy benefit must be self-administered. If office administration is being requested documentation must be provided identifying why the member or caregiver is unable to administer the medication.
- Must be ordered by or with consult from a rheumatologist, immunologist, dermatologist, gastroenterologist or colorectal surgeon
- Must be prescribed for an FDA approved indication

**B. Plaque Psoriasis**

Ustekinumab may be considered for coverage when the following criteria is met:
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- The medication is ordered by or in consultation with a dermatologist

- A diagnosis of moderate to severe chronic plaque psoriasis and one of the following:
    - Crucial body areas (e.g. hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected OR
    - At least 10% of the body surface area (BSA) is affected OR
    - At least 3% of the body surface area (BSA) is affected AND the member meets any of the following criteria:
        - Member has had an inadequate response or intolerance to either phototherapy (e.g. UVB, PUVA) OR
        - Member has had an inadequate response or intolerance to pharmacologic treatment with methotrexate, cyclosporine, or acitretin

**Initial approval** will be for 12 months

**Extensions requests** will be approved up to 3 years if the member has a continued benefit to therapy. Extension requests where the ustekinumab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

**Medicaid Variation:** Initial approval duration will be for 6 months and continuation approval duration will be for 12 months for applicable medical benefit drugs.

**C. Psoriatic Arthritis (PsA)**

Ustekinumab may be considered for coverage when the following criteria is met:

- Member has a diagnosis of moderate to severe psoriatic arthritis as indicated by three or more tender joints AND three or more swollen joints on two separate occasions at least one month apart
- Chart notes documenting failure of at least one NSAID at maximum tolerated dose unless the member has contraindications to NSAID therapy such as cardiovascular disease, peptic ulcer disease or renal disease **AND**
- Chart notes documenting failure to an adequate trial of at least one of the following nonbiologic disease modifying anti-rheumatic drugs (DMARDs): leflunomide, sulfasalazine, or methotrexate.
    - **Members with pure axial manifestations** do not have to have a trial of nonbiologic disease modifying anti-rheumatic drugs (DMARDs)

- If a trial of methotrexate is not appropriate due to alcohol use and **both** leflunomide and sulfasalazine are not clinically appropriate, chart notes must be provided indicating that the member has been counseled on the need to abstain from alcohol use while taking methotrexate and is unwilling to abstain from alcohol use.

**Initial approval** will be for 12 months.

**Extensions requests** will be approved up to 3 years if the member has a continued benefit to therapy. Extension requests where the ustekinumab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

**Medicaid Variation:** Initial approval duration will be for 6 months and continuation approval duration will be for 12 months for applicable medical benefit drugs.

**D. Crohn's Disease**

Ustekinumab may be considered for coverage when the following criteria is met:

- Diagnosis of moderate to severe active Crohn's disease confirmed by endoscopy (or capsule endoscopy when appropriate)
- Documentation should include:
  - Assessment of growth, nutrition, extraintestinal complications, therapy-induced complications and functional ability.
  - Any clinical signs and symptoms outlined in Crohn's Disease Activity Index (CDAI) such as frequent liquid stools >4/day, severity grade and frequency of abdominal pain, presence of an abdominal mass, general well-being, extra-intestinal symptoms (arthralgia, uveitis, erythema, stomatitis, abscess, fever >37.5 in the last week), taking opiates or diphenoxylate/atropine for diarrhea, anemia, and weight loss >10%.

**Initial approval** will be for 12 months.

**Extensions requests** will be approved up to 3 years if the member has a continued benefit to therapy. Extension requests where the ustekinumab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

**Medicaid Variation:** Initial approval duration will be for 6 months and continuation approval duration will be for 12 months for applicable medical benefit drugs.

### E. Ulcerative Colitis

Ustekinumab may be considered for coverage when the following criteria is met:

- A diagnosis of moderate to severe Ulcerative Colitis
- Chart notes are provided identifying inadequate response, intolerance, or contraindication to conventional therapy for maintenance of remission (i.e., anti-inflammatory aminosalicylates [e.g., mesalamine (5-ASA), sulfasalazine], 6-mercaptopurine, and azathioprine)
    - If conventional therapy is not considered medically appropriate, documentation must be provided

**Initial approval** will be for 12 months.

**Extensions requests** will be approved up to 3 years if the member has a continued benefit to therapy. Extension requests where the ustekinumab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

**Medicaid Variation:** Initial approval duration will be for 6 months and continuation approval duration will be for 12 months for applicable medical benefit drugs.

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## Exclusions

The use of ustekinumab will not be covered for the following situations:

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling
- Combination therapy that is not supported by current guidelines

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## References

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5. ACG Clinical Guideline: Ulcerative Colitis in Adults. The American Journal of Gastroenterology: March 2019 - Volume 114 - Issue 3 - p 384-413 doi: 10.14309/ajg.0000000000000152. Accessed: ACG Clinical Guideline: Ulcerative Colitis in Adults : Official journal of the American College of Gastroenterology | ACG (lww.com)

6. AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis. Gastroenterology 2020;158:1450–1461; Published:January 13,2020 DOI:https://doi.org/10.1053/j.gastro.2020.01.006.

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8. Lichtenstein, Gary R MD, FACG[1]; Loftus, Edward V MD, FACG[2]; Isaacs, Kim L MD, PhD, FACG[3]; Regueiro, Miguel D MD, FACG[4]; Gerson, Lauren B MD, MSc, MACG (GRADE Methodologist)[5,†]; Sands, Bruce E MD, MS, FACG[6]. ACG Clinical Guideline: Management of Crohn's Disease in Adults. American Journal of Gastroenterology: April 2018 - Volume 113 - Issue 4 - p 481-517 doi: 10.1038/ajg.2018.27

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care for the management and treatment of psoriasis with biologics - Journal of the American Academy of Dermatology (jaad.org)

| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Medicare Gold Giveback | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D |
| 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 | 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).** | |
| *© 2024 MVP Health Plan, Inc. All rights reserved. Descriptions contained within MVP's Medical Policies are not a guarantee of coverage. Each MVP Group or Subscriber Contract contains specific limitations, exclusions and requirements that may affect a Policy. If there is any discrepancy between your Group or Subscriber Contract and a Policy, your Group or Subscriber Contract shall in all cases govern.* | |

***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 |

**MVP Health Care Medical Policy**

**Medicare Part B: Ustekinumab**

| | |
|---|---|
| **Type of Policy:** | **Drug/Medical Therapy** |
| **Prior Approval Date:** | **11/01/2023** |
| **Approval Date:** | **10/01/2024** |
| **Effective Date:** | **12/01/2024** |
| **Related Policies:** | **Abatacept, Certolizumab, Golimumab, Infliximab, Risankizumab, Tocilizumab** |

Refer to the Medicare Part D formulary for drugs that may be covered under the Part D benefit.

## Drugs Requiring Prior Authorization under the medical benefit

J3358 Stelara (ustekinumab intravenous injection, 1mg)

## Overview/Summary of Evidence

Ustekinumab (Stelara®) is a human IgG1 monoclonal antibody that binds to the p40 protein used by both IL-12 and IL-23 cytokines.

Ustekinumab is indicated for moderate to severe plaque psoriasis in members 6 years or older who are candidates for phototherapy or systemic therapy, active psoriatic arthritis (PsA) alone or in combination with methotrexate (MTX), moderately to severely active Crohn's disease (CD), and moderately to severely active ulcerative colitis (UC).

Members should be screened for immunologic and infectious disease prior to initiating therapy.

## Indications/Criteria

**A. For all indications, the following criteria must be met in addition to the specific diagnosis criteria below.**

- Self-administered formulations fall under the Medicare Part D (pharmacy) benefit.
    - Refer to the Medicare Part D Formulary and Part D policies for drugs that may be covered under the Part D benefit.
- Must be ordered by or with consult from a rheumatologist, immunologist, dermatologist, gastroenterologist or colorectal surgeon
- Must be prescribed for an FDA approved indication

**B. Psoriasis**

Ustekinumab may be considered for coverage when the following criteria is met:

- Documentation of moderate to severe chronic plaque psoriasis OR involvement of the palms, soles of feet and scalp, with an inadequate response, intolerance or contraindication with TWO of the following therapies: Enbrel, Humira, Otezla, Skyrizi.

**Initial approval** will be for **6 months**

**Extensions requests** will be approved **up to 12 months** if the member has a continued benefit to therapy. Extension requests where the ustekinumab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

**C. Psoriatic Arthritis (PsA)**

Ustekinumab may be considered for coverage when the following criteria is met:

- Documentation of active psoriatic arthritis with an inadequate response, intolerance or contraindication with TWO of the following therapies: Enbrel, Humira, Otezla, Xeljanz/XR.

**Initial approval** will be for **6 months**.

**Extensions requests** will be approved **up to 12 months** if the member has a continued benefit to therapy. Extension requests where the ustekinumab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

### D. Crohn's Disease

Ustekinumab may be considered for coverage when the following criteria is met:

- Documentation of moderate to severely active disease, with a previous trial, intolerance, or contraindication to Humira

**Initial approval** will be for **6 months**.

**Extensions requests** will be approved **up to 12 months** if the member has a continued benefit to therapy. Extension requests where the ustekinumab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

### E. Ulcerative Colitis

Ustekinumab may be considered for coverage when the following criteria is met:

- Documentation of moderately to severely active ulcerative colitis, with an inadequate response, intolerance, or contraindication to Humira and Xeljanz/XR.

**Initial approval** will be for **6 months.**

**Extensions requests** will be approved **up to 12 months** if the member has a continued benefit to therapy. Extension requests where the ustekinumab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

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## Exclusions

The use of ustekinumab will not be covered for the following situations:

- Dosing, age, and/or frequency exceeding the FDA approved package labeling.
- Combination therapy that is not supported by current guidelines

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## References

1. Stelara injection, subcutaneous. Prescribing Information. Horsham, PA, Janssen Biotech Inc.; November 2019.

2. Ritchlin CT, Kavanaugh A, Gladman DD, et al: (2008) Treatment recommendations for psoriatic arthritis. Ann Rheum Dis 2009 Sep;68(9):1387-94.

