Pharmacy Policy Changes

Effective October 1, 2026

At-a-Glance: Policies With Changes

Policy	Status
Agents for Primary Immunoglobulin A Nephropathy	New
Belimumab	Updated
Daybue (trofinetide)	Updated
Duchenne Muscular Dystrophy	Updated
Gabapentin ER	Updated
Hypertriglyceridemia Agents (formerly Tryngolza)	Updated
Medicare Part B Step Therapy	Updated
Movement Disorders	Updated
Omidubicel	Updated
Medicare Part B: Omidubicel	Updated

New and Updated Policies

NEW

Agents for Primary Immunoglobulin A Nephropathy

Summary of change

- New policy containing Voyxact and Filspari.
- Voyxact is a Proliferation Inducing Ligand blocker indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy at risk for disease progression. It is approved under accelerated approval based on reduction of proteinuria.
- Filspari is an oral endothelin and angiotensin II receptor antagonist indicated to slow kidney function decline in individuals with primary immunoglobulin A nephropathy who are at risk for rapid disease progression and to reduce proteinuria in focal segmental glomerulosclerosis without nephrotic syndrome.

UPDATED

Belimumab

Summary of change

- Removed request for documentation that the member has had an inadequate response to standard therapy alone before belimumab for active lupus nephritis.

UPDATED

Daybue (trofinetide)

Summary of change

- Simplified inclusion criteria to request confirmation of Rett Syndrome diagnosis.
- Removed detailed criteria language regarding typical or atypical Rett Syndrome diagnostic features. Removed "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".

UPDATED

Duchenne Muscular Dystrophy

Summary of change

- Added 6 months for duration of therapy upon approval for Exondys 51, Vyondys 53, Amondys 45, and Viltepso for the Medicaid variation.
- Added a one-time dose limit within 6 months upon approval for Elevidys.

UPDATED

Gabapentin ER

Summary of change

- Removed requirement for a 1-month trial and failure to ropinirole or pramipexole before Horizant for restless legs syndrome.

UPDATED

Hypertriglyceridemia Agents (formerly Tryngolza)

Summary of change

- Added Redemplo, a new apolipoprotein C-III-directed small interfering ribonucleic acid indicated as an adjunct to diet to reduce triglycerides in adults with familial chylomicronemia syndrome.
- Added a new indication for Tryngolza for adults with severe hypertriglyceridemia (triglycerides 500mg/dL or greater) to reduce the risk of acute pancreatitis.
- Under familial chylomicronemia syndrome, removed the requirement for a trial of fibrates or omega-3 fatty acids.

UPDATED

Medicare Part B Step Therapy

Summary of change

- Added Neulasta OnPro as a preferred agent.
- Added Armlupeg, Nypozi, Ryzneuta, Avgemsi, Focinvez, and Posfrea as non-preferred agents.
- Removed Infugem as a non-preferred agent.

UPDATED

Movement Disorders

Summary of change

- Removed Austedo and Austedo XR from the policy.
- Removed requirement to switch from a first-generation antipsychotic to a second-generation antipsychotic before initial Ingrezza treatment for tardive dyskinesia.
- Removed a specific AIMS score reduction needed for continuation of Ingrezza therapy for tardive dyskinesia.
- Added hepatic impairment to exclusion criteria for Xenazine (brand and generic).

UPDATED

Omidubicel

Summary of change

- Added criteria for treatment of severe aplastic anemia.

UPDATED

Medicare Part B: Omidubicel

Summary of change

- Added criteria for treatment of severe aplastic anemia.

Policies Reviewed With No Content Changes

Reviewed - No Content Changes	
Amtagvi	Palforzia
Arimoclomol	Radicava
GABA-Receptor Modulators	Medicare Part B: Radicava
Ganaxolone	Remestemcel
Hetlioz (tasimelteon)	Medicare Part B: Remestemcel
Lenmeldy	Tecelra
Medicare Part B Drug Therapy	Tofersen
Medicare Part B: Amtagvi	Ozanimod
Medicare Part B: Lenmeldy	Medicare Part B: Tecelra
Niktimvo (axatilimab-csfr)	Vimseltinib
Nuedexta	Zoladex - Medicaid

MVP Health Care Medical Policy

Agents for Primary Immunoglobulin A Nephropathy

Type of Policy: Drug therapy (administered by the pharmacy department)

Prior Approval Date: NA

Approval Date: 08/01/2026

Effective Date: 10/01/2026

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

Voyxact (sibeprenlimab-szsi)

Filspari (sparsentan)

Overview

Sibeprenlimab (Voyxact) is a Proliferation Inducing Ligand (APRIL) blocker, indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk for disease progression. Sibeprenlimab is approved for this indication under accelerated approval based on reduction of proteinuria.

