2026 MVP Health Care® Pharmacy Policies

Updated June 1, 2026

MVP Pharmacy Policies

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MVP Health Care Medical Policy

Abatacept

Type of Policy:	Medical Therapy
Prior Approval Date:	**02/01/2024**
Approval Date:	**11/01/2025**
Effective Date:	**01/01/2026**
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.

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 or contracted provider office. Prior Authorization and medical justification is required for Abatacept IV (Orencia) 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 and Medicaid, CHP members

C. **Rheumatoid Arthritis**

Abatacept may be considered for coverage for Rheumatoid Arthritis when the above criteria are 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 are 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 are met **AND** documentation that the member is undergoing hematopoietic 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.

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 05/2024.
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 Health Care Medical Policy

Medicare Part B: Abatacept

Type of Policy:	**Medical Therapy**
Prior Approval Date:	**02/01/2024**
Approval Date:	**11/01/2025**
Effective Date:	**01/01/2026**
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 are 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 are 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 are met **AND** documentation that the member is undergoing hematopoietic 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.

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 05/2024.
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:	**08/01/2024**
Approval Date:	**11/01/2025**
Effective Date:	**01/01/2026**
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.

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

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

References

1. Nexletol (bempedoic acid) [prescribing information]. Ann Arbor, MI: Esperion Therapeutics, Inc; Approved 2020. Revised 07/2025.
2. Nexlizet (bempedoic acid and ezetimibe) [prescribing information]. Ann Arbor, MI: Esperion Therapeutics, Inc; Approved 2020. Revised 07/2025.
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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.

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7. Guidelines for the Management of High Blood Cholesterol - Endotext - NCBI Bookshelf (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 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 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.
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MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	
POS in Plan	Prior Auth
POS OOP	Prior Auth
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MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part D
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UVM Health Advantage Secure PPO	Refer to the MVP website for the Medicare Part B and Part D
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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
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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:	**02/01/2025**
Approval Date:	**02/01/2026**
Effective Date:	**04/01/2026**

Related Policies:

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

Drugs Requiring Prior Authorization under the Medical benefit

J0800 (Injection, corticotropin, Acthar gel, up to 40 units)

Drugs Requiring Prior Authorization under the Pharmacy benefit

Acthar injection gel auto injector (subcutaneous)

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 • Mycophenolate AND dexamethasone
IgA Nephropathy	• ACE-inhibitor OR ARB • 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; February 2024.
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.
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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)

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 Premier Plus HDHP	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
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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:	12/01/2024
Approval Date:	07/01/2025
Effective Date:	09/01/2025
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.
- Chart notes documenting 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 or contracted provider office. Prior Authorization and medical justification are required for Adakveo 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

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
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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
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MVP Premier Plus HDHP	Prior Auth
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MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	
POS in Plan	Prior Auth
POS OOP	Prior Auth
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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: Adakveo

Type of Policy:	Drug Therapy
Prior Approval Date:	NA
Approval Date:	07/01/2025
Effective Date:	09/01/2025
Related Policies:	N/A

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.

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.
- Chart notes documenting 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.

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.

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

MVP Health Care Medical Policy

Adalimumab

Type of Policy:	Drug Therapy
Prior Approval Date:	**10/01/2024**
Approval Date:	**11/01/2025**
Effective Date:	**01/01/2026**
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 are 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 are 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 are 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 are 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 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 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 are 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 are 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 are 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; Approved 2002. Revised 07/2025/

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.

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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)

10. Alikhan, A., Sayed, C., Afsaneh, A., et al. (2019). North American clinical management guidelines for hidradenitis suppurativa: A publication from the

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)

13. 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

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

Agents for Fabry Disease

Type of Policy: Drug
Prior Approval Date: N/A
Approval Date: 10/01/2025
Effective Date: 11/01/2025
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

J2508 Elfabrio (Injection, pegunigalsidase alfa-iwxj, 1 mg)

J0180 Fabrazyme (Injection, agalidase beta, 1mg)

Overview

Pegunigalsidase alfa (Elfabrio) is a hydrolytic lysosomal neutral glycosphingolipid-specific enzyme given by intravenous infusion for the treatment of confirmed Fabry disease in adults. Agalsidase Beta (Fabrazyme) is a recombinant human alpha-galactosidase A enzyme given by intravenous infusion in adult and pediatric patients 2 years and older.
Patients with Fabry disease have a deficiency of the lysosomal enzyme, ceramidetrihexosidase or alpha-galactosidase A, which breaks down glycosphingolipids (predominantly globotriaosylceramide or GL-3). Glycosphingolipids accumulate in the lining of blood vessels in the heart, kidney, and other organs in patients without an adequate presence of alpha-galactosidase A.

Indications/Criteria

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

- Elfabrio or Fabrazyme are prescribed by or in consultation with a geneticist, endocrinologist, a metabolic disorder specialist or a physician who specializes in the treatment of lysosomal storage disorder.

- Per the MVP Health Care Pharmacy Management Programs policy, Elfabrio and Fabrazyme are 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 Elfabrio 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. Fabry disease treatment

Elfabrio or Fabrazyme may be considered for coverage for Fabry disease treatment when the following criteria is met:

- Chart notes documenting that the member has a confirmed diagnosis of Fabry disease with supporting laboratory results.
    - Member has a laboratory test demonstrating deficient α-galactosidase A activity in leukocytes or fibroblasts; OR member has a molecular genetic test demonstrating pathogenic variants in the galactosidase alpha gene

Initial approval will be for 6 months

Extension requests will be approved for up to 12 months with current documentation supporting that the member has a continued benefit to therapy.

Exclusions

The use of Elfabrio 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 use with Fabrazyme and/or Galafold

The use of Fabrazyme 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 use with Elfabrio and/or Galafold

References

1. Pegunigalsidase alfa (Elfabrio). In: Clinical Pharmacology [database on the Internet]. Tampa (FL): Elsevier. publication year [September 3, 2025]. Available from: www.clinicalpharmacology.com. Subscription required to view.

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4. Fabrazyme [package insert]. Cambridge, MA: Genzyme Corporation; revised July 2024. Available at: fabrazyme.pdf

5. Agalsidase Beta (Fabrazyme). In: Clinical Pharmacology [database on the Internet]. Tampa (FL): Elsevier. publication year [September 3, 2025]. Available from: www.clinicalpharmacology.com. Subscription required to view.

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.
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MVP DualAccess Plus D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
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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

Agents for Female Sexual Dysfunction

Type of Policy: Drug Therapy
Prior Approval Date: **08/01/2025**
Approval Date: **06/01/2026**
Effective Date: **06/01/2026**
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.

Essential Plan Variation

Medications with sexual dysfunction or erectile dysfunction indications are excluded from coverage.