3. Ward Michael, Atul Deodhar et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondylosrthritis Research

and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. Arthritis and Rheumatology. Vol 71 (No. 10). October 2019, pp 1599-1613. Available at: https://www.rheumatology.org/Portals/0/Files/AxialSpA-Guideline-2019.pdf

4. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis & Rheumatology Vol. 71, No. 1, January 2019, pp 5–32 DOI 10.1002/art.40726. 2018 American College of Rheumatology/ National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis

5. ACG Clinical Guideline: Ulcerative Colitis in Adults. The American Journal of Gastroenterology: March 2019 - Volume 114 - Issue 3 - p 384-413 doi: 10.14309/ajg.0000000000000152. Accessed: ACG Clinical Guideline: Ulcerative Colitis in Adults : Official journal of the American College of Gastroenterology | ACG (lww.com)

6. AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis. Gastroenterology 2020;158:1450–1461; Published:January 13,2020 DOI:https://doi.org/10.1053/j.gastro.2020.01.006.

7. Feuerstein JD, Ho EY, Shmidt E, Singh H, Falck-Ytter Y, Sultan S, Terdiman JP; American Gastroenterological Association Institute Clinical Guidelines Committee. AGA Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn's Disease. Gastroenterology. 2021 Jun;160(7):2496-2508. doi: 10.1053/j.gastro.2021.04.022. PMID: 34051983; PMCID: PMC8988893.

8. Lichtenstein, Gary R MD, FACG[1]; Loftus, Edward V MD, FACG[2]; Isaacs, Kim L MD, PhD, FACG[3]; Regueiro, Miguel D MD, FACG[4]; Gerson, Lauren B MD, MSc, MACG (GRADE Methodologist)[5,†]; Sands, Bruce E MD, MS, FACG[6]. ACG Clinical Guideline: Management of Crohn's Disease in Adults. American Journal of Gastroenterology: April 2018 - Volume 113 - Issue 4 - p 481-517 doi: 10.1038/ajg.2018.27

**MVP Health Care Medical Policy**

**Valchlor**

| | |
|---|---|
| **Type of Policy:** | **Drug Therapy** |
| **Prior Approval Date:** | **04/01/2024** |
| **Approval Date:** | **04/01/2025** |
| **Effective Date:** | **06/01/2025** |
| **Related Policies:** | **N/A** |

## Drug Requiring Prior Authorization (covered under the pharmacy benefit)

Valchlor gel (mechlorethamine)

Refer to the Medicare Part D formulary for drugs that may be covered under the Part D benefit

## Overview

Mycosis fungoides is the most common type of cutaneous T-Cell Lymphoma (CTCL), with approximately 16,000 to 20,000 cases across the United States, accounting for half of all CTCLs. Mechlorethamine, also known as nitrogen mustard, is an alkylating agent which inhibits rapidly proliferating cells.

## Indications/Criteria

Valchlor may be considered for coverage when all of the following criteria are met:

- Chart notes are provided that include skin biopsy results identifying Stage 1A or 1B mycosis fungoides-type cutaneous T-cell lymphoma
- Lymph node biopsy and/or assessment of peripheral blood for Sézary cells must be provided if definitive diagnosis cannot be made from skin biopsy.
- Must be prescribed by an oncologist or dermatologist
- Must have failed one of the following skin-directed therapies:
    - Topical corticosteroids
    - Topical retinoids (bexarotene, tazarotene)

    - Phototherapy (UVB, nbUVB for patch/thin plaques; PUVA for thicker plaques)
    - Topical imiquimod
    - Local radiation (ISRT- involved site radiation therapy)
- Criteria and use of this agent must follow the FDA package label and the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. MVP reserves the right to deviate from the NCCN guidelines if new safety information becomes available prior to updated NCCN guidelines. The NCCN guidelines may be accessed at www.nccn.org

**Initial approval for 1 year**

**Extension requests** will be reviewed on a case-by-case basis based on current guidelines. All extension requests require documentation of response to therapy and clinical rationale for maintenance therapy.

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**Exclusions**

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling
- Severe hypersensitivity to mechlorethamine

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**References**


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2. Valchlor (mechlorethamine) gel. Prescribing Information. South San Francisco, CA. Actelion Pharmaceuticals, Inc. January 2020.
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4. NCCN Guidelines for Patients. Mycosis Fungoides/Sezary Syndrome. 2021. NCCN Guidelines for Patients Mycosis Fungoides/Sézary Syndrome

| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Complete Wellness | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| USA Care PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

**Vyepti**

| | |
|---|---|
| **Type of Policy:** | Drug Therapy |
| **Prior Approval Date:** | 08/01/2024 |
| **Approval Date:** | 10/01/2024 |
| **Effective Date:** | 01/01/2025 |
| **Related Policies:** | |

## Codes Requiring Prior Authorization (covered under the medical benefit)

J3032 Vyepti (injection, eptinezumab-jjmr, 1mg)

## Overview

Migraine is a common disabling primary headache disorder. In the Global Burden of Disease Study 2010 (GBD2010), it was ranked as the third most prevalent disorder in the world. In GBD2015, it was ranked the third-highest cause of disability worldwide in both males and females under the age of 50 years.

Calcitonin Gene-Related Peptides (CGRP) receptor antagonists are a group of medications indicated in either the prophylaxis or acute treatment of migraine headaches. Vyepti is a humanized monoclonal antibody that binds to the CGRP ligand and blocks it's binding to the receptor.

## Indications/Criteria

- Vyepti may be considered for coverage for migraine prophylaxis when all the following are met:
    - Confirmed diagnosis of chronic or episodic migraines
    - For chronic migraines:
        - Inadequate response (defined as less than a 2 day decrease per month in headache frequency) to at least a 1 (one) trial to at least **1** (one) prophylactic medication (i.e., topiramate, divalproex, propranolol,

metoprolol, timolol, amitriptyline, verapamil, venlafaxine) at maximally tolerated doses

- For episodic migraines:
  - Inadequate response (defined as less than a 2 day decrease per month in headache frequency) to at least a 1 (one) trial to at least **1** (one) prophylactic medication (i.e., topiramate, divalproex, propranolol, metoprolol, timolol, amitriptyline, verapamil, venlafaxine) at maximally tolerated doses
- Documentation identifying medical necessity, and why the member is unable to use a self-administered product (such as a failure, intolerance, or contraindication to self-administered products)
  - If applicable, documentation should also include why the member or caregiver is unable to administer a self-administered product

**Initial approval** will be for **3 months.**

**Extension requests** will be approved for **up to 12 months** if the member has continued benefit to therapy.

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**Medicaid Variation:**

Medications that are a pharmacy benefit are covered and billed to New York State Fee-For-Service (FFS) program. They are defined as medications that go through a retail or specialty pharmacy, including self administered injectable products. Pharmacy medications are subject to FFS's clinical criteria including (but not limited to) coverage, quantity limit, step therapy, and prior authorization. Pharmacy benefit information can be found here: https://www.emedny.org/info/fullform.pdf

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**Exclusions**

- Indication, age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling
- History of hemiplegic ophthalmoplegic, migraine with brainstem aura, or persistent daily headaches
- Use of devices (i.e., nerve blocks and transcranial magnetic stimulation)

## References


1. Olesen J, Bes A, Kunkel R, et al. The international classification of headache disorders, 3rd edition. Cephalagia. 2018; 38(1):1-211.
2. American Headache Society. The American Headache Society position statement on integrating new migraine treatments into clinical practice. Headache 2018; 59:1-18.
3. Ailani J, Burch RC, Robbins MS; Board of Directors of the American Headache Society. The American Headache Society Consensus Statement: Update on integrating new migraine treatments into clinical practice. Headache. 2021;61(7):1021-1039. doi:10.1111/head.14153.
4. Eptinezumab – Vyepti. In: Clinical Pharmacology [database on the Internet]. Tampa (FL): Elsevier. [2024]. Available from: www.clinicalpharmacology.com. Subscription required to view.
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8. Andrew C. Charles MD, Kathleen B. Digre MD, Peter J. Goadsby MD, PhD, Matthew S. Robbins MD, Andrew Hershey MD, PhD, The American Headache Society. (2024) Calcitonin gene-related peptide-targeting therapies are a first-line option for the prevention of migraine: An American Headache Society position statement update. Headache Journal.


| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |

| | |
|---|---|
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Medicare Gold Giveback | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Secure PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Preferred PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | 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).** | |

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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 |

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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 |

**MVP Health Care Medical Policy**

# Weight Loss Medications

**Type of Policy:** **Drug/Medical Therapy**
**Prior Approval Date:** **04/01/2025**
**Approval Date:** **06/01/2025**
**Effective Date:** **07/01/2025**
**Related Policies:** **NA**

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies.

## Drugs Requiring Prior Authorization under the pharmacy benefit

Saxenda (liraglutide)

Wegovy (semaglutide)

Zepbound (tirzepatide)

## Overview

Glucagon-like peptide-1 receptor agonists (GLP-1 RA) are part of a class of anti-diabetic medications known as incretin mimetics that exert their main effect once released into circulation through the gut by stimulating glucose-dependent insulin release from the pancreatic islets. Primarily used for treatment of type 2 diabetes, some GLP-1 RAs also provide benefit in reducing the risk of both nonfatal cardiovascular disease and cardiovascular mortality in patients with Type 2 diabetes and facilitate weight loss. Saxenda, Zepbound and Wegovy carry indications for FDA-approved, on-label use as weight loss agents to treat obesity.