Sparsentan (Filspari) is an oral endothelin and angiotensin II receptor antagonist indicated to slow kidney function decline in individuals with primary immunoglobulin A nephropathy (IgAN) who are at risk for rapid disease progression and to reduce proteinuria in individuals with focal segmental glomerulosclerosis (FSGS) without nephrotic syndrome.

Indications/Criteria

A. Filspari

1. Filspari may be considered for coverage to slow kidney function decline in adults with primary immunoglobulin A nephropathy (IgAN) who are at risk for disease progression when the following criteria are met:

    - Prescribed by or in consultation with a nephrologist enrolled in the Filspari REMS program
    - Chart notes documenting a confirmed diagnosis of primary IgAN by renal biopsy.
    - Chart notes documenting failure, intolerance or contraindication to glucocorticosteriods
    - Provider attestation that the member is currently maximized on a stable dose of one of the following:
        - maximally tolerated dose of either an angiotensin-converting enzyme inhibitor (ACE inhibitors) **OR**
        - an angiotensin II receptor blocker (ARB) **OR**
        - Documentation that the member has a contraindication or intolerance to ACE inhibitors and ARBs **AND**
        - Provider attestation that the use of renin-angiotensin-aldosterone system (RAAS) inhibitors (ie. ACE inhibitors, ARBs) and endothelin receptor antagonists (ERAs) will be discontinued prior to initiating treatment
    - Chart notes documenting eGFR ≥30 mL/min/1.73 m2
    - Provider attestation that the member is at risk of progressive loss of kidney function

    Initial approval will be for 6 months

    Extension requests will be approved for 12 months if the request is accompanied by current documentation that the member has a continued benefit to therapy. Extension requests where Filspari did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

2. Filspari may be considered for coverage to reduce proteinuria in adult and pediatric patients aged 8 years and older with focal segmental glomerulosclerosis (FSGS) without nephrotic syndrome when the following criteria are met:
    - Prescribed by or in consultation with a nephrologist enrolled in the Filspari REMS program
    - Chart notes documenting a confirmed diagnosis of focal segmental glomerulosclerosis (FSGS) either by renal biopsy or generic testing.
    - Documentation that the member does not have nephrotic syndrome
    - Chart notes documenting eGFR ≥30 mL/min/1.73 m2
    - Chart notes documenting urine protein/creatinine (UP/C) ≥1.5 g/g (170 mg/mmol)

Initial approval will be for 6 months

Extension requests will be approved for 12 months if the request is accompanied by current documentation that the member has a continued benefit to therapy including a reduction in proteinuria. Extension requests where Filspari did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

B. Voyxact (sibeprenlimab)

Voyxact may be considered for coverage for the reduction of proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk for disease progression when the following criteria are met :

- Prescribed by or in consultation with a nephrologist
- Chart notes documenting a confirmed diagnosis of primary IgAN by renal biopsy.
- Chart notes documenting failure, intolerance or contraindication to glucocorticosteriods
- Provider attestation that the member is currently maximized on a stable dose of one of the following:
    - maximally tolerated dose of either an angiotensin-converting enzyme inhibitor (ACE inhibitors) **OR**
    - an angiotensin II receptor blocker (ARB) **OR**

    - Documentation that the member has a contraindication or intolerance to ACE inhibitors and ARBs
- Chart notes documenting a current urine screening of one of the following:
    - protein/creatinine ratio (uPCR) ≥ 0.75 g/g or
    - urine protein ≥ 1.0 g/day
- Chart notes documenting eGFR ≥30 mL/min/1.73 m2
- Chart notes documenting that current IgG is greater than 600mg/dL
- Provider attestation that, if applicable, the member has controlled Type 2 diabetes and controlled hypertension.
- Provider attestation that live vaccines will not be administered 30 days prior to the initiation of Voyxact