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 December 2025.
2. Vyleesi (bremelanotide injection), for subcutaneous use. Prescribing Information. Waltham, MA: AMAG Pharmaceuticals, Inc. June 2019. Revised March 2024
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	Not Covered
MVP Medicaid Managed Care	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Not Covered
MVP Child Health Plus	Prior Auth
MVP Harmonious Health Care Plan	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Not Covered
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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).	
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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

Amtagvi (Lifileucel)

Type of Policy:	Medical Therapy (administered by the pharmacy department)
Prior Approval Date:	06/01/2024
Approval Date:	08/01/2025
Effective Date:	10/01/2025
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

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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 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: Amtagvi (Lifileucel)

Type of Policy:	Medical Therapy (administered by the pharmacy department)
Prior Approval Date:	06/01/2024
Approval Date:	08/01/2025
Effective Date:	10/01/2025
Related Policies:	CAR T-Cell Therapy

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

Refer to 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

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

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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

Anifrolumab

Type of Policy: Drug Therapy
Prior Approval Date: N/A
Approval Date: 10/01/2025
Effective Date: 11/01/2025
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

J0491 Saphnelo (Injection, anifrolumab-fnia, 1 mg)

Overview

Anifrolumab is a type 1 interferon receptor antagonist approved for the treatment of moderate to severe systemic lupus erythematosus (SLE) in adult patients who are receiving standard therapy.

Indications/Criteria

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

- Saphnelo is prescribed by or in consultation with a rheumatologist, clinical immunologist, nephrologist, neurologist, or dermatologist.
- Per the MVP Health Care Pharmacy Management Programs policy, Saphnelo 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 Saphnelo

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. Moderate to severe systemic lupus erythematosus

Saphnelo may be considered for coverage when all of 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 Saphnelo therapy (i.e. hydroxychloroquine, methotrexate, azathioprine, mycophenolate, corticosteroids).
- Documentation that the member has had an inadequate response to standard therapy alone.

Initial approval will be for 12 months

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

Exclusions

The use of Saphnelo 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 Benlysta
- Members with severe active lupus nephritis
- Members with severe active central nervous system lupus
- Combination with other biologic products

References

1. 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

2. Saphnelo (anifrolumab-fnia). In: Clinical Pharmacology [database on the Internet]. Tampa (FL): Elsevier. publication year [cited July 11, 2025]. Available from: www.clinicalpharmacology.com. Subscription required to view.

3. Saphnelo (anifrolumab-fnia). [Package Insert]. Wilmington, DE. AstraZeneca. Revised August 2024. Available at: SAPHNELO Full Prescribing Information

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.
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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.
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.
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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
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: **12/01/2024**
Approval Date: **12/01/2025**
Effective Date: **02/01/2026**
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/.
4. 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
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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 Medicare WellSelect 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
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 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

Apremilast

Type of Policy: Drug Therapy
Prior Approval Date: 11/01/2025
Approval Date: 04/01/2026
Effective Date: 05/01/2026
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)

Otezla XR (apremilast)

Overview

Apremilast is an oral phosphodiesterase-4 (PDE4) inhibitor and is considered a targeted synthetic DMARD. Apremilast is indicated for the following:

Adult patients with:

- Active psoriatic arthritis
- Plaque psoriasis who are candidates for phototherapy or systemic therapy
- Oral ulcers associated with Behçet's Disease

Pediatric patients 6 years of age and older with:

- Active psoriatic arthritis
- Moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy

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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.

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; Approved 2014. Revised 08/2025.

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
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PPO OOP	Prior Auth
POS in Plan	Prior Auth
POS OOP	Prior Auth
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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
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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

Arimoclomol

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

Prior Approval Date: N/A

Approval Date: 08/01/2025

Effective Date: 10/01/2025

Related Policies: Orphan Drugs and Biologicals

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

Drugs Requiring Prior Authorization under the pharmacy benefit

Miplyffa (arimoclomol) capsules

Overview

Arimoclomol is indicated for use in combination with miglustat for the treatment of neurological manifestations of Niemann-Pick disease type C (NPC). NPC is a rare inherited autosomal recessive genetic disorder where the body is unable to transport cholesterol and other lipids within a cell. This leads to the accumulation of cholesterol and other lipids inside various tissues of the body, including brain tissue. NPC is caused by changes in the NPC1 gene or the NPC2 gene.

Indications/Criteria

A. Niemann-Pick disease Type C

Miplyffa (arimoclomol) may be considered for coverage when all of the following criteria is met:

- Member has a confirmed diagnosis of Niemann-Pick disease type C
- Chart notes documenting genetic confirmation of Niemann-Pick disease type C analyzing the NPC1 gene and NPC2 gene.
- Chart notes documenting baseline or current assessment with NPC Clinical Severity Scales (i.e. 17-doman NPCCSS, 5-domain NPCCS)
- Chart notes documenting neurological manifestations of Niemann-Pick disease type C
- Provider attestation that Miplyffa is prescribed in combination with miglustat

Initial approval will be for 12 months

Extension requests will be approved for up to 12 months when all the following criteria is met:

- Continuation requests must indicate that Miplyffa is being used in combination with miglustat. Claims history will be reviewed for confirmation.
- Chart notes indicating that the member has a continued benefit to therapy such as slowed progression based on current assessment with NPC Clinical Severity Scales (i.e. 17-doman NPCCSS, 5-domain NPCCS)

Exclusions

The use of Miplyffa (arimoclomol) will not be covered for the following situations:

- Used in combination with Levacetylleucine (Aqneursa)
- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling

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References

1. National Organization for Rare Disorders (NORD). Niemann-Pick Disease Type C [Internet]. Danbury (CT): NORD; 2024 Sep 25 [cited 2025 Jul 2]. Available from: Niemann Pick Disease Type C - Symptoms, Causes, Treatment | NORD
2. Zevra Therapeutics, Inc. MIPLYFFA (arimoclomol) prescribing information [Internet]. Celebration (FL): Zevra Therapeutics; 2024 Sep [cited 2025 Jul 2]. Available from: https://zevra.com/documents/MIPLYFFA-Prescribing-Information.pdf
3. Miplyffa. In: Clinical Pharmacology [database on the Internet]. Tampa (FL): Elsevier. 2025 [July 2025]. Available from: www.clinicalpharmacology.com. Subscription required to view.
4. Yanjanin NM, Vélez JI, Gropman A, King K, Bianconi S, Conley SK, et al. Linear clinical progression, independent of age of onset, in Niemann-Pick disease, type C. *Orphanet J Rare Dis*. 2021;16:63. Available from:

MVP Health Care Medical Policy

Asfotase alfa

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

Prior Approval Date: 08/01/2025
Approval Date: 02/01/2026
Effective Date: 04/01/2026
Related Policies: Orphan Drugs and Biologicals

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

Drugs Requiring Prior Authorization under the pharmacy benefit

Strensiq (Asfotase alfa) solution for injection

Overview

Asfotase alfa is an enzyme replacement therapy for treatment of perinatal/infantile- and juvenile-onset hypophosphatasia (HPP). HPP is caused by mutations in the tissue nonspecific alkaline phosphatase (TNSALP) enzyme, which is encoded by the alkaline phosphatase (ALP) gene. TNSALP is responsible for formation of an essential mineral in normal bone; deficient TNSALP results in defective bone mineralization that can result in bone and skeletal system abnormalities, as well as systemic complications such as muscle weakness and respiratory failure. HPP is a genetic, chronic, progressive, and potentially life-threatening metabolic disease that affects less than 20 patients per one million in the general population.