**Saxenda** is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in:

- Adult patients with an initial body mass index (BMI) of

  - 30 kg/m2 or greater (obese), or
  - 27 kg/m2 or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g. hypertension, type 2 diabetes mellitus, or dyslipidemia) (1).
- Pediatric patients aged 12 years and older with:
  - body weight above 60 kg and an initial BMI corresponding to 30 kg/m2 for adults (obese) by international cut-offs

**Wegovy** is indicated in combination with a reduced calorie diet and increased physical activity:

- to of risk of major cardiovascular events in individuals with established cardiovascular disease and obesity or who are overweight.
- To reduce excess body weight and maintain weight reduction long term in adults and pediatric patients aged 12 years and older with obesity and adults who are overweight with the presence of at least one weight related comorbid condition.

**Zepbound** is indicated in combination with a reduced-calorie diet and increased physical activity:

- to reduce excess body weight and maintain weight reduction long term in adults with obesity or adults with overweight in the presence of at least one weight-related comorbid condition.

to treat moderate to severe obstructive sleep apnea (OSA) in adults with obesity.

## Indications/Criteria

For Medicare, ASO (Self-Funded) and Child Health Plus members, see Variation details

### A. Weight loss for adult members

Saxenda, Zepbound and Wegovy may be considered for coverage for weight loss **for adults** when all the following criteria is met:

- Chart notes documenting all the of following:
  - Member's current body mass index (BMI) of 35 or greater
  - Member's current body weight and height
- Provider attestation of a failure of lifestyle modifications for at least 6 months. This must include an exercise program AND calorie deficit meal plan to the maximum extent clinically possible.
- Chart notes documenting proof of consult with an appropriate healthcare professional regarding the benefits of dietary changes and exercise for

weight loss. The following specialties are not considered an appropriate consult: anesthesiology, dentistry, emergency medicine, nuclear medicine, ophthalmology, pathology, and radiology.

**Initial approval** will be for 6 months

**Extension requests** will be approved up to 6 months when

- Current chart notes documenting ALL of the following:
    - Clinical benefit to the medication which can include:
        - Continues to meet the criteria above
        - A decrease in baseline Body Mass Index (BMI)
        - A decrease in baseline body weight (at least 5 percent of baseline)
- Member's prescription history must show compliance with medication.
- Provider attestation indicating compliance with an appropriate exercise and calorie deficit meal plan to the maximum extent clinically possible

**B. Cardiovascular disease risk reduction**

Wegovy may be considered for coverage to reduce the risk of heart attack and stroke in obese or overweight adults with cardiovascular disease when the following criteria is met:

- 
- Member's current body mass index (BMI)
    - 30 kg/$m^2$ or greater (obesity), or
    - 27 kg/$m^2$ or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, obstructive sleep apnea, type 2 diabetes mellitus, or dyslipidemia)
    - Member's current body weight and height
- Provider attestation of a failure of lifestyle modifications for at least 6 months. This must include an exercise program AND calorie deficit meal plan to the maximum extent clinically possible.
- Chart notes documenting proof of consult with an appropriate healthcare professional regarding the benefits of dietary changes and exercise for weight loss. The following specialties are not considered an appropriate consult: anesthesiology, dentistry, emergency medicine, nuclear medicine, ophthalmology, pathology, and radiology
- Member does not have type 2 diabetes

- Provider attestation that Wegovy is being used to reduce the risk of heart attack and stroke in obese or overweight adults with cardiovascular disease
- Chart notes documenting a cardiovascular diagnosis
- Chart notes documenting that the member is concurrently taking guidelines-directed management and therapy for cardiovascular disease (i.e. lipid lowering agents, antiplatelets, beta-blockers, etc). Claims history will be reviewed.

**Initial approval** will be for 6 months

**Extension requests** will be approved up to 6 months when current chart notes documenting ALL of the following:

- Clinical benefit to the medication which can include:
  - Continues to meet the criteria above
  - A decrease in baseline Body Mass Index (BMI)
  - A decrease in baseline body weight (at least 5 percent of baseline)
- Member's prescription history must show compliance with medication.
- Provider attestation indicating compliance with an appropriate exercise and calorie deficit meal plan to the maximum extent clinically possible

## C. Weight loss for pediatric members

Saxenda and Wegovy may be considered for coverage for weight loss **for pediatric members** when all the following criteria is met:

- Member is 12 years of age of older
- For Wegovy requests
  - Member has an initial BMI at the 95$^{th}$ percentile or greater for age and sex
- For Saxenda requests:
  - Body weight above 60 kg (132 pounds) **AND**
  - Initial BMI corresponding to 30 kg/m$^2$ or greater for adults (obese) by international cut-offs (Cole Criteria: provided in prescribing information)
- Chart notes documenting Health Behavior and Lifestyle Treatment including:
  - Age-appropriate exercise program
  - Calorie deficit meal plan to the maximum extent clinically possible
  - Nutritional counseling or skill building sessions

**Initial approval** will be for 4 months

**Extension requests** will be approved up to 6 months when current chart notes documenting ALL of the following:

- Clinical benefit to the medication which can include:
    - Continues to meet the criteria above
    - A decrease in baseline Body Mass Index (BMI)
    - A decrease in baseline body weight (at least 5 percent of baseline)
- Member's prescription history must show compliance with medication.
- Compliance with an appropriate exercise and calorie deficit meal plan to the maximum extent clinically possible

**D. Zepbound for Obstructive Sleep Apnea**

Zepbound for moderate to severe obstructive sleep apnea (OSA) in adults with obesity may be considered for coverage when the following criteria is met:

- Chart notes documenting member's has a body mass index (BMI) of 30 $kg/m^2$ or greater (obesity)
- Chart notes documenting the member's current body weight and height
- Provider attestation that Zepbound will be used in combination with a reduced-calorie diet and increased physical activity.
- Chart notes documenting a diagnosis of moderate to severe obstructive sleep apnea

**Initial approval** will be for 6 months

**Extension requests** will be approved up to 6 months when

- Current chart notes documenting ALL of the following:
    - Clinical benefit to the medication which can include:
        - Improvement in OSA
        - Continues to meet the criteria above
- Member's prescription history must show compliance with medication.
- Provider attestation indicating compliance with an appropriate exercise and calorie deficit meal plan to the maximum extent clinically possible

## Medicare Variation

Weight loss products are not covered for Medicare members. Some Employer group plans do allow for coverage of weight loss products.
Weight loss products when used for Medically Accepted Indications (MAIs) will be considered for coverage when they meet prescribing criteria in the drug package insert/prescribing information

**Child Health Plus (CHP) Variation**
Medications used for weight loss management are not covered for Child Health Plus members. Weight loss products when used for other Medically Accepted Indications (MAIs) will be considered for coverage when they meet the specific indication criteria in this policy.

**ASO Variation**
Refer to the Specific Plan Design

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**Exclusions**

The use of the medications listed in this policy will not be covered for the following situations:

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling.
- Combination therapy with other products for weight loss
- Over-the-counter products are not a covered benefit
- Saxenda, Zepbound and Wegovy used for the treatment of type 2 diabetes or in combination with another GLP-1 Receptor agonist.

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3. WEGOVY® (semaglutide) injection, for subcutaneous use. Prescribing Information. Plainsboro, NJ. Novo Nordisk, Inc.; November 2023.

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5. Clinical Pharmacology. Semaglutide. Revised 04/03/2023. Accessed 06/12/2023.

6. Clinical Practice Guideline for the Evaluation and Treatment of Children and Adolescents With Obesity | Pediatrics | American Academy of Pediatrics (aap.org)

| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Not Covered |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Not Covered |
| MVP Complete Wellness | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| USA Care PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

**Xolair® (omalizumab)**

**Type of Policy:** **Medical Therapy *(administered by the pharmacy department)***
**Prior Approval Date:** **04/01/2024**
**Approval Date:** **02/01/2025**
**Effective Date:** **04/01/2025**
**Related Policies:** **Dupixent, Select Injectables for Asthma**

**Drugs Requiring Prior Authorization (covered under the medical benefit)**
J2357 Xolair® (omalizumab)

Refer to Medicare Part B coverage criteria

**Drugs Requiring Prior Authorization (covered under the pharmacy benefit)**
Xolair (omalizumab) pre-filled syringes

Refer to the Medicare Part D formulary for drugs that may be covered under the Part D benefit.

**Overview**
Omalizumab (Xolair®) is a recombinant DNA-derived humanized IgG1k monoclonal antibody that selectively binds to human immunoglobulin E (IgE). It inhibits the binding of IgE to the high-affinity IgE receptor (FceRI) on the surface of mast cells and basophils and reduces the number of FceRI receptors on basophils. It is administered once or twice a month, with dosing based on the member's weight and IgE level. Xolair inhibits inflammation at its source versus suppressing inflammation once it has occurred. Symptom improvement is seen by four weeks from the start of treatment.

The Food and Drug Administration (FDA) reports that serious and life-threatening anaphylactic reactions have occurred in patients after treatment with Xolair®. Usually, these reactions occur within two hours of receiving a Xolair subcutaneous injection. However, new reports include patients who had delayed anaphylaxis—with onset two to 24 hours or even longer after receiving Xolair treatment. Anaphylaxis may occur after *any* dose of Xolair (including the first dose), even if the patient had no allergic reaction to the first dose. The symptoms and signs of anaphylaxis in these reported patients include bronchospasm, hypotension, syncope, urticaria, and angioedema of the

throat or tongue. Health care professionals who administer Xolair should be prepared to manage life-threatening anaphylaxis and should observe their Xolair-treated patients for at least two hours after the drug is given. Patients under treatment with Xolair should be fully informed about the signs and symptoms of anaphylaxis, their chance of developing delayed anaphylaxis following Xolair treatment, and how to treat it when it occurs.