Initial approval will be for 6 months

Extension requests will be approved for 12 months if the request is accompanied by current documentation that the member has a continued benefit to therapy including a reduction in proteinuria. Extension requests where Voyxact did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

Exclusions

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

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

- Current chronic or acute infectious disease
- Nephrotic syndrome

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

- Members who are pregnant
- Co-administration with ARBs, ERAs, or aliskiren
- For FSGS
    - FSGS secondary to another condition
    - markers indicating acute or chronic hepatitis B virus infection or hepatitis C infection
- For primary IgA nephropathy

- IgAN secondary to another condition

References

1. Wasfy JH, McQueen RB, McKenna A, DiStefano MJ, Lee W, Zemplenyi A, Phillips M, Paratane D, Rind DM. **B-Cell Directed Therapies for IgA Nephropathy: Effectiveness and Value; Final Report** [Internet]. Boston (MA): Institute for Clinical and Economic Review (ICER); 2026 Mar 31 [cited 2026 Jul 1]. Available from: ICER IgAN Final Report

2. KDIGO 2025 Clinical Practice Guideline for the Management of Immunoglobulin A Nephropathy (IgAN) and Immunoglobulin A Vasculitis (IgAV). Kidney Disease: Improving Global Outcomes. 2025. Garabed Eknoyan, Norbert Lameire, Wolfgang C. Winkelmayer, et al

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4. Otsuka America Pharmaceutical, Inc. **VOYXACT® (sibeprenlimab-szsi) injection, for subcutaneous use: prescribing information** [Internet]. Rockville (MD): Otsuka America Pharmaceutical, Inc.; 2025 Nov [cited 2026 Jul 1]. Available from: VOYXACT Prescribing Information.

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6. Travere Therapeutics, Inc. **FILSPARI® (sparsentan) tablets, for oral use: prescribing information** [Internet]. San Diego (CA): Travere Therapeutics, Inc.; 2026 Apr 13 [cited 2026 Jul 1]. Available from: FILSPARI Prescribing Information.

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8. Kidney Disease: Improving Global Outcomes (KDIGO) Glomerular Diseases Work Group. KDIGO 2021 Clinical Practice Guideline for the Management of Glomerular Diseases: 2024 chapter updates [Internet]. Brussels (BE): KDIGO; 2024 [cited 2026 Jul 1]. Available from: KDIGO 2021 Clinical Practice Guideline for the Management of Glomerular Diseases.
9. ClinicalTrials.gov. **Study of Sparsentan in Patients With Primary Focal Segmental Glomerulosclerosis (FSGS) (DUPLEX)** (NCT03493685) [Internet]. Bethesda (MD): National Library of Medicine (US); 2018– [updated 2026 Apr 17; cited 2026 Jul 1]. Available from: ClinicalTrials.gov Study Record NCT03493685.

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 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 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 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.
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 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).**

***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

Belimumab

Type of Policy: Drug Therapy
Prior Approval Date: 10/01/2025
Approval Date: 08/01/2026
Effective Date: 10/01/2026
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

J0490 Benlysta (injection, belimumab, 10mg)

Overview

Belimumab is a human monoclonal antibody that inhibits B lymphocyte stimulator protein (BLyS). Inhibition of BLyS inhibits the survival of B cells including autoreactive B cells and reduces the differentiation of B cells into immunoglobulin-producing plasma cells. Belimumab is indicated as an adjunct to standard therapy for the treatment of active systemic lupus erythematosus (SLE) and active lupus nephritis.

Indications/Criteria

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

- Benlysta IV is prescribed by or in consultation with a rheumatologist, clinical immunologist, nephrologist, neurologist, or dermatologist.