Indications/Criteria

A. Perinatal/infantile or juvenile-onset hypophosphatasia (HPP)

Strensiq may be considered for coverage when all of the following criteria is met:

- Member has a diagnosis of perinatal/infantile or juvenile-onset hypophosphatasia (HPP)

- HPP diagnosis is supported by the following:
  - Documentation of genetic testing documenting Alkaline Phosphatase (ALPL) gene variants
    - **OR**
  - Documentation of low baseline serum alkaline phosphatase (ALP) **AND**
  - Documentation of an elevated tissue-nonspecific alkaline phosphatase (TNSALP) substrate level (i.e., serum pyridoxal 5'-phosphate, serum, or urinary inorganic pyrophosphate, urinary phosphoethanolamine)
  - **AND**
  - Radiographic imaging demonstrating skeletal abnormalities

- Member currently has or a history of clinical manifestations consistent with hypophosphatasia OR has a family history (parent or sibling) of hypophosphatasia.
  - Examples of clinical manifestation include but are not limited to: early tooth loss, growth failure, delayed milestones, slow to heal fractures, Rickets, hypercalcemia, hypercalciuria, joint/bone pain, etc.

- Symptom or disease onset occurred ≤18 years of age

- Strensiq is prescribed by or in consultation with a geneticist, endocrinologist, or prescriber with HPP experience or expertise

Initial approval will be for 6 months

Extension requests will be approved for up to 12 months when accompanied by current documentation indicating that the member has a continued benefit to therapy.

Exclusions

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

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

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References

1. Mayo Clinic. Hypophosphatasia: clinical updates and therapeutic advances [Internet]. Rochester (MN): Mayo Foundation for Medical Education and Research; [cited 2025 Jul 2]. Available from: https://www.mayoclinic.org/medical-professionals/endocrinology/news/hypophosphatasia-clinical-updates-and-therapeutic-advances/mac-20477637
2. Strensiq Title. In: Clinical Pharmacology [database on the Internet]. Tampa (FL): Elsevier. 2025 [December 2025]. Available from: www.clinicalpharmacology.com. Subscription required to view.
3. Strensiq [package insert]. Boston MA: Alexion Pharmaceuticals; July 2024.
4. Whyte MP, Rockman-Greenberg C, Ozono K, Riese R, Moseley S, Melian A, Thompson DD, Bishop N, Hofmann C. Asfotase Alfa Treatment Improves Survival for Perinatal and Infantile Hypophosphatasia. J Clin Endocrinol Metab. 2016 Jan;101(1):334-42. doi: 10.1210/jc.2015-3462. Epub 2015 Nov 3. PMID: 26529632; PMCID: PMC4701846.

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).	
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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:	04/01/2024
Approval Date:	06/01/2024
Effective Date:	01/01/2026
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.

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.

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
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	
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

Belimumab

Type of Policy: Drug Therapy
Prior Approval Date: N/A
Approval Date: 10/01/2025
Effective Date: 11/01/2025
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

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).
- Documentation that the member has had an inadequate response to standard therapy alone.

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

References

1. 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

2. Benlysta (Belimumab). In: Clinical Pharmacology [database on the Internet]. Tampa (FL): Elsevier. publication year [cited July 11, 2025]. Available from: www.clinicalpharmacology.com. Subscription required to view.

3. Benlysta (benlimumab). [Package Insert]. Revised June 2025. Available at: BENLYSTA-PI-MG-IFU.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 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.
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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
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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

Brensocatib

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

Prior Approval Date: NA

Approval Date: 04/01/2026

Effective Date: 06/01/2026

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

Brinsupri (brensocatib)

Overview

Brinsupri (brensocatib) is a dipeptidyl peptidase 1 (DPP1) inhibitor indicated for the treatment of non-cystic fibrosis bronchiectasis. During neutrophil maturation in the bone marrow, DPP1 activates pro-inflammatory neutrophil serine proteases (NSPs), including neutrophil elastase, cathepsin G, and proteinase 3. These activated NSPs play a key role in the inflammation associated with neutrophil-mediated non-cystic fibrosis bronchiectasis (NCFB). In cell-based assays, DDP1 inhibition by brensocatib reduces the activity of NSPs, thereby potentially mitigating inflammation and tissue damage related to excessive neutrophil activity.

Indications/Criteria

Brinsupri (brensocatib) may be considered for coverage when all of the following criteria is met:

- Chart notes documenting a diagnosis of non-cystic fibrosis bronchiectasis confirmed by chest computed tomography (CT).
- For members aged older than 18 years, chart notes documenting that the member has had two (2) pulmonary exacerbations in the past twelve (12) months.
- For members 12 years to 18 years old, chart notes documenting that the member has had one (1) pulmonary exacerbation in the past twelve (12) months.
- Brinsupri is prescribed by or in consultation with a pulmonologist or infectious disease specialist.
- The provider attests that the member
    - Is not a current smoker
    - Does not have bronchiectasis due to cystic fibrosis
    - Does not have a known history of human immunodeficiency virus (HIV) infection.
- The provider attests that the member has not received any live attenuated vaccines within 4 weeks prior to the first administration of brensocatib.

Initial approval will be for twelve (12) months

Extension requests will be approved for up to twelve (12) months when the provider attests that the member currently has a positive clinical benefit.

Exclusions

The use of Brinsupri (brensocatib) will not be covered in the following situations:

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

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References

1. Institute for Clinical and Economic Review (ICER). *Non-Cystic Fibrosis Bronchiectasis: Final Evidence Report.* 2025 Oct 30. Available from: https://icer.org/wp-content/uploads/2025/10/ICER_NCFB-Final-Report_For-Publication_103025.pdf

2. Brensocatib. In: Clinical Pharmacology [database on the Internet]. Tampa (FL): Elsevier. publication year [January 27, 2026]. Available from: www.clinicalpharmacology.com. Subscription required to view.

3. Brinsupri [package insert]. Bridgewater, NJ: Insmed Incorporated; August 2025BRINSUPRI (brensocatib) Full Prescribing Information

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 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
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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

CAR-T Cell Therapy

Type of Policy: Medical Therapy (administered by the pharmacy department)
Prior Approval Date: 08/01/2025
Approval Date: 04/01/2026
Effective Date: 04/01/2026

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)
Q2058 Aucatzyl (obecabtagene 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 CAR T-Cell therapy listed in the policy requires prior authorization for all sites of service. This includes when the member is currently in an inpatient facility.