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**Medicare Variation**

- Self-administration of Xolair is a Medicare Part D benefit and follows the Medicare Part D Prior Authorization criteria requirements.

**Indications/Criteria**

Xolair (omalizumab) is FDA approved for:

- Moderate to severe persistent asthma in adults and pediatric patients 6 years of age and older who have a positive skin test or *in vitro* reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids
- Chronic idiopathic urticaria in adults and adolescents 12 years of age and older who remain symptomatic despite H1 antihistamine treatment.
- Nasal polyps in adults' patients 18 years of age and older with inadequate response to nasal corticosteroids, as add-on maintenance treatment,
- IgE mediated food allergies in adult and pediatric patients aged 1 year and older for the reduction of allergic reactions (Type I), including anaphylaxis, that may occur with accidental exposure to one or more foods. To be used in conjunction with food allergen avoidance.

**A. For all indications, the following criteria must be met in addition to the specific diagnosis criteria below.**

- Members must meet age requirements based on the FDA approved labeling for the applicable FDA approved indicated. **AND**
- Must be prescribed for an FDA approved indication
- Xolair injection for office administration may be considered for coverage if the following is provided:
    - Rationale and documentation are provided identifying why the member or caregiver is unable to self-administer using the pre-filled syringe **OR**
    - Member has coverage under Medicare Part B and meets the criteria for a provider administered drug.

- See **Medicare Variation** for self-administration requirements.

**B. Moderate to severe persistent asthma**

**Xolair** may be considered for coverage for moderate to severe persistent asthma when the following criteria is met:

- Must be ordered by or in consult with an allergist, immunologist, or pulmonologist
- Member has a diagnosis of moderate to severe persistent asthma supported with chart notes documenting:
  - Continual or daily symptoms (daytime or nighttime)
  - Limited physical activity or exacerbations affecting activities of daily living (ADL's)
  - Frequent exacerbations or exacerbations at least 2 times a week which may last days
  - $FEV_1$ or PEF ≤80% predicted
  - PEF variability >30%
  - Increasing use of short acting beta2 agonist or use >2 days/week for symptom relief
- Member has evidence of compliance with:
  - High dose Inhaled Corticosteroids (ICS) required for daily control
  - Inadequate control on combination therapy (moderate dose ICS and a Long-Acting Beta-Agonist, formoterol OR ICS and Long-Acting Muscarinic Antagonist as an alternative) for at least 6 months
  - Oral Corticosteroid use of at least two courses within the past 12 months for asthmatic exacerbations or the inability to wean from systemic corticosteroids
- Member is a non-smoker by history or have a successful smoking cessation for at least 6 weeks.
- Documentation that other medical and environmental conditions known to exacerbate asthma have been evaluated and treated.
- Specific relevant allergic sensitivities to perennial aeroallergens (dust mites, mold, animal dander, cockroaches, etc.) determined by:
  - Skin tests or
  - *In vitro* testing
- Use in accordance with product literature or supporting clinical documentation for consideration on a case-by-case basis when outside published dosing limits:
  - Baseline IgE level (>30 IU/ml and ≤700 IU/ml)
  - Body Weight (≤150 kg)

**Initial approval** will be for 12 months

**Continued authorizations** will be approved up to 3 years when current documentation indicates the following:

- Improvement in asthma control, which includes but is not limited to:
  - Improved function and quality of life, reduction in the lost days of work or school due to asthma, reduction in ER/hospital/office visits due to asthma, or decreased use of other asthma medications.
- Increase in percent predicted FEV1 from baseline
- Xolair is used in addition to an ICS containing maintenance medication

- **Medicaid Variation approval durations:** Initial approval duration will be for 6 months and continuation approval duration will be for 12 months for applicable medical benefit drugs.

**C. Chronic idiopathic urticaria:**

Xolair may be considered for coverage for chronic idiopathic urticaria when the following criteria is met:

- Prescribed by or in consultation with an allergist, immunologist, or dermatologist
- Urticaria is persistent or recurring over 6 weeks in duration; **AND**
- Individual lesions of urticaria lasting less than 24hours (if longer than 24 hours then urticarial vasculitis must first be ruled out, which may include ESR, complement assays, and biopsy); **AND**
- Other causes for urticaria (such as occupational, insect sting/bite, medications, food, infection, physical sensitivity) has been ruled out; **AND**
- Member has remained symptomatic despite:
  - At least a two-week trial of a maximally tolerated dose of a potent H1 antihistamine (such as Hydroxyzine or Doxepin) in combination with <u>one</u> of the following:
    - Another Second Generation H1 antihistamine
    - H2 antihistamine
    - First-generation H1 antihistamine at night
    - Leukotriene receptor antagonist

**Initial approval** will be for a 12months

**Continued authorization** will be up to 3 years if current chart notes document that the member has a continued benefit to therapy. Improvement in chronic idiopathic urticaria includes but is not limited to a decrease in itching or a decrease in hive count. Extension requests where Xolair did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

**Medicaid Variation approval durations:** Initial approval duration will be for 6 months and continuation approval duration will be for 12 months for applicable medical benefit drugs.

**D. Chronic Rhinosinusitis with nasal polyps**

Xolair may be considered for coverage for Chronic Rhinosinusitis with nasal polyps when the following criteria is met:

- Confirmed diagnosis of nasal polyps. Chart notes must document diagnosis confirmation by examination, endoscopy or sinus computed tomography (CT) scan.
- Prescribed by or in consultation with an allergist, otolaryngologist or immunologist
- Attestation that Xolair will be add on maintenance in combination with an intranasal corticosteroid
- Documented trial and failure of three (3) months, to at least one intranasal corticosteroid indicated to treat nasal polyps
- Documented failure, contraindication, intolerance, or allergy to other therapy used in the management of nasal polyps such as nasal saline irrigations, or antileukotriene agents (i.e. montelukast, zafirlukast, zileuton)
- Documentation of prior oral corticosteroid therapy and/or sinus surgery

**Initial coverage** will be for 12 months.

**Continued authorization** up to 12 months, must be accompanied by current chart notes identifying a continued benefit and compliance with combination therapy. Claims history must show compliance with combination therapy

**Medicaid Variation approval durations:** Initial approval duration will be for 6 months and continuation approval duration will be for 12 months for applicable medical benefit drugs.

**E. IgE-mediated Food Allergies**

Xolair may be considered for coverage for IgE-mediated Food Allergies when the following criteria is met:

- Chart notes documenting a confirmed diagnosis of one or more IgE mediated food allergy which is confirmed by one of the following below AND performed by a board certified allergist/immunologist:

1. A positive skin prick test ≥4mm wheal **OR**
2. Documentation of member total serum IgE (kIU/L) ≥ 6 kIU/L measured no longer than three months prior to request **OR**
3. Documentation of a positive double-blind placebo-controlled food challenge (DBPCFC) with a single dose of food protein as performed by an allergist or immunologist

- Prescribed by or in consultation with a board certified allergist /immunologist
- Provider attestation that Xolair will be used in conjunction with food allergen avoidance
- Documentation of member's current body weight

**Initial Coverage** will be for 12 months

**Continued authorization** up to 12 months must be accompanied by current chart notes identifying the following:

- Current body weight to verify dosing
- Provider attestation of food allergen avoidance

**Medicaid Variation approval durations:** Initial approval duration will be for 6 months and continuation approval duration will be for 12 months for applicable medical benefit drugs.

**Medicaid Variation:**
Initial approval duration will be for 6 months and continuation approval duration will be for 12 months for applicable medical benefit drugs.
Medications that are a pharmacy benefit are covered and billed to New York State Fee-For-Service (FFS) program. They are defined as medications that go through a retail or specialty pharmacy, including self-administered injectable products. Pharmacy medications are subject to FFS's clinical criteria including (but not limited to) coverage, quantity limit, step therapy, and prior authorization. Pharmacy benefit information can be found here: https://www.emedny.org/info/fullform.pdf

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**Exclusions**

**For all indications:**

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling

- Combination use with other biologics (e.g., Cinqair, Dupixent, Fasenra, Nucala)

**For moderate to severe persistent asthma:**

- Current smokers
- A diagnosis other than allergic asthma, including allergic rhinitis, other allergic conditions, non-allergic asthma, allergic bronchopulmonary aspergillosis, acute bronchospasm or status asthmaticus
- Current treatment has not been optimized using applicable strategies such as
  - High dose inhaled corticosteroids (ICS)
  - Leukotriene modifiers or theophylline if preferred therapies (ICS, LABA/LAMA) are not appropriate.
  - Long-acting beta agonists
  - Allergy injections (immunotherapy)
  - Member compliance
  - Inhaler technique
  - Environmental controls

**For chronic idiopathic urticaria:**

- A diagnosis other than chronic idiopathic urticaria
  - Xolair is not indicated for acute urticaria, urticarial vasculitis, or urticaria with a known cause

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| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Complete Wellness | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| USA Care PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

**Medicare Part B: Xolair® (omalizumab)**

| | |
|---|---|
| **Type of Policy:** | **Medical Therapy *(administered by the pharmacy department)*** |
| **Prior Approval Date:** | **04/01/2024** |
| **Approval Date:** | **02/01/2025** |
| **Effective Date:** | **04/01/2025** |
| **Related Policies:** | **Select Injectables for Asthma** |

**Drugs Requiring Prior Authorization (covered under the medical benefit)**
J2357 Xolair® (omalizumab)

Refer to the Medicare Part D formulary for drugs that may be covered under the Part D benefit.

**Overview/Summary of Evidence**

Omalizumab (Xolair®) is a recombinant DNA-derived humanized IgG1k monoclonal antibody that selectively binds to human immunoglobulin E (IgE). It inhibits the binding of IgE to the high-affinity IgE receptor (FceRI) on the surface of mast cells and basophils and reduces the number of FceRI receptors on basophils. It is administered once or twice a month, with dosing based on the member's weight and IgE level. Xolair inhibits inflammation at its source versus suppressing inflammation once it has occurred. Symptom improvement is seen by four weeks from the start of treatment.