- Rationale and documentation are provided identifying why the member or caregiver is unable to self-administer with Benlysta prefilled syringe

- Per the MVP Health Care Pharmacy Management Programs policy, Benlysta IV 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 Benlysta IV obtained and administered in a non-preferred site of care (i.e. outpatient hospital setting).
    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, CHP members

B. Systemic Lupus Erythematosus (SLE)

Benlysta IV may be considered for coverage for active systemic lupus erythematosus (SLE) when the following criteria is met:

- Chart notes documenting a confirmed diagnosis of active systemic lupus erythematosus (SLE)
- Documentation that the member is currently receiving standard therapy and will be used in combination with Benlysta therapy (i.e. hydroxychloroquine, methotrexate, azathioprine, mycophenolate, corticosteroids)

C. Active Lupus Nephritis

Benlysta IV may be considered for coverage for active lupus nephritis the following criteria is met:

- Chart notes documenting a confirmed diagnosis of active lupus nephritis
- Documentation that the member is currently receiving standard therapy and will be used in combination with Benlysta therapy (i.e. hydroxychloroquine, methotrexate, azathioprine, mycophenolate, corticosteroids).

Initial approval will be for 12 months

Extension requests will be approved for up to 12 months when the member has continued benefit to therapy and continues to require Benlysta over self-administered options.

Exclusions

The use of Benlysta IV 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 with other biologic products
- Combination with Saphnelo
- Severe active central nervous system lupus

1. **References** American College of Rheumatology. 2025 Guideline Summary for the Treatment of Systemic Lupus Erythematosus (SLE) [Internet]. Atlanta (GA): American College of Rheumatology; 2025 [cited 2025 Jul 10]. Available from: https://assets.contentstack.io/v3/assets/bltee37abb6b278ab2c/bltec93920aad624e33/sle-guideline-summary-2025.pdf
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3. Benlysta (benlimumab). [Package Insert]. Revised June 2025. Available at: BENLYSTA-PI-MG-IFU.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 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
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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

Daybue™ (trofinetide)

Type of Policy: **Drug Therapy**
Prior Approval Date: **08/01/2025**
Approval Date: **08/01/2026**
Effective Date: **10/01/2026**

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, packets

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.

Indications/Criteria

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

- Member has a confirmed Rett Syndrome (RTT) diagnosis
- For members with Typical RTT, the following clinical criteria must be met:
  - ALL **Main Criteria** and ALL **Exclusion Criteria** listed below.
- For members with Atypical RTT, the 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.

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 2026.
2. Clinical Pharmacology. Trofinetide. Revised 01/07/2026. Accessed 06/20/2026.
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.
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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 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	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 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.
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 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).**

***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

Duchenne Muscular Dystrophy

Type of Policy:	**Drug Therapy**
Prior Approval Date:	**08/01/2025**
Approval Date:	**08/01/2026**
Effective Date:	**10/01/2026**

Drug Requiring Prior Authorization (covered under the pharmacy benefit)

Emflaza (deflazacort)

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.

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 approved 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 for Exondys 51, Vyondys 53, Amondys 45, Viltepso and Elevidys

- 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

  Approval will be for 6 months.

- Requests for Elevidys 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 **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 **AND**
    - Member has a confirmed diagnosis of Duchenne Muscular Disease (DMD) **AND**
    - Documentation of genetic testing must confirm the DMD gene mutation **AND**
    - Confirmation that the member is ambulatory **AND**
    - 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

Elevidys 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 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 treat non-ambulatory members with Duchenne Muscular Dystrophy, as the clinical benefit has not been confirmed.

References

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3. Emflaza (deflazacort tablets/suspension). Prescribing Information. Warren, NJ. PTC Therapeutics. Revised May 2024.
4. Exondys 51 (eteplirsen) injection. Prescribing Information. Cambridge, MA: Sarepta Therapeutics, Inc. Revised August 2025.
5. Viltepso (viltolarsen) injection, for intravenous use. Prescribing Information. Paramus, NJ: NS Pharma. August 2020. Revised March 2021.
6. Amondys 45 (casimersen) injection. Prescribing Information. Cambridge, MA: Sarepta Therapeutics, Inc. Revised January 2026.
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. Prescribing Information. Cambridge, MA: Sarepta Therapeutics, Inc. Revised November 2025.
9. Agamree. Prescribing Information. Coral Gables, FL: Santhera Pharmaceuticals. Revised June2024.