1. Kymriah

Kymriah may be considered for coverage when ALL of the following criteria are met

- 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 member has 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

- Prescribed by or in consultation with an oncologist
- Chart notes confirming a diagnosis of an FDA approved labeled indication:
    - Adult patients with large B-cell lymphoma that is refractory to first-line chemoimmunotherapy or that relapses within 12 months of first-line chemoimmunotherapy.
    - Adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including 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.
    - Adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy
- Chart notes documenting a failure of previous therapies:
    - For relapsed or refractory large B-cell lymphoma, must have failure of first line chemoimmunotherapy that included rituximab and an anthracycline

    - For Relapsed/Refractory Follicular Lymphoma must have a failure of two or more lines of therapy including 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 two 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 two prior lines of systemic therapy, including a Bruton tyrosine kinase (BTK) inhibitor.
  - Relapsed or refractory marginal zone lymphoma (MZL) who have received at least two prior lines of systemic therapy.
- 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 two or 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.

7. Aucatzyl

- Prescribed by or in consultation with an oncologist
- Chart notes confirming a diagnosis of relapsed or refractory B-Cell precursor acute lymphoblastic leukemia including one of the following:
    i. Chart notes documenting relapse following a remission **OR**
    ii. Chart notes documenting a failure of two or more prior lines of systemic therapy **OR**
    iii. Chart notes documenting relapsed or refractory ALL at least greater than 3 months after allogeneic stem cell transplantation (SCT)
- Member is 18 years of age or older
- Member has not received any live vaccines for at least 6 weeks prior to the start of lymphodepleting chemotherapy and during Aucatzyl treatment
- Member will receive cyclophosphamide and fludarabine for 3 days before infusion of Aucatzyl
- Member has been screened for HBV, HCV and HIV before collection of cells for manufacturing
- ECOG score ≤ 2
- 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 Aucatzyl must be appropriately authorized to do so. Please see link for treatment centers below: Home | AUCATZYL® (obecabtagene autoleucel) Patient Site

Aucatzyl 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 (excluded for all except Yescarta)
- Active infection requiring antimicrobials
- 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
- **Auctzyl**
    - Members with isolated extra medullary disease
    - Members with active graft vs. host disease
    - Members with history or presence of CNS disorders

References

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8. 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(suppl):2531-44.
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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.
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).	
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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

Casgevy (Exagamglogene Autotemcel)

Type of Policy:	Medical Therapy (administered by the pharmacy department)
Prior Approval Date:	07/01/2025
Approval Date:	02/01/2026
Effective Date:	01/01/2026
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

J3392 Casgevy (Exagamglogene Autotemcel)

Overview

Casgevy (Exagamglogene Autotemcel)as is an autologous genome edited hematopoietic stem cell-based gene therapy for mems 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 member 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 members with transfusion dependent beta-thalassemia to potentially become transfusion independent.

Medicaid Variation:

- Please see Section D
- 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, Casgevy may be considered for coverage when the following criteria are met:

- 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.

D. Medicaid Variation

In addition to the criteria above, Casgevy will be considered for coverage for Medicaid members when the following additional criteria is met:

- The treatment center participates with the Center for International Blood & Marrow Transplant Research- CIBMTR. The list of participating centers may be found here: CIBMTR Participating Centers.
- Provider attestation that the member will have provider access for at least one year after receiving Casgevy therapy.

Casgevy 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. Casgevy (the medication only) is **reviewed** by MVP Health Care and **billed** through the member's NYRX Medicaid benefit.

Exclusions

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

- More than one infusion per lifetime

- 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 member 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:

- More than one infusion per lifetime
- 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*

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. Revised 09/2025

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: Casgevy (Exagamglogene Autotemcel)

Type of Policy:	Medical Therapy (administered by the pharmacy department)
Prior Approval Date:	06/01/2024
Approval Date:	07/01/2025
Effective Date:	09/01/2025
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

J3392 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:

- More than one infusion per lifetime
- 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:

- More than one infusion per lifetime

- 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*

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:	10/01/2024
Approval Date:	07/01/2025
Effective Date:	09/01/2025
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.

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 February 2025. 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).
7. Rebyota. Prescribing Information. Roseville, MN: Ferring Pharmaceuticals. Revised November 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 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: C. Difficile Drug Therapy

Type of Policy: **Drug Therapy**
Prior Approval Date: **10/01/2024**
Approval Date: **07/01/2025**
Effective Date: **09/01/2025**
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 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.

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)

7. Rebyota. Prescribing Information. Roseville, MN: Ferring Pharmaceuticals.. Revised November 2022.

MVP Health Care Medical Policy

Certolizumab

Type of Policy: **Medical Therapy**
Prior Approval Date: **02/01/2025**
Approval Date: **02/01/2026**
Effective Date: **04/01/2026**
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 **AND**
   - Member meets the diagnosis specific criteria below.

B. **For all indications,** 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 **AND**
   - Member meets the diagnosis specific criteria below.

C. **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.

D. **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.

E. **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.

F. **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.

G. **Ankylosing Spondylitis and Non-radiographic axial spondyloarthritis**

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

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.

Exclusions

The use of certolizumab 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. 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. September 2025.
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 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).	
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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:	**02/01/2025**
Approval Date:	**02/01/2026**
Effective Date:	**04/01/2026**
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 **AND**
- Member meets the diagnosis specific criteria below.

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
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 Non-radiographic axial spondylarthritis**

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

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. **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:

- 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. September 2025
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.

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 • 10mcg/kg daily for up to 14 days for BMT/PBPC/Radiation indications • 6mcg/kg twice daily for Severe Congenital Neutropenia
Neulasta, Udenyca and Fulphila, Ziextenzo, Nyvepria All other indications*	<10 kg = 0.1 mg/kg 10-20 kg = 1.5 mg 21-30 kg = 2.5 mg 31-44 kg = 4 mg 45 kg and up = 6 mg 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

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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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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: **12/01/2024**
Approval Date: **12/01/2025**
Effective Date: **02/01/2026**
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
- Must be obtained from a participating pharmacy

- 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

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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
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 Medicare WellSelect 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
USA Care PPO	Refer to the MVP website for the Medicare Part B and Part
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).	

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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:	04/01/2025
Approval Date:	04/01/2026
Effective Date:	06/01/2026
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.