The Food and Drug Administration (FDA) reports that serious and life-threatening anaphylactic reactions have occurred in patients after treatment with Xolair®. Usually, these reactions occur within two hours of receiving a Xolair subcutaneous injection. However, new reports include patients who had delayed anaphylaxis—with onset two to 24 hours or even longer after receiving Xolair treatment. Anaphylaxis may occur after *any* dose of Xolair (including the first dose), even if the patient had no allergic reaction to the first dose. The symptoms and signs of anaphylaxis in these reported patients include bronchospasm, hypotension, syncope, urticaria, and angioedema of the throat or tongue. Health care professionals who administer Xolair should be prepared to manage life-threatening anaphylaxis and should observe their Xolair-treated patients for at least two hours after the drug is given. Patients under treatment with Xolair should be fully informed about the signs and symptoms of anaphylaxis, their chance of developing delayed anaphylaxis following Xolair treatment, and how to treat it when it occurs.

## Indications/Criteria

- Self-administration of Xolair is a Medicare Part D benefit and follows the Medicare Part D Prior Authorization criteria requirements.
- For Medicare Part B coverage, please refer to the current coverage guidelines LCD L33394, "Drugs and Biologicals, Coverage of, for Label and Off-Label Uses" and CMS Billing and Coding Article "Omalizumab:, article A52448.

Xolair (omalizumab) is FDA approved for:

- Moderate to severe persistent asthma in adults and pediatric patients 6 years of age and older who have a positive skin test or *in vitro* reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids
- Chronic idiopathic urticaria in adults and adolescents 12 years of age and older who remain symptomatic despite H1 antihistamine treatment.
- Nasal polyps in adults' patients 18 years of age and older with inadequate response to nasal corticosteroids, as add-on maintenance treatment
- IgE-mediated food allergy in adult and pediatric patients at least 1 year of age and older for the reduction of allergic reactions (Type I), including anaphylaxis, that may occur with accidental exposure to one or more foods

**A. Treatment with Xolair for ALL indications will be considered when the following criteria is met. Please see section B for indication specific criteria.**

- Members must meet age requirements based on the FDA approved labeling for the applicable FDA approved indication **AND**
- Must be prescribed for an FDA approved indication
- Self-administration of Xolair is a Medicare Part D benefit and follows the Medicare Part D Prior Authorization criteria requirements.

**B. Moderate to severe persistent asthma**

**Xolair** may be considered for coverage for moderate to severe persistent asthma when the following criteria is met:

- Must be ordered by or in consult with an allergist, immunologist, or pulmonologist
- Member has a diagnosis of moderate to severe persistent asthma supported with chart notes documenting:
  - Continual or daily symptoms (daytime or nighttime)

- Limited physical activity or exacerbations affecting activities of daily living (ADL's)
- Frequent exacerbations or exacerbations at least 2 times a week which may last days
- $FEV_1$ or PEF ≤80% predicted
- PEF variability >30%
- Increasing use of short acting beta2 agonist or use >2 days/week for symptom relief

- Member has evidence of compliance with:
  - High dose Inhaled Corticosteroids (ICS) required for daily control
  - Inadequate control on combination therapy (moderate dose ICS and a Long-Acting Beta-Agonist, formoterol OR ICS and Long-Acting Muscarinic Antagonist as an alternative) for at least 6 months
  - Oral Corticosteroid use of at least two courses within the past 12 months for asthmatic exacerbations or the inability to wean from systemic corticosteroids
- Member is a non-smoker by history or have a successful smoking cessation for at least 6 weeks.
- Documentation that other medical and environmental conditions known to exacerbate asthma have been evaluated and treated.
- Specific relevant allergic sensitivities to perennial aeroallergens (dust mites, mold, animal dander, cockroaches, etc.) determined by:
  - Skin tests or
  - *In vitro* testing
- Use in accordance with product literature or supporting clinical documentation for consideration on a case-by-case basis when outside published dosing limits:
  - Baseline IgE level (>30 IU/ml and ≤700 IU/ml)
  - Body Weight (≤150 kg)

**Initial authorization** for 12 months

**Continued authorizations** will be approved up to 12 months. Clinical documentation showing a positive clinical response must be provided.

C. **Chronic idiopathic urticaria**

**Xolair** may be considered for coverage for chronic idiopathic urticaria when the following criteria is met:

- Prescribed by or in consultation with anallergist, immunologist, or dermatologist
- Urticaria is persistent or recurring over 6 weeks in duration; **AND**
- Individual lesions of urticaria lasting less than 24hours (if longer than 24 hours then urticarial vasculitis must first be ruled out, which may include ESR, complement assays, and biopsy); **AND**
- Other causes for urticaria (such as occupational, insect sting/bite, medications, food, infection, physical sensitivity) has been ruled out; **AND**
- Member has remained symptomatic despite:
    - At least a two-week trial of a maximally tolerated dose of a potent H1 antihistamine (such as Hydroxyzine or Doxepin) in combination with <u>one</u> of the following:
        - Another Second Generation H1 antihistamine
        - H2 antihistamine
        - First-generation H1 antihistamine at night
        - Leukotriene receptor antagonist

**Initial authorization** for 12 months

**Continued authorization** will be up to 12 months based on improvement in chronic idiopathic urticaria on Xolair therapy. Improvement in chronic idiopathic urticaria includes but is not limited to a decrease in itching or a decrease in hive count.

**D. Chronic rhinosinusitis with nasal polyps**

Xolair may be considered for coverage for Chronic Rhinosinusitis with nasal polyps when the following criteria is met:
:

- Confirmed diagnosis of nasal polyps. Chart notes must document diagnosis confirmation by examination, endoscopy, or sinus computed tomography (CT) scan.
- Prescribed by or in consultation with an allergist, otolaryngologist or immunologist
- Xolair (omalizumab) will be add on maintenance in combination with an intranasal corticosteroid

- Documented failure, contraindication, intolerance, or allergy to at least one intranasal corticosteroid indicated to treat nasal polyps

**Initial coverage** will be for 12 months.

**Continued authorization** up to 12 months, must be accompanied by current chart notes identifying a continued benefit. Extension of therapy for up to one year will be based upon a positive clinical response.

### E. IgE-mediated Food Allergies

Xolair may be considered for coverage for IgE-mediated Food Allergies when the following criteria is met:

- Chart notes documenting a confirmed diagnosis of one or more IgE-mediated food allergy which is confirmed by one of the following below AND performed by a board certified allergist/immunologist:
    1. A positive skin prick test ≥4mm wheal OR
    2. Documentation of member total serum IgE (kIU/L) ≥ 6 kIU/L measured no longer than three months prior to request OR
    3. Documentation of a positive double-blind placebo-controlled food challenge (DBPCFC) with a single dose of food protein as performed by an allergist or immunologist
- Prescribed by or in consultation with a board certified allergist/immunologist
- Provider attestation that Xolair will be used in conjunction with food allergen avoidance
- Documentation of member's current body weight

**Initial coverage** will be for 12 months.

**Continued authorization** up to 12 months must be accompanied by current chart notes identifying the following:

- Current body weight to verify dosing
- Provider attestation of food allergen avoidance

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### Exclusions

For all indications:

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling

- Combination use with other biologics (e.g., Cinqair, Dupixent, Fasenra, Nucala)

**For moderate to severe persistent asthma:**

- Current smokers
- A diagnosis other than allergic asthma, including allergic rhinitis, other allergic conditions, non-allergic asthma, allergic bronchopulmonary aspergillosis, acute bronchospasm or status asthmaticus
- Ctreatment has not been optimized using applicable strategies such as
    - High dose inhaled corticosteroids (ICS)
    - Leukotriene modifiers or theophylline if preferred therapies (ICS, LABA/LAMA) are not appropriate.
    - Kong-acting beta agonists
    - Allergy injections (immunotherapy)
    - Member compliance
    - Inhaler technique
    - Environmental controls

**When used for chronic idiopathic urticaria:**

- A diagnosis other than chronic idiopathic urticaria
    - omalizumab (Xolair) is not indicated for acute urticaria, urticarial vasculitis, or urticaria with a known cause

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**References**


1. Xolair® (omalizumab). Prescribing Information. South San Francisco, CA: Genentech Inc.; February 2024.
2. Rosenwasser, L.J. & Nash, D.B. (2003). Incorporating omalizumab into asthma treatment guidelines: consensus panel recommendations. P&T 28(6) 400-10.
3. National Asthma Education and Prevention Program. Guidelines for the diagnosis and management of asthma: expert panel report 3. Bethesda, Md.: U.S. Dept. of Health and Human Services, Public Health Service, National Institutes of Health, National Heart, Lung, and Blood Institute, 2007; NIH publication no. 08-5846.
4. National Government Services, Inc. Article for omalizumab (e.g., Xolair) – Related to LCD L25820 (A46088). Original Article Effective Date 12/01/2007. Article Revision Effective Date 6/5/2009. Available: http://www.ngsmedicare.com
5. 2020 Focused Updates to the Asthma Management Guidelines: A Report from the National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group | NHLBI, NIH
6. Acute and Chronic Urticaria: Evaluation and Treatment - American Family Physician (aafp.org)

7. A Comparison of the United States and International Perspective on Chronic Urticaria Guidelines (jaci-inpractice.org)
8. National Asthma Education and Prevention Program. *Asthma Care Quick Reference: Diagnosing and Managing Asthma*. National Heart, Lung, and Blood Institute, 2011. Available at: https://www.nhlbi.nih.gov/files/docs/guidelines/asthma_qrg.pdf.
9. **Centers for Medicare & Medicaid Services.** (n.d.). Article: Omalizumab (A52448). Retrieved from: Article - Billing and Coding: Omalizumab (A52448)
10. **Centers for Medicare & Medicaid Services.** (n.d.). Local Coverage Determination (LCD): Omalizumab (L33394). LCD - Drugs and Biologicals, Coverage of, for Label and Off-Label Uses (L33394)

**MVP Health Care Medical Policy**

**Zinplava (bezlotoxumab)**

| | |
|---|---|
| **Type of Policy:** | **Drug Therapy** |
| **Prior Approval Date:** | **12/01/2023** |
| **Approval Date:** | **12/01/2024** |
| **Effective Date:** | **02/01/2025** |
| **Related Policies:** | **C. Difficile Drug Therapy** |

## Codes Requiring Prior Authorization (covered under the medical benefit)

J0565 Zinplava (injection, bezlotoxumab 10mg)

## Overview

C. difficile is the most common cause of infectious diarrhea in hospitalized members. About 1/3 of members have recurrent C. Difficile infection (CDI) after completing their initial antibiotic therapy. Recurrent C. difficile is more difficult to treat and leads to more severe outcomes and greater treatment costs.