10. Sarepta Therapeutics. Community Letter: Safety Update regarding Elevidys in non-ambulatory individuals with Duchenne [Internet]. Cambridge (MA): Sarepta Therapeutics; 2025 Jun 15 [cited 2025 Jul 2]. Available from: https://www.sarepta.com/community-letter-safety-update-regarding-elevidys-non-ambulatory-individuals-duchenne
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12. Vyondys 53 (golodirsen) injection, for intravenous use. Prescribing Information. Cambridge, MA: Sarepta Therapeutics, Inc. Revised 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 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 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 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.
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 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).**

***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:	**08/01/2025**
Approval Date:	**08/01/2026**
Effective Date:	**10/01/2026**
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.

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

Initial approval will be for 6 months

Extension requests will be approved up to 12 months, if there is documentation of continued benefit to therapy and improvement in International Restless Legs Syndrome Rating Scale score.

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.

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
    - Members on hemodialysis

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2. Gralise (gabapentin). Prescribing Information. Morristown, NJ: Almatica Pharma LLC. Revised April 2023.
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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 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 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 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.
USA Care PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
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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
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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 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).	

***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

Hypertriglyceridemia Agents

Type of Policy: Drug therapy (administered by the pharmacy department)

Prior Approval Date: 10/01/2025

Approval Date: 08/01/2026

Effective Date: 10/01/2026

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 pharmacy benefit

J3490 Tryngolza (olezarsen) 80 mg/0.8 mL in a single-dose subcutaneous autoinjector

Redemplo (Plozasiran)

Overview

Olezarsen (Tryngolza) is an APOC-III-directed antisense oligonucleotide (ASO) indicated as an adjunct to diet to reduce triglycerides in adults with familial chylomicronemia syndrome (FCS). It is also indicated for severe hypertriglyceridemia (triglycerides 500mg/dL or greater) to reduce the risk of acute pancreatitis.

Plozasiran (Redemplo) is an apolipoprotein C-III (apoC-III)-directed small interfering ribonucleic acid (siRNA) indicated as an adjunct to diet to reduce triglycerides in adults with familial chylomicronemia syndrome (FCS); it is designated as an orphan drug by the FDA for this indication.

Familial chylomicronemia syndrome (FCS) is an ultrarare, inherited disorder caused by impaired lipolysis leading to pathological accumulation of chylomicrons, severe hypertriglyceridemia (HTG), and systemic manifestations, the most serious of which is acute pancreatitis.

Indications/Criteria

A. Familial Chylomicronemia Syndrome (FCS)

Tryngolza and Redemplo may be considered for coverage for familial chylomicronemia syndrome (FCS) in adults, when the following criteria are met:

- Prescribed by or in consult with an endocrinologist, cardiologist, or a specialized physician
- Chart notes documenting the following:
  - A confirmed diagnosis of FCS
  - Current fasting triglyceride (TG) levels ≥880 mg/dL
  - Adherence to a low-fat diet with ≤20 grams fat per day
- Documentation that the member has received genetic testing and meets ONE of the following:
  1. Biallelic pathogenic variants with biallelic loss of function in any of the following:
     - Lipoprotein lipase (LPL)
     - Glycosylphosphatidylinositol-anchored high-density lipoprotein-binding protein 1 (GPIHBP1)
     - Apolipoprotein C-II (APOC2)
     - Apolipoprotein A 5 (APOA5)
     - Lipoprotein maturation factor 1 (LMF1)
  2. FCS score of ≥ to 10

Familial Chylomicronemia Syndrome (FCS) Scoring Table

	Score
Fasting TGs > 10 mmol/L for three consecutive blood analyses	+5
Fasting TGs > 20 mmol/L at least once	+1
Previous TGs < 2 mmol/L	−5
No secondary factor (except pregnancy and thinylestradiol)	+2
History of pancreatitis	+1

Unexplained recurrent abdominal pain	+1
No history of familial combined hyperlipidemia	+1
No response (TG decrease <20%) to hypolipidemic treatment	+1
Onset of symptoms at age: • <40 years • <20 years • <10 years	 +1 +2 +3

Score > 10: FCS very likely; Score < 9: FCS unlikely; Score < 8: FCS very unlikely.