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

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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	

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).	
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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:	04/01/2025
Approval Date:	04/01/2026
Effective Date:	06/01/2026
Related Policies:	Cosmetic and Reconstructive Surgery Vitiligo Treatment 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
dihydroxyacetone	Vitadye, Dy-o-derm solution
estriol	Sivora
finasteride 1mg	Propecia
hydroquinone	Kaxm, Keido, Kuxm, Kutea, , Blanche cream, Keya, Medorfa, Medorfa Plus, Medorfa HP
hydroquinone-hydrocortisone	Keya, Mimora
hydroquinone-hydrocortisone-tretinoin	Kataryaxn, Ketarya, Kuvarya, Katarya, Yaxatarxyn, Yokatar, Kutaryaxmpa, Kutaryaxm, Melondis, Melondis Plus, Melidu, Molexi, Mekam, Mekam HP, Kevarya, Mecorix, Mecorix Plus, Mecorix HP, Kuvarye, Mythius

hydroquinone-fluocinolone-tretinoin	Tri-Luma
hydroquinone-tretinoin	Katarvia, Mokura, Mokura plus, Mokura lp, Mokura mod, Kevartia, Kutar, Kutarvia
hydroquinone- tretinoin-triamcinolone	Kotaraxap, Kevaraxap, Kataraxap, Mavilo, Mavilo LP, Mavilo HP
kinetin	Kinerase
minoxidil	Rogaine, Rogaine X-S, , Gainextra, Hair Regrow, Hair Regrowth
onabotulinumtoxin A (Cosmetic)	Botox Cosmetic. Botox when used for non-cosmetic purposes is eligible for coverage but is subject to prior authorization
prabotuliniumtoxinA- XVFS (Cosmetic)	Jeuveau
various tretinoin products labeled for facial wrinkles	Renova

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, etc.) 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 is a topical medication used as adjunctive treatment of fine wrinkles, mottled hyperpigmentation, and tactile roughness of facial skin
- Renova is 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 medical 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
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POS OOP	Prior Auth

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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

Crinecerfont

Type of Policy: Drug therapy (administered by the pharmacy department)
Prior Approval Date: N/A
Approval Date: 10/01/2025
Effective Date: 11/01/2025
Related Policies: Orphan Drugs and Biologicals

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

Drugs Requiring Prior Authorization under the pharmacy benefit

Crenessity (crinecerfont)- all formulations

Overview

Crenessity (crinecerfont) is a corticotropin-releasing factor (CRF) type 1 receptor antagonist indicated for classic congenital adrenal hyperplasia (CAH) as an adjunctive treatment to glucocorticoid replacement. Congenital adrenal hyperplasia is a rare genetic condition affecting the adrenal glands. Individuals with CAH do not produce enough cortisol and produce an excess of androgens. They require high doses of glucocorticoids, which increase cortisol and help reduce the excess androgen concentrations. Treatment with crinecerfont reduces excessive adrenal androgen production, therefore reducing the amount of glucocorticoid treatment needed.

Indications/Criteria

A. Classic Congenital Adrenal Hyperplasia (CAH)

Crenessity may be considered for coverage when all of the following criteria is met:

- Crenessity is prescribed by or in consultation with a urologist or endocrinologist.
- The member has a documented diagnosis of classic congenital adrenal hyperplasia (CAH) due to 21-hydroxylase deficiency
- Documentation is submitted confirming a diagnosis of classic congenital adrenal hyperplasia. The diagnosis is confirmed by one of the following:
    - Newborn screening with confirmatory testing (such as genetic testing or 17-hydroxyprogesterone levels)
    - Genetic testing (confirming mutation in the CYP21A2 gene)
    - Cosyntropin (ACTH) Stimulation test
    - Elevated 17-hydroxyprogesterone level
- Documentation that Crenessity with be used concurrently with systemic glucocorticoid treatment. Claims history will be reviewed with each request.

Initial approval will be for 12 months

Extension requests will be approved for up to 12 months if documentation is submitted supporting that the member has a continued benefit to therapy including but not limited to: decreased 17-hydroxyprogesterone levels, decreased androstenedione levels, reduction in glucocorticoid dose from baseline or stabilization in CAH.
Extension requests where Crenessity did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

Exclusions

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

- Age, dose, frequency of dosing and/or duration of therapy outside of FDA approved package labeling.
- Crenessity as monotherapy without concurrent systemic glucocorticoid therapy
- Diagnosis of Nonclassic Classic Congenital Adrenal Hyperplasia (CAH)
- Members with severe renal impairment or end-stage renal disease

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2. Crenessity. In: Clinical Pharmacology [database on the Internet]. Tampa (FL): Elsevier; 2017 [cited 2025 July 30]. Available from: www.clinicalpharmacology.com. Subscription required to view.

3. Crenessity [package insert]. San Diego, CA. Neurocrine Biosciences, Inc; Revised December 2024

4. Cleveland Clinic. Congenital adrenal hyperplasia. Cleveland (OH): Cleveland Clinic; [updated 2024; cited 2025 Jul 29]. Available from: https://my.clevelandclinic.org/health/diseases/17817-congenital-adrenal-hyperplasia

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

Cystic Fibrosis (select agents for inhalation)

Type of Policy:	Drug Therapy
Prior Approval Date:	07/01/2024
Approval Date:	07/01/2025
Effective Date:	09/01/2025
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].

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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11. KITABIS PAK (tobramycin inhalation solution, USP). Prescribing Information. Midlothian, VA: PARI Respiratory, Inc. Revised 08/2021.
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14. NHIC, Inc. Local Coverage Determination (LCD) for Nebulizers (L33370). Original Determination Effective Date 10/1/2015. Revised Effective Date 01/01/2024. Available from: LCD - Nebulizers (L33370) (cms.gov)
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
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MVP DualAccess Complete D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
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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

Cystic Fibrosis (select oral agents)

Type of Policy:	Drug Therapy
Prior Approval Date:	04/01/2024
Approval Date:	07/01/2025
Effective Date:	09/01/2025
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)
Alyftrek (vanzacaftor/tezacaftor/deutivacaftor) tablets

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.

Kalydeco (ivacaftor) is a cystic fibrosis transmembrane conductance regulator (CFTR) potentiator indicated for the treatment of cystic fibrosis (CF) in patients aged 1 month and older who have at least one mutation in the CFTR gene that is responsive to ivacaftor based on clinical and/or in vitro assay data. 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.

Orkambi (lumacaftor and ivacaftor) is a combination of ivacaftor, a cystic fibrosis transmembrane conductance regulator (CFTR) potentiator, and lumacaftor, indicated for

the treatment of cystic fibrosis (CF) in patients aged 1 year and older who are homozygous for the 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 the F508del mutation on both alleles of the CFTR gene

Trikafta is a combination of ivacaftor, a CFTR potentiator, tezacaftor, and elexacaftor indicated for the treatment of cystic fibrosis (CF) in patients aged 2 years and older who have at least one F508del mutation in the CFTR gene or a mutation in the CFTR gene that is responsive based on clinical and/or in vitro data. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to confirm the presence of at least one indicated mutation.

Symdeko (tezacaftor/ivacaftor) is a combination of tezacaftor and ivacaftor, indicated for the treatment of cystic fibrosis (CF) in patients aged 6 years and older who are homozygous for the F508del mutation or who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to tezacaftor/ivacaftor based on in vitro data and/or clinical evidence. 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.

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 member'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

Initial approval will be for 6 months

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

- Stabilization or improvement in $ppFEV_1$ from baseline
- Increase in BMI from baseline
- Decrease in the number of pulmonary exacerbations from baseline

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 member'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

Initial approval will be for 6 months

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

- Stabilization or improvement in $ppFEV_1$ from baseline
- Increase in BMI from baseline
- Decrease in the number of pulmonary exacerbations from baseline

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 member'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.