Zinplava is a human monoclonal antibody that is indicated to reduce recurrence of C. Difficile infection (CDI) in adult and pediatric members 1 year and older who are receiving antibacterial therapy and are at a high risk for CDI recurrence. Zinplava is not an antibacterial drug and should not be used as monotherapy. It is meant to be used in combination with standard C. Difficile treatment. It works by binding and neutralizing the effect of C. difficile toxin B.

## Indications/Criteria

- Prescribed by or in consultation with infectious disease or gastroenterologist
- Member must be diagnosed with C-difficile

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    - defined as diarrhea (≥3 unformed bowel movements [5 to 7 on the Bristol stool scale] in 24hrs)
    - stool test result that was positive for toxigenic C. difficile
- Member must be receiving standard C. diff therapy (vancomycin, fidaxomicin (preferred therapy), metronidazole)
- Must be at high risk of CDI recurrence or at high risk for CDI-related adverse outcome as defined by having **at least one** of the following risk factors:
    - Age ≥ 65
    - Prior episode of C. difficile Infection within the past 6 months
    - Clinically severe C. difficile infection (Zar Score of greater than or equal to 2)
    - Immunocompromised state
    - Disease states that represent an increased risk such as solid organ transplant, stem cell transplant, chronic kidney disease, end stage renal disease, Inflammatory Bowel Disease, cancer
    - Prolonged antibiotic therapy

If the member has a history of congestive heart failure (CHF), the provider must attest that the benefits outweigh the risk.

**Initial coverage** will be for a **single dose** of 10mg/kg IV infused over 60 minutes

**Requests for continuation: see exclusions**

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**Exclusions**

- Any repeat dose is considered experimental or investigational
- Indication, age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling. Zinplava monotherapy used to treat C-difficile infection
    - Must used in conjunction with antibacterial drug treatment for CDI
- Combined with fecal transplantation

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**References**

1. Wilcox M.H.Poxton. I.R et al. Bezlotoxumab for Prevention of Recurrent Clostridium difficile Infection. The New England Journal of Medicine. January

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2017; 376: 306-17 Available at : http://www.nejm.org/doi/pdf/10.1056/NEJMoa1602615

2. Zinplava (Bezlotoxumab) Injection. Prescribing Information. Whitehouse Station, NJ: Merck Co.INC ; 2016. Revised May 2023.
3. McDonald, L.C., Gerding D., et al. Clinical Practice Guidelines for Clostridium difficile Infection in Adults and Children: 2017 Update by the Infectious Disease Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA). Clinical Infectious Diseases, Volume 66, Issue 7; March 2018; e1-e48. Available at: https://academic.oup.com/cid/article/66/7/e1/4855916
4. Infectious Disease Society of America. Clinical Practice Guidelines for Clostridium difficile Infection in Adults and Children: 2017 Update by the Infectious Diseases Society of America. Clinical Infectious Diseases, Volume 66, Issue 7. April 2018; pages e1-e48. Available at: Clinical Practice Guidelines for Clostridium difficile Infection in Adults and Children: 2017 Update by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA) (idsociety.org)
5. Stuart Johnson, Valéry Lavergne, Andrew M Skinner. Clinical Infectious Diseases. Clinical Practice Guidelines for the Management of Clostridioides difficile Infection in Adults: 2021 Update by SHEA/IDSA. Published 06/14/2021

| 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 Medicaid Managed Care | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Prior Auth |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Complete Wellness | Refer to the MVP website for the Medicare Part B and Part D |
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| USA Care PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Retrospective Review Required |
| Not Covered | Service is not a covered benefit. |
| See SPD | See Specific Plan Design |

**MVP Health Care Medical Policy**

**Medicare Part B: Zinplava (bezlotoxumab)**

| | |
|---|---|
| **Type of Policy:** | **Drug Therapy** |
| **Prior Approval Date:** | **01/01/2024** |
| **Approval Date:** | **12/01/2024** |
| **Effective Date:** | **02/01/2025** |
| **Related Policies:** | **C. Difficile Drug Therapy** |

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies.

## Codes Requiring Prior Authorization (covered under the medical benefit)

J0565 Zinplava (injection, bezlotoxumab 10mg)

## Overview/Summary of Evidence

C. difficile is the most common cause of infectious diarrhea in hospitalized members. About 1/3 of members have recurrent C. Difficile infection (CDI) after completing their initial antibiotic therapy. Recurrent C. difficile is more difficult to treat and leads to more severe outcomes and greater treatment costs.

Zinplava is a human monoclonal antibody that is indicated to reduce recurrence of C. Difficile infection (CDI) in adult and pediatric members 1 year and older who are receiving antibacterial therapy and are at a high risk for CDI recurrence. Zinplava is not an antibacterial drug and should not be used as monotherapy. It is meant to be used in combination with standard C. Difficile treatment. It works by binding and neutralizing the effect of C. difficile toxin B.

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**Indications/Criteria**

- Prescribed by or in consultation with infectious disease or gastroenterologist
- Member must be diagnosed with C-difficile
    - defined as diarrhea (≥3 unformed bowel movements [5 to 7 on the Bristol stool scale] in 24hrs)
    - stool test result that was positive for toxigenic C. difficile
- Member should be receiving standard C. diff therapy (vancomycin, fidaxomicin (preferred therapy), metronidazole)
- Must be at high risk of CDI recurrence or at high risk for CDI-related adverse outcome as defined by having **at least one** of the following risk factors:
    - Age ≥ 65
    - Prior episode of C. difficile Infection within the past 6 months
    - Clinically severe C. difficile infection (Zar Score of greater than or equal to 2)
    - Immunocompromised state
    - Disease states that represent an increased risk such as solid organ transplant, stem cell transplant, chronic kidney disease, end stage renal disease, Inflammatory Bowel Disease, cancer
    - Prolonged antibiotic therapy

If the member has a history of congestive heart failure (CHF), the provider must attest that the benefits outweigh the risk.

**Initial coverage will be for a single dose** of 10mg/kg IV infused over 60 minutes

**Requests for continuation: see exclusions**

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**Exclusions**

- Any repeat dose is considered experimental or investigational
- Indication, age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling. Zinplava monotherapy used to treat C-difficile infection
    - Must be used in conjunction with antibacterial drug treatment for CDI
- Combined with fecal transplantation

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**References**


1. Wilcox M.H.Poxton. I.R et al. Bezlotoxumab for Prevention of Recurrent Clostridium difficile Infection. The New England Journal of Medicine. January 2017; 376: 306-17 Available at : http://www.nejm.org/doi/pdf/10.1056/NEJMoa1602615
2. Zinplava (Bezlotoxumab) Injection. Prescribing Information. Whitehouse Station, NJ: Merck Co.INC ; 2016. Revised May 2023.
3. McDonald, L.C., Gerding D., et al. Clinical Practice Guidelines for Clostridium difficile Infection in Adults and Children: 2017 Update by the Infectious Disease Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA). Clinical Infectious Diseases, Volume 66, Issue 7; March 2018; e1-e48. Available at: https://academic.oup.com/cid/article/66/7/e1/4855916
4. Infectious Disease Society of America. Clinical Practice Guidelines for Clostridium difficile Infection in Adults and Children: 2017 Update by the Infectious Diseases Society of America. Clinical Infectious Diseases, Volume 66, Issue 7. April 2018; pages e1-e48. Available at: Clinical Practice Guidelines for Clostridium difficile Infection in Adults and Children: 2017 Update by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA) (idsociety.org)
5. Stuart Johnson, Valéry Lavergne, Andrew M Skinner. Clinical Infectious Diseases. Clinical Practice Guidelines for the Management of Clostridioides difficile Infection in Adults: 2021 Update by SHEA/IDSA. Published 06/14/2021


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**MVP Health Care Medical Policy**

# Zoladex- Medicaid

**Type of Policy:** **Medical Therapy**
**Prior Approval Date:** **11/01/2023**
**Approval Date:** **11/01/2024**
**Effective Date:** **01/01/2025**
**Related Policies:** **N/A**

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies.

## Drugs Requiring Prior Authorization under the medical benefit (for Medicaid Only)

J9202 Zoladex (goserelin)

## Overview

Zoladex is a synthetic gonadotropin-releasing hormone (GnRH) agonist. It is indicated for palliative treatment of advanced prostate cancer or breast cancer, endometriosis management, dysfunction uterine bleeding and adjunct medical management of uterine myomas (fibroids).

Effective May 14, 2022, the New York State Department of Health requires prior authorization for medical necessity. Zoladex (goserelin implant) is a practitioner-administered drug manufactured by TerSera Therapeutics which is available through a Patient Assistance Program from the manufacturer free of charge for those who qualify. For program applications and additional information please visit https://www.zoladexhcp.com/access-support/ or contact TerSera Support Source at 855-686-8725.