Initial approval will be for 6 months.

Extension requests will be approved for 12 months if current documentation indicates the member has continued benefit to therapy (i.e. reduction in triglyceride levels, reduction in episodes of acute pancreatitis).
Extension requests where the member did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

B. Severe Hypertriglyceridemia

Tryngolza may be considered for coverage for the treatment of severe hypertriglyceridemia to reduce the risk of acute pancreatitis when the following criteria are met:

- Member has a diagnosis of severe hypertriglyceridemia, confirmed by current fasting triglycerides of ≥500mg/dL
- Documentation of an inadequate response, intolerance or contraindication to conventional therapy (i.e fibrates, omega-3 fatty acids). Documentation of Adherence to a low-fat diet with ≤20 grams fat per day

Initial approval will be for 6 months.

Extension requests will be approved for 12 months if current documentation indicates the member has continued benefit to therapy (i.e. reduction in triglyceride levels, reduction in episodes of acute pancreatitis).

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

Exclusions

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

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References

1. Tryngolza™ subcutaneous injection [prescribing information]. Carlsbad, CA: Ionis; Approved 2024. Revised 06/2026.

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the Management of Dyslipidemia: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines.

Member Product	Medical Management Requirements*
New York Products	
HMO	Prior Auth
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PPO OOP	Prior Auth
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MVP Medicare WellSelect 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 Premier Plus HDHP	Prior Auth
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Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	
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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).	

***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 Step Therapy

Type of Policy:	**Administrative**
Prior Approval Date:	**06/01/2025**
Approval Date:	**08/01/2026**
Effective Date:	**10/01/2026**

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 Mvasi	Avastin Alymsys Vegzelma
Herceptin Trazimera Herceptin Hylecta	Kanjinti Ogivri Ontruzant Herzuma Hercessi
Neulasta Neulasta OnPro Udenyca	Fulphila Ziextenzo Fylnetra Rolvedon Stimufend Nyvepria Armlupeg
Nivestym Releuko	Zarxio Neupogen Granix Nypozi Ryzneuta
Ruxience Rituxan Rituxan Hycela	Truxima Riabni
Gemcitabine	Avgemsi
Leucovorin (Wellcovorin)	Levoleucovorin (Fusilev, Khapzory)
Aranesp Retacrit Procrit/Epogen	N/A
Aloxi Emend Fosaprepitant	Akynzeo Cinvanti Sustol Focinvez Posfrea

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
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MVP Health Care Medical Policy

Movement Disorders

Type of Policy: **Drug Therapy**
Prior Approval Date: **07/01/2025**
Approval Date: **08/01/2026**
Effective Date: **10/01/2026**
Related Policies: **N/A**

Drug Requiring Prior Authorization (covered under the pharmacy benefit)

- 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 known 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 and valbenazine are vesicular monoamine transporter 2 (VMAT2) inhibitors. The precise mechanism by which it exerts its anti-chorea effects and treatment of tardive dyskinesia is unknown.

Indications/Criteria

A. Huntington's disease

Xenazine (brand and generic) and Ingrezza may be considered for coverage for Huntington's disease when the following criteria is met:

- Member has a diagnosis of Huntington's disease including family history, clinical features (i.e., chorea, abnormal eye movement) and genetic testing
- Documentation of baseline Total Chorea Score from the Unified Huntington's Disease Rating Scale
- Approval for **brand** Xenazine will require contraindication or therapeutic failure of tetrabenazine (generic Xenazine).

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.

B. Tardive Dyskinesia

Ingrezza may be considered for coverage for Tardive Dyskinesia when the following criteria is met:

- Member has a 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
- Documentation of baseline Abnormal Involuntary Movement Scale (AIMS)-items 1 to 7 scores

Initial approval will be for 12 weeks.

Extension requests 2will be approved for up to 12 months if the member has continued benefit to therapy.