Initial approval will be for 6 months

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

- Stabilization or improvement in $ppFEV_1$ from baseline
- Increase in BMI from baseline
- Decrease in the number of pulmonary exacerbations from baseline

C. 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 indicated mutation.
      .

Initial approval will be for 6 months

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

- Stabilization or improvement in $ppFEV_1$ from baseline
- Increase in BMI from baseline
- Decrease in the number of pulmonary exacerbations from baseline

D. Alyftrek

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

- 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 indicated mutation.

Initial approval will be for 6 months

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

- Stabilization or improvement in ppFEV$_1$ from baseline
- Increase in BMI from baseline
- Decrease in the number of pulmonary exacerbations from baseline

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Exclusions

- Age, dose, frequency, outside of the FDA package label.
- Kalydeco in patients homozygous for the F508del mutation in the CFTR gene
- Alyftrek in patients with severe hepatic impairment (Child-Pugh Class C) or patients with moderate hepatic impairment (Child-Pugh Class B).

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4. Mogayzel PJ et al. Cystic Fibrosis Pulmonary Guidelines: Chronic Medications for Maintenance of Lung Health. Am J Respir Crit Care Med. 1 Apr 2013; 187(7): 680-689.
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10. Vertex Pharmaceuticals Incorporated. (2024). *Vanzacaftor, tezacaftor, and deutivacaftor tablets: U.S. prescribing information*. https://pi.vrtx.com/files/uspi_vanzacaftor_tezacaftor_deutivacaftor.pdf

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 Complete Wellness	Refer to the MVP website for the Medicare Part B and Part D policies.
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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.
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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).	

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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: **11/01/2024**
Approval Date: **08/01/2025**
Effective Date: **10/01/2025**

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.

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 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.; September 2024

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: **10/01/2024**
Approval Date: **04/01/2026**
Effective Date: **06/01/2026**
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 are 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

- 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. Approved 2020. Revised 10/2023. Ultragenyx Pharmaceutical Inc. Novato, CA.
2. 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.
3. Gillingham MB, Heitner SB, Martin J, Rose S, Goldstein A, El-Gharbawy AH, Deward S, Lasarev MR, Pollaro J, DeLany JP, Burchill LJ, Goodpaster B, Shoemaker J, Matern D, Harding CO, Vockley J. Triheptanoin versus trioctanoin for long-chain fatty acid oxidation disorders: a double blinded, randomized controlled trial. J Inherit Metab Dis. 2017 Nov;40(6):831-843. doi: 10.1007/s10545-017-0085-8. Epub 2017 Sep 4. PMID: 28871440; PMCID: PMC6545116.

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 Medicare WellSelect 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
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 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

Donislecel

Type of Policy: **Drug Therapy**
Prior Approval Date: **02/01/2025**
Approval Date: **02/01/2026**
Effective Date: **04/01/2026**
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

6. American Diabetes Association Professional Practice Committee; 9. Pharmacologic Approaches to Glycemic Treatment: Standards of Care in Diabetes—2025. *Diabetes Care* 1 January 2025; 48 (Supplement_1): S181–S206. https://doi.org/10.2337/dc25-S009

Member Product	Medical Management Requirements*
New York Products	
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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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ASO	See SPD
Vermont Products	
POS in Plan	Prior Auth
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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: Donislecel

Type of Policy: Drug Therapy
Prior Approval Date: 02/01/2025
Approval Date: 02/01/2026
Effective Date: 04/01/2026
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

6. American Diabetes Association Professional Practice Committee; 9. Pharmacologic Approaches to Glycemic Treatment: Standards of Care in Diabetes—2025. *Diabetes Care* 1 January 2025; 48 (Supplement_1): S181–S206. https://doi.org/10.2337/dc25-S009

MVP Health Care Medical Policy

Dose Rounding for Systemic Therapy

Type of Policy: **Drug/Medical Therapy**
Prior Approval Date: **12/01/2024**
Approval Date: **12/01/2025**
Effective Date: **01/01/2026**
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®)
J9035	Bevacizumab (Avastin®)

J9041	Bortezomib (Velcade®)
J9042	Brentuximab (Adcetris®)
J9064	Cabazitaxel
J9043	Cabazitaxel (Jevtana®)
J9046	Bortezomib(dr. reddy's)
J9047	Carfilzomib (Kyprolis®)
J9048	Bortezomib(Fresenius kabi)
J9049	Bortezomib(Hospira)
J9055	Cetuximab (Erbitux®)
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®)
J9292	Pemetrexed (Avyxia)
J9051	Bortezomib (Bortezo)

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 Medicare 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 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 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
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 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: Dose Rounding for Systemic Therapy

Type of Policy: **Drug/Medical Therapy**
Prior Approval Date: **12/01/2024**
Approval Date: **12/01/2025**
Effective Date: **01/01/2026**
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.

Drug table for Dose Rounding

HCPCS Code	Drug
J0893	Decitabine(sun pharma)
J0894	Decitabine (Dacogen®)
J9025	Azacitidine (Vidaza®)
J9033	Bendamustine (Treanda®)
J9035	Bevacizumab (Avastin®)

J9041	Bortezomib (Velcade®)
J9042	Brentuximab (Adcetris®)
J9043	Cabazitaxel (Jevtana®)
J9046	Bortezomib(dr. reddy's)
J9064	Cabazitaxel
J9047	Carfilzomib (Kyprolis®)
J9048	Bortezomib(Fresenius kabi)
J9049	Bortezomib(Hospira)
J9055	Cetuximab (Erbitux®)
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®)
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Q5119	Rituximab-pvvr, biosimilar (Ruxience®)
Q5123	Rituximab-arrx, biosimilar (Riabni®)
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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.

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MVP Health Care Medical Policy

Duchenne Muscular Dystrophy

Type of Policy:	**Drug Therapy**
Prior Approval Date:	**11/01/2024**
Approval Date:	**08/01/2025**
Effective Date:	**10/01/2025**

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.

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

References

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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
3. Emflaza (deflazacort tablets/suspension). Prescribing Information. South Plainfiled, NJ. PTC Therapeutics
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MVP Premier Plus HDHP	Prior Auth
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MVP EPO	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
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♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).	
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***Medical Management Requirements**

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

MVP Health Care Medical Policy

Dupixent

Type of Policy:	**Drug Therapy**
Prior Approval Date:	**12/01/2024**
Approval Date:	**04/01/2026**
Effective Date:	**06/01/2026**
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, eosinophilic esophagitis, chronic spontaneous urticaria, bullous pemphigoid, and allergic fungal rhinosinusitis.

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 are 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
f. Dupixent will be add on maintenance in combination with an intranasal corticosteroid.

Initial coverage will be for 12 months.