## Indications/Criteria

Zoladex may be considered for coverage when members are unable to obtain the medication through the Patient Assistance Program **AND** who meet the following:

- Documentation indicating why Zoladex cannot be obtained from the Patient Assistance Program
- Use for an FDA-approved indication for which there are **no alternative options**. Documentation of medical necessity for Zoladex must be provided including why other alternative therapies are inappropriate or contraindicated.
- Continuation of established therapy if another gonadotropin-releasing hormone (GnRH) product has been tried and failed or if transition to another GnRH is medically contraindicated

Approval will be for 6 months

## References

1. New York State Medicaid Update - March 2022 Volume 38 - Number 3 (ny.gov)
2. Clinical Criteria Worksheet: Zoladex (ny.gov)

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| Member 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 | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP Child Health Plus | Potential for Retrospective Review |
| MVP Harmonious Health Care Plan | Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization |
| MVP 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 Plus HMO | Potential for Retrospective Review |
| MVP VT HDHP 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).** | |
| *© 2025 MVP Health Plan, Inc. All rights reserved. Descriptions contained within MVP's Medical Policies are not a guarantee of coverage. Each MVP Group or Subscriber Contract contains specific limitations, exclusions and requirements that may affect a Policy. If there is any discrepancy between your Group or Subscriber Contract and a Policy, your Group or Subscriber Contract shall in all cases govern.* | |

***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 |

**MVP Health Care Medical Policy**

**Zynteglo**

**Type of Policy:** **Drug/Medical Therapy**
**Prior Approval Date:** **01/01/2024**
**Approval Date:** **12/01/2024**
**Effective Date:** **02/01/2025**
**Related Policies:** **CAR-T Cell Therapy**

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies.
Refer to the MVP website for the Medicare Part B policies for coverage criteria of drugs covered under the medical benefit.

## Drugs Requiring Prior Authorization under the medical benefit

J3393 Zynteglo (betibeglogene autotemcel)

## Overview

Zynteglo is a cell-based gene therapy that is indicated for the treatment of pediatric and adult members with beta-thalassemia who require regular red blood cell (RBC) transfusion.

## Indications/Criteria

Zynteglo may be considered for coverage when the following criteria are met:

a. Submission of medical records (chart notes) related to the medical necessity criteria is REQUIRED on all requests for authorizations. Records will be reviewed at the time of submission. Please provide documentation related to diagnosis, step therapy, and clinical markers (i.e., genetic, and mutational testing) supporting initiation when applicable.
b. Coverage is provided in the following conditions:
    i. Member is at least 4 years of age; **AND**

ii. Member has been screened for hepatitis B virus (HBV), hepatitis C virus (HCV), human T-lymphotrophic virus 1 & 2 (HTLV-1/HTLV-2), and human immunodeficiency virus (HIV) in accordance with clinical guidelines prior to collection of cells (leukapheresis); **AND**
iii. Member has not used prophylactic HIV anti-retroviral medication or hydroxyurea within 30 days prior to mobilization (or for the expected duration for elimination of those medications) and until all cycles of apheresis are completed
    - Note: if a member requires anti-retrovirals for HIV prophylaxis, confirm a negative test for HIV before beginning mobilization **AND**
iv. Iron chelation therapy has been discontinued for at least 7 days prior to initiating myeloablative conditioning therapy; **AND**
v. Females of reproductive potential have a negative pregnancy test prior to start of mobilization and re-confirmed prior to conditioning procedures and again before administration of betibeglogene autotemcel; **AND**
vi. Used as single agent therapy (not applicable to lymphodepleting or bridging therapy while awaiting manufacture); **AND**
vii. Provider attestation that the member will receive periodic life-long monitoring for hematological malignancies; **AND**
viii. Provider attestation that the member is eligible to undergo hematopoietic stem cell transplant (HSCT) and has not had prior HSCT or other gene-therapy; **AND**
ix. Member has a documented diagnosis of beta thalassemia (excludes alpha-thalassemia and hemoglobin S/ß-thalassemia variants) as outlined by the following:
    - Member diagnosis is confirmed by HBB sequence gene analysis showing biallelic pathogenic variants; **OR**
    - Member has severe microcytic hypochromic anemia, anisopoikilocytosis with nucleated red blood cells on peripheral blood smear, and hemoglobin analysis that reveals decreased amounts or complete absence of hemoglobin A and increased amounts of hemoglobin F; **AND**
    - Member has transfusion-dependent disease defined as a history of transfusions of at least 100 mL/kg/year of packed red blood cells (pRBCs) or with 8 or more transfusions of pRBCs per year in the 2 years preceding therapy; **AND**
    - Member does not have any of the following:

- Severely elevated iron in the heart (i.e., members with cardiac T2* less than 10 msec by magnetic resonance imaging [MRI]); **OR** Advanced liver disease; **OR**
- Members with an MRI of the liver with results demonstrating liver iron content ≥ 15 mg/g (unless biopsy confirms absence of advanced disease)

Zynteglo will be approved as a **one-time dose** and will not need to be continued for maintenance. Coverage is contingent on eligibility at the time of infusion.

**Medicaid Variation**

Zynteglo will be covered for Medicaid members when the following criteria is met:

- Member has a confirmed diagnosis of transfusion-dependent beta-thalassemia
  - Transfusion-depended beta-thalassemia is defined as a history of at least 100 mL/kg/year of packed red blood cells (pRBC) in the two (2) years preceding administration of betibeglogene autotemcel or with greater than or equal to eight (8) transfusions of pRBCs per year in the two(2) years preceding administration of betibeglogene autotemcel.
- Member is a candidate to undergo allogeneic hematopoietic cell transplantation, but ineligible due to the absence of a suitable donor
- Member has the minimum number of blood stem cells ($5.0 \times 10^6$ CD34+ cells/kg)
- Member is less than or equal to fifty (50) years of age
- For members less than five (5) years of age, the member weighs greater than or equal to six (6) kilograms.
  - Zynteglo® is not covered for members less than four [4] years of age regardless of weight
- Documentation indicating whether the member is on any anti-retroviral medications
- Documentation indicating the member has not received previous Zynteglo therapy.

Zynteglo will be approved as a **one-time dose** and will not need to be continued for maintenance. Coverage is contingent on eligibility at the time of infusion. Zynteglo (the medication only) is reviewed by MVP Health Care and billed through the member's NYRX Medicaid benefit.

## Exclusions

The use of Zynteglo will not be covered for the following situations:

- More than one treatment per lifetime
- Requests for replacement due to lost or damaged product will not be covered
- Indication, age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling

## Appendix I: Dosing and Administration

A. Dosing Limits
    a. Quantity Limit (max daily dose) [NDC Unit]: A single dose of Zynteglo containing a minimum of $5.0 \times 10^6$ CD34+ cells/kg of body weight, in one or more infusion bags.
    b. Max Units (per dose and over time) [HCPCS Unit]:A single dose of Zynteglo containing a minimum of $5.0 \times 10^6$ CD34+ cells/kg of bodyweight, in one or more infusion bags

| Indication | Dose |
|---|---|
| **Beta Thalassemia** | **Mobilization and Apheresis**<br>– Patients are required to undergo HSC mobilization followed by apheresis to obtain CD34+ cells for product manufacturing. The target number of CD34+ cells to be collected is ≥ $12 \times 10^6$ CD34+ cells/kg. ***(Note**: If the minimum dose of 5.0 × $10^6$ CD34+ cells/kg is not met, the patient may undergo additional cycles of mobilization and apheresis, separated by at least 14 days, in order to obtain more cells for additional manufacture. Up to two drug product lots may be administered to meet the target dose.)*<br>– A back-up collection of CD34+ cells of ≥ $1.5 \times 10^6$ CD34+ cells/kg (if collected by apheresis) or > $1.0 \times 10^8$ TNC/kg (Total Nucleated Cells, if collected by bone marrow harvest) is required. These cells must be collected from the patient and be cryopreserved prior to myeloablative conditioning. The back-up collection may be needed for rescue treatment if there is:<br>o Compromise of hematopoietic stem cells or Zynteglo before infusion<br>o Primary engraftment failure<br>o Loss of engraftment after infusion with Zynteglo<br>– Note: G-CSF and plerixafor were used for mobilization<br>**Myeloablative Conditioning**<br>– Full myeloablative conditioning must be administered before infusion of Zynteglo. Consult prescribing information for the myeloablative conditioning agent(s) prior to treatment.<br>– Prophylaxis for hepatic veno-occlusive disease (VOD) is recommended and prophylaxis for seizures should be considered, as appropriate.<br>– Do not begin myeloablative conditioning until the complete set of infusion bag(s) constituting the dose of Zynteglo has been received and stored at the treatment center and the availability of the back-up collection is confirmed. After completion of the myeloablative conditioning, allow a minimum of 48 hours of washout before Zynteglo infusion.<br>– Note: busulfan was used for myeloablative conditioning<br>**Administration**<br>– Verify that the patient's identity matches the unique patient identification information on the Zynteglo infusion bag(s) prior to infusion.<br>– Do not sample, alter, or irradiate Zynteglo.<br>– Do not use an in-line blood filter or an infusion pump.<br>– Administer each infusion bag of Zynteglo via intravenous infusion over a period of less than 30 minutes. Product must be administered within 4 hours after thawing. |
| **For autologous use only. For intravenous use only.**<br>– Match the identity of the patient with the patient identifiers on the metal cassette(s), infusion bag(s), and Lot Information Sheet upon receipt. Keep the infusion bag(s) in the metal cassette(s) and store in the vapor phase of liquid nitrogen at less than or equal to -140°C (≤ -220°F) until ready for thaw and administration. Thaw prior to infusion, do not re-freeze after thawing. Do not irradiate as this could lead to inactivation.<br>– It is *recommended* that patients be maintained at a hemoglobin (Hb) ≥ 11 g/dL for at least 30 days prior to mobilization and 30 days prior to myeloablative conditioning. | |

## References


1. Zynteglo [package insert]. Somerville, MA; Bluebird bio, Inc: August 2022. Accessed August 2022.

2. Lai, X., Liu, L., Zhang, Z. et al. Hepatic veno-occlusive disease/sinusoidal obstruction syndrome after hematopoietic stem cell transplantation for thalassemia major: incidence, management, and outcome. Bone Marrow Transplant 56, 1635–1641 (2021)

3. Galanello R and Origa R. Beta-thalassemia. Orphanet J Rare Dis. 2010 May 21;5:11.Available at: https://ojrd.biomedcentral.com/articles/10.1186/1750-1172-5-11. Accessed August 2022.