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
- For Xenazine (brand and generic), members with hepatic impairment

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References

1. Bhidayasiri R, Fahn S, Weiner W, et al. Evidence-based guideline: Treatment of tardive syndromes. Report of the Guidelines Development Subcommittee of the American Academy of Neurology. Neurology, Jul 2013, 81(5) 463-469
2. Tarsy, Daniel MD. Tardive dyskinesia: Prevention and treatment. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com (Accessed on 1/3/2018)
3. Suchowersky, Oksana MD. Huntington disease: Management. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com (Accessed on 1/3/2018)
4. Ingrezza (valbenazine) capsules. Prescribing Information. San Diego, CA. Neurocrine Biosciences, Inc. October 2017. Revised 04/2026.
5. Xenazine (tetrabenazine) tablets. Prescribing Information. Deerfield, IL. Valeant Pharmaceuticals North America LLC. Revised 11/2019.
6. 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
7. Chorea & Huntington's Disease. (2013). Movementdisorders.org. https://www.movementdisorders.org/MDS/About/Movement-Disorder-Overviews/Chorea--Huntingtons-Disease.htm
8. Bhidayasiri R, Jitkritsadakul O, Friedman JH, Fahn S. Updating the recommendations for treatment of tardive syndromes: A systematic review of new evidence and practical treatment algorithm. J Neurol Sci. 2018 Jun 15;389:67-75. doi: 10.1016/j.jns.2018.02.010. Epub 2018 Feb 5. PMID: 29454493.

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 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 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 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.
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 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).	

***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:	08/01/2025
Approval Date:	08/01/2026
Effective Date:	10/01/2026
Related Policies:	Donislecel 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 a nicotinamide-modified allogeneic hematopoietic progenitor cell therapy derived from cord blood indicated for the treatment of 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 infections. Omidubicel is also indicated for the treatment of adult and pediatric patients 6 years and older with severe aplastic anemia (SAA) following reduced intensity conditioning. The FDA has designated omidubicel as an orphan drug for both indications.

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: Find an Omisirge® (omidubicel-onlv) treatment near you
- 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
    - Human serum albumin
    - Bovine material

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.

Severe Aplastic Anemia

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

- Member is 6 years of age or older

- Member has a documented diagnosis of severe aplastic anemia
- Member has received or will receive reduced intensity conditioning prior to administration of omidubicel
- Documentation that the member has not received a prior allogeneic hematopoietic stem cell transplant (allo-HSCT)
- 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: Find an Omisirge® (omidubicel-onlv) treatment near you
- Documentation that administration of omidubicel will be under the supervision of a physician experienced in treatment of severe aplastic anemia
- Documentation that the member does not have a known allergy or hypersensitivity to the following:
    - Dimethyl sulfoxide (DMSO)
    - Dextran 40
    - Gentamicin
    - Human serum albumin
    - Bovine material

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.

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

References

1. Omidubicel. Clinical Pharmacology. Revised 02/18/2026. Accessed July 23, 2026.

2. Prescribing Information. Omisirge. Gamida Cell, Inc. Boston, MA. Initial Approval 2023. Revised 02/2026. Omisirge-final-PI.pdf (gamida-cell.com)

Member Product	Medical Management Requirements*
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MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD
♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).	

***Medical Management Requirements**

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

MVP Health Care Medical Policy

Medicare Part B: Omidubicel

Type of Policy:	Medical Therapy (administered by the pharmacy department)
Prior Approval Date:	08/01/2025
Approval Date:	08/01/2026
Effective Date:	10/01/2026
Related Policies:	Donislecel 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.
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

J3590 omidubicel (Omsirge), cell therapy suspension for infusion

Overview/Summary of Evidence

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- Member is 12 years of age or older
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- 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: Find an Omisirge® (omidubicel-onlv) treatment near you
- 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
    - Human serum albumin
    - Bovine material

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

- Member is 6 years of age or older
- Member has a documented diagnosis of severe aplastic anemia

- Member has received or will receive reduced intensity conditioning prior to administration of omidubicel
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- Prescribed by or in consultation with a hematologist or oncologist
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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.

Exclusions

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2. Prescribing Information. Omisirge. Gamida Cell, Inc. Boston, MA. Initial Approval 2023. Revised 02/2026. Omisirge-final-PI.pdf (gamida-cell.com)