Continued authorization up to 3 years must 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 are 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**
    ii. FeNO ≥ 25ppb **OR**
    Documented diagnosis of oral corticosteroid dependent asthma with at least 1 month of daily oral corticosteroid use within the last 3 months
b. Member must be followed by an allergist, immunologist or pulmonologist
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)

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 are 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 are met:

a. Prescribed by or in consult with a gastroenterologist

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)

c. Secondary causes of eosinophilic esophagitis have been ruled out (such as food allergy and hypereosinophilic syndrome)

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 are 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 are 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.

7. **Chronic Spontaneous Urticaria (CSU)**
   Dupixent may be considered for coverage for CSU when the following criteria are met:
   a. Confirmed diagnosis CSU
   b. Member is followed by an allergist, immunologist, or dermatologist
   c. Documentation of inadequate control despite highest tolerated dose for a 2-week trial of H1 antihistamine 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.

8. **Bullous Pemphigoid (BP)**
   Dupixent may be considered for coverage for BP when the following criteria are met:

a. Confirmed diagnosis of BP
b. Bullous Pemphigoid Disease Area Index (BPDAI) activity score ≥ 24 on a scale of 0-360 AND a weekly average Peak Pruritus NRS score ≥ 4 on a scale of 0-10
c. Member is followed by an allergist, immunologist or dermatologist

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.

9. Allergic Fungal Rhinosinusitis (AFRS)
Dupixent may be considered for coverage for AFRS when the following criteria are met:

a. Confirmed diagnosis of AFRS with a history of sino-nasal surgery
b. Prescribed by or in consultation with an allergist, otolaryngologist or immunologist
c. Evidence of sinus opacification on the Lund Mackay (LMK) sinus CT scan with a LMK score of ≥9 for members with unilateral polyps and >12 for members with bilateral polyps
d. Nasal polyps score (NPS) of ≥2 for unilateral polyps or ≥3 for bilateral polyps

Initial approval will be for 6 months.

Continued authorization up to 12 months must be accompanied by current chart notes identifying continued benefit and improvement in symptoms from baseline.

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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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).	
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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

Eculizumab

Type of Policy:	**Medical Therapy**
Prior Approval Date:	**07/01/2025**
Approval Date:	**02/01/2026**
Effective Date:	**09/01/2025**
Related Policies:	Orphan Drug(s) and Biologicals, Ravulizumab-cwvz

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

Drugs Requiring Prior Authorization under the medical benefit

J1299 Soliris, Injection, eculizumab, 2 mg
Q5152 Bkemv, Injection, eculizumab-aeeb, biosimilar, 2 mg
Q5151 Epysqli, Injection, eculizumab-aagh, biosimilar, 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 as appropriate
    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. For Soliris and Bkemv requests, member has had an inadequate response, contraindication or intolerance to a trial of ravulizumab (Ultomiris) **AND** eculizumab-aagh (Epysqli)
d. Site of Care
    i. Per the MVP Health Care Pharmacy Management Programs policy, Soliris, Bkemv and Epysqli are 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 are 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)

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 show **no evidence of disease progression** while **on current regimen AND documentation of positive response** to therapy, which may include the following per applicable indication:

PNH

- Reduction in blood transfusions, stabilization in hemoglobin concentrations, reduction of exacerbations, improved quality of life scores/fatigue, and/or normalization of LDH levels

aHUS

- Normalization of lactate dehydrogenase (LDH) levels, platelet counts, improvement in renal function from baseline

gMG

- Improvement in MG-ADL score, changes compared to baseline in Quantitative Myasthenia Gravis (QMG) total score

NMOSD

- Improvement in EDSS score, decreased hospitalizations, improvement in stability, reduced plasma exchange treatments

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Exclusions

- Treatment of members with Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS)
- 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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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
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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 Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
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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

Eladocagene exuparvovec

Type of Policy: Medical therapy (administered by the pharmacy department)
Prior Approval Date: N/A
Approval Date: 10/01/2025
Effective Date: 11/01/2025
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 Kebilidi (eladocagene exuparvovec)

Overview

Eladocagene exuparvovec is an adeno-associated virus vector-based gene therapy indicated for the treatment of aromatic L-amino acid decarboxylase (AADC) deficiency. AADC deficiency is a rare genetic neurological disorder due to a mutation in the DDC gene, which leads to a decrease or lack of the AADC enzyme. A deficiency in the AADC enzyme leads to the body's inability to make dopamine and serotonin. Without dopamine, patients suffer from movement disorders, including hypokinesia, dystonia, and oculogyric crisis; they also have behavioral problems, autonomic dysfunction, and developmental delay.

The administration of eladocagene exuparvovec has the potential risk for procedure-related adverse events, including cranial cerebrospinal fluid leak, intracranial bleeding, inflammation, acute infarction, and infection. Additionally, respiratory arrest and cardiac arrest have occurred within 24 hours of the neurosurgical procedure and during post-surgical care. Continuous cardiorespiratory monitoring is recommended during hospitalization. Eladocagene exuparvovec was approved based on the change from

baseline in gross motor milestone achievement at 48 weeks after treatment with eladocagene exuparvovec.

Kebilidi administration involves an infusion into the brain and requires hospitalization. Kebilidi requires prior authorization for all site of services including when the member is currently in an inpatient facility.

Indications/Criteria

A. Aromatic L-amino acid decarboxylase (AADC) deficiency

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

- Kebilidi is prescribed by or in consultation with a neurosurgeon, geneticist or neurologist
- Member is ≥16 months of age
- Member has a diagnosis of AADC deficiency which is confirmed by the following:
  - Documentation of genetic test results indicating biallelic mutations in the dopa decarboxylase (DDC) gene OR cerebrospinal fluid (CSF) or plasma neurotransmitter profile consistent with AADC deficiency **AND**
  - Decreased AADC enzyme activity in plasma
- Documentation that the member has severe phenotype AADC deficiency demonstrated by the following:
  - Inability to sit, stand, walk, or ambulate independently
- Documentation that the member shows clinical symptoms of AADC deficiency such as:
  - Oculogyric crises
  - Hypokinesia
  - Hypotonia
  - Developmental delays
  - Ptosis
  - Autonomic dysfunction (excessive sweating, temperature instability, ptosis, nasal congestion, hypoglycemic episodes)

- Documentation of a failure, contraindication, symptom instability, adverse reaction to standard of care therapies.
    - Standard of care includes: dopamine agonists (pramipexole, ropinirole, bromocriptine), MAO inhibitors (selegiline or tranylcypromine), vitamin B_6 (pyridoxine, pyridoxal phosphate)

- For pediatric members, documentation of neuroimaging indicating that the member has achieved skull maturity, which is required for stereotactic neurosurgical administration.

- Documentation that anti-AAV2 neutralizing antibody titers are not over 1:1200.

- Provider confirmation that the member has not previously received Kebilidi. Claims history will be reviewed.

Kebilidi 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 administration.

Exclusions

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

- Member has not achieved skull maturity assessed by neuroimaging
- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling
- More than one administration per lifetime
- Members with anti-AAV2 neutralizing antibody titers over 1:1200.