4. Origa R. Beta-Thalassemia. 2000 Sep 28 [Updated 2021 Feb 4]. GeneReviews® [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2022. Available from https://www.ncbi.nlm.nih.gov/books/NBK1426/. Accessed August 2022.

5. Locatelli F, Thompson AA, Kwiatkowski JL, et al. Betibeglogene Autotemcel Gene Therapyfor Non-β(0)/β(0) Genotype β-Thalassemia. N Engl J Med. 2022 Feb 3;386(5):415-427. doi:10.1056/NEJMoa2113206. Epub 2021 Dec 11.

6. Schneiderman, J, Thompson AA, Walters MC, et al. Interim Results from the Phase 3 Hgb207(Northstar-2) and Hgb-21) (Northstar-3) Studies of Betibeglogene Autotemcel Gene Therapy (LentiGlobin) for the Treatment of Transfusion-Dependent β-Thalassemia. Bio Blood Marrow Trnsplt. Volume 26, Issue 3, Supplement, March 2020,Pages S87-S88. https://doi.org/10.1016/j.bbmt.2019.12.588.

7. Magrin E, Semeraro M, Hebert N, et al. Long-term outcomes of lentiviral gene therapy for the β-hemoglobinopathies: the HGB-205 trial. Nat Med. 2022 Jan;28(1):81-88. Doi 10.1038/s41591-021-01650-w. Epub 2022 Jan 24.

8. Beaudoin FL, Richardson M, Synnott PG, et al. Betibeglogene Autotemcel for Beta Thalassemia: Effectiveness and Value; Final Evidence Report. Institute for Clinical and Economic Review, July 19, 2022. https://icer.org/beta-thalassemia-2022/#timeline

9. Medicaid Managed Care Plan Clinical Criteria Worksheet: Zynteglo (betibeglogene autotemcel). October 27, 2023. zynteglo_worksheet.pdf (ny.gov)

10. New York State Medicaid Fee-For-Service Practitioner Administered Drug Policies and Billing Guidance. Medicaid Managed Care: New York State Medicaid Fee-for-Service Practitioner Administered Drug Policies and Billing Guidance (ny.gov)

Department of Health Pharmacy Technical Workgroup Meeting #78. August 1, 2023.

| **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. *Zynteglo (the drug only) is reviewed by MVP Health Care and billed to NYRX via coordination with NYS Department of Health |
| MVP Child Health Plus | Prior Authorization |
| MVP Harmonious Health Care Plan | Prior Authorization. *Zynteglo (the drug only) is reviewed by MVP Health Care and billed to NYRX via coordination with NYS Department of Health |
| MVP Complete Wellness | Refer to the MVP website for the Medicare Part B and Part D |

**MVP Health Care Medical Policy**

**Medicare Part B: Zynteglo**

**Type of Policy:** **Drug/Medical Therapy**
**Prior Approval Date:** **01/01/2024**
**Approval Date:** **12/01/2024**
**Effective Date:** **02/01/2025**
**Related Policies:** **N/A**

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies.

Please refer to relevant CMS LCDs/NCDs/Policy Articles for most up to date Medicare Part B guidance if available.

## Drugs Requiring Prior Authorization under the medical benefit

J3393 Zynteglo (betibeglogene autotemcel)

## Overview/Summary of Evidence

Zynteglo is a cell-based gene therapy that is indicated for the treatment of pediatric and adult members with beta-thalassemia who require regular red blood cell (RBC) transfusion.

## Indications/Criteria

Zynteglo may be considered for coverage when the following criteria are met:

A. Initial Approval Criteria
   a. Submission of medical records (chart notes) related to the medical necessity criteria is REQUIRED on all requests for authorizations. Records will be reviewed at the time of submission. Please provide documentation

related to diagnosis, step therapy, and clinical markers (i.e., genetic, and mutational testing) supporting initiation when applicable.

b. Coverage is provided in the following conditions:
    i. Member is at least 4 years of age; **AND**
    ii. Member has been screened for hepatitis B virus (HBV), hepatitis C virus (HCV), human T-lymphotrophic virus 1 & 2 (HTLV-1/HTLV-2), and human immunodeficiency virus (HIV) in accordance with clinical guidelines prior to collection of cells (leukapheresis); **AND**
    iii. Member has not used prophylactic HIV anti-retroviral medication or hydroxyurea within 30 days prior to mobilization (or for the expected duration for elimination of those medications) and until all cycles of apheresis are completed (Note: if a Member requires anti-retrovirals for HIV prophylaxis, confirm a negative test for HIV before beginning mobilization); **AND**
    iv. Iron chelation therapy has been discontinued for at least 7 days prior to initiating myeloablative conditioning therapy; **AND**
    v. Females of reproductive potential have a negative pregnancy test prior to start of mobilization and re-confirmed prior to conditioning procedures and again before administration of betibeglogene autotemcel; **AND**
    vi. Used as single agent therapy (not applicable to lymphodepleting or bridging therapy while awaiting manufacture); **AND**
    vii. Provider attestation that the member will receive periodic life-long monitoring for hematological malignancies; **AND**
    viii. Provider attestation that the member is eligible to undergo hematopoietic stem cell transplant (HSCT) and has not had prior HSCT or other gene-therapy; **AND**
    ix. Member has a documented diagnosis of beta thalassemia (excludes alpha-thalassemia and hemoglobin S/ß-thalassemia variants) as outlined by the following:
        - Member diagnosis is confirmed by HBB sequence gene analysis showing biallelic pathogenic variants; **OR**
        - Member has severe microcytic hypochromic anemia, anisopoikilocytosis with nucleated red blood cells on peripheral blood smear, and hemoglobin analysis that reveals decreased amounts or complete absence of hemoglobin A and increased amounts of hemoglobin F; **AND**
        - Member has transfusion-dependent disease defined as a history of transfusions of at least 100 mL/kg/year of packed

red blood cells (pRBCs) or with 8 or more transfusions of pRBCs per year in the 2 years preceding therapy; **AND**

- Member does not have any of the following:
    - Severely elevated iron in the heart (i.e., members with cardiac T2* less than 10 msec by magnetic resonance imaging [MRI]); **OR** Advanced liver disease; **OR**
    - Members with an MRI of the liver with results demonstrating liver iron content ≥ 15 mg/g (unless biopsy confirms absence of advanced disease)

Zynteglo will be approved as a **one-time dose** and will not need to be continued for maintenance. Coverage is contingent on eligibility at the time of infusion

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**Exclusions**

The use of Zynteglo will not be covered for the following situations:

- More than one treatment per lifetime
- Requests for replacement due to lost or damaged product will not be covered

Indication, age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling

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## References

1. Zynteglo [package insert]. Somerville, MA; Bluebird bio, Inc: August 2022. Accessed August 2022.

2. Lai, X., Liu, L., Zhang, Z. et al. Hepatic veno-occlusive disease/sinusoidal obstruction syndrome after hematopoietic stem cell transplantation for thalassemia major: incidence, management, and outcome. Bone Marrow Transplant 56, 1635–1641 (2021)

3. Galanello R and Origa R. Beta-thalassemia. Orphanet J Rare Dis. 2010 May 21;5:11.Available at: https://ojrd.biomedcentral.com/articles/10.1186/1750-1172-5-11. Accessed August 2022.

4. Origa R. Beta-Thalassemia. 2000 Sep 28 [Updated 2021 Feb 4]. GeneReviews® [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2022. Available from https://www.ncbi.nlm.nih.gov/books/NBK1426/. Accessed August 2022.

5. Locatelli F, Thompson AA, Kwiatkowski JL, et al. Betibeglogene Autotemcel Gene Therapyfor Non-β(0)/β(0) Genotype β-Thalassemia. N Engl J Med. 2022 Feb 3;386(5):415-427. doi:10.1056/NEJMoa2113206. Epub 2021 Dec 11.

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7. Magrin E, Semeraro M, Hebert N, et al. Long-term outcomes of lentiviral gene therapy for the β-hemoglobinopathies: the HGB-205 trial. Nat Med. 2022 Jan;28(1):81-88. Doi 10.1038/s41591-021-01650-w. Epub 2022 Jan 24.

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|---|---|
| MVP Medicare Preferred Gold HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare WellSelect Plus PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Patriot Plan PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Complete D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP DualAccess Plus D-SNP HMO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| UVM Health Advantage Select PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| USA Care PPO | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | Refer to the MVP website for the Medicare Part B and Part D policies. |
| MVP Medicare Secure Plus HMO POS | Refer to the MVP website for the Medicare Part B and Part D policies. |
| 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 | 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).** | |

*© 2025 MVP Health Plan, Inc. All rights reserved. Descriptions contained within MVP's Medical Policies are not a guarantee of coverage. Each MVP Group or Subscriber Contract contains specific limitations, exclusions and requirements that may affect a Policy. If there is any discrepancy between your Group or Subscriber Contract and a Policy, your Group or Subscriber Contract shall in all cases govern.*

***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 |