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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).	
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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

Elinzanetant (Lynkuet)

Type of Policy: Drug therapy (administered by the pharmacy department)
Prior Approval Date: NA
Approval Date: 04/01/2026
Effective Date: 04/01/2026
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

Lynkuet (elinzanetant)

Overview

Elinzanetant is an oral neurokinin 1 (NK1) and neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms (VMS) due to menopause. VMS, during menopause, are predicted to result from increased kisspeptin/neurokinin B/dynorphin (KNDy) neuron activity from estrogen withdrawal.

Indications/Criteria

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

- Current chart notes indicate that the member has a confirmed diagnosis of moderate to severe vasomotor symptoms (hot flashes) due to menopause.
- Documentation is provided indicating that hormone replacement therapy (HRT) is not appropriate for the member OR documentation that the member has had a trial and failure of HRT.

- Documentation of the following:
  - Baseline hepatic laboratory tests to evaluate for hepatic function and injury [including serum alanine aminotransferase (ALT), serum aspartate aminotransferase (AST), serum alkaline phosphatase (ALP), and serum bilirubin (total and direct)] before initiating treatment with Lynkuet.
  - Do not start Lynkuet if ALT or AST is ≥ 2 times upper limit of normal (ULN) or if the total bilirubin is ≥ 2 times ULN

Initial approval will be for 12 months. The quantity is limited to twice a day dosing (i.e. member can fill per their benefit: 60 capsules per 30 days, 120 capsules per 60 days, 180 capsules per 90 days)

Extension requests will be approved for up to 12 months when current documentation is provided indicating the member has a continued benefit therapy. The quantity is limited to twice a day dosing (i.e. member can fill per their benefit: 60 capsules per 30 days, 120 capsules per 60 days, 180 capsules per 90 days)

Exclusions

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

- Members with moderate (Child-Pugh Class B) or severe (Child-Pugh Class C) hepatic impairment

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References

1. Lynkuet. In: Clinical Pharmacology [database on the Internet]. Tampa (FL): Elsevier. publication year [February 2, 2026]. Available from: www.clinicalpharmacology.com. Subscription required to view.

2. Lynkuet [package insert]. Whippany, NJ. Bayer HealthCare Pharmaceuticals Inc; 2025. Lynkuet_PI.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 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).	
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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:	**10/01/2024**
Approval Date:	**04/01/2026**
Effective Date:	**06/01/2026**
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 BCAD 1 POW BCAD 2 POW CAMINO PRO15 LIQ COMPLEX MSD POW JUNIOR	PHENYLD GMP POW DHA/FIBR PHENYLD GMP POW DHA/FIBR PHENYLD GMP POW DHA/FIBR

COMPLEX MSD POW VANILLA	PHENYL-FREE POW 1
COMPLEX MSUD BAR AMINO AC	PHENYL-FREE POW 2
COMPLEX MSUD POW	PHENYL-FREE POW 2HP
CYCLINEX-1 POW	PHLEXY-VITS
CYCLINEX-2 POW	PKU 2 POW
GA POW	PKU 3 POW
GA DIET POW	PKU COOLER LIQ 15
GLUTAREX-1 POW	PKU COOLR 10 LIQ
GLUTAREX-2 POW	PKU COOLR 15 LIQ
GLYTACTIN POW APPLE	PKU COOLR 20 LIQ
GLYTACTIN POW PUNCH	PKU EXP20 PAK
GLYTACTIN POW TROPICAL	PKU EXPRESS POW
HCY 1 POW	PKU GEL PAK
HCY 1 DIET POW	PKU LOPHLEX LIQ LQ 20
HCY 2 POW	PKU SPHERE LIQ 20 VAN
HOM 2 POW	PKU SPHERE LIQ NEXT 15
HOMINEX-1 POW	PKU START POW
HOMINEX-2 POW	PKU START POW
I-VALEX-1 POW	PKU TRIO POW
I-VALEX-2 POW	PORTAGEN POW
KETONEX-1 POW	PROMACTIN AA PLUS
KETONEX-2 POW	PROPIMEX-1 POW
LANAFLEX PAK	PROPIMEX-2 POW
LMD POW	TYR COOLER LIQ
LMD DIET POW	TYR COOLER LIQ 20
LOPHLEX POW	TYR EXP20 PAK
METHIONAID POW	TYR EXPRESS PAK
MSUD 2 POW	TYR GEL PAK
MSUD AID POW	TYR LOPHLEX LIQ LQ
MSUD ANALOG POW	TYREX-1 POW
MSUD COOLER LIQ	TYREX-2 POW
MSUD COOLER LIQ 20	TYROS 1 POW
MSUD EXP20 PAK	UCD 2 POW
MSUD EXPRESS PAK	UCD ANAMIX POW JUNIOR
MSUD GEL PAK	UCD TRIO POW
MSUD LOPHLEX LIQ LQ	WND POW
MSUD MAXAMAD POW	WND 1 POW
MSUD MAXAMUM POW	WND 2 POW
OA 1 POW	XLEU ANALOG POW
OA 1 DIET POW	XLEU MAXAMAD POW
OA 2 POW	XLEU MAXAMUM POW
OA 2 DIET POW	XLYS XTRP POW ANALOG
OS 2 POW	XLYS-XTRP POW MAXAMAID
PEPTAMEN JR LIQ	XLYS-XTRP POW MAXAMUM
PEPTAMEN JR LIQ PHGG 1.2	XMET ANALOG POW
PERIFLEX POW INFANT	XMET MAXAMAD POW
PERIFLEX POW JUNIOR	XMET MAXAMUM POW
PERIFLEX LQ LIQ PKU	XMTVI ANALOG POW
PFD 1 POW	XMTVI MAXAMD POW
PFD 2 POW	XMTVI MAXAMU POW
PHENEX-1 POW	XPHE MAXAMAD POW
	XPHE MAXAMUM POW

PHENEX-2 POW PHENYLADE PHENYLADE POW ESSNTL PHENYLADE POW GMP ULTR PHENYLADE POW GMP ULTR PHENYLADE POW GMP ULTR PHENYLADE POW GMP ULTR PHENYLADE POW GMP ULTR PHENYLADE POW MTE PHENYLADE40 POW PHENYLADE60 POW PHENYLADE60 POW DRNK MIX	XPHE-XTYR POW ANALOG XPHE-XTYR POW MAXAMAID XPTM ANALOG POW

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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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/formfile.aspx

ASO Variation

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. National Cancer Institute (Updated May 16, 2024). Nutrition. PDQâ -Supportive Care-Patients. -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. Pediatr Rev. 1992 Dec;13(12):453-60. Failure to thrive/growth deficiency**.** Bithoney WG, Dubowitz H, Egan H. Harvard Medical School, Boston, MA.
6. New York Law, Title 18 (Social Services) Paragraph (3) of Subdivision (g) of Section 505.5
7. Local Coverage Determination for Enteral Nutrition (L38955). Original Effective Date: 09/05/2021. Revision Effective Date: 01/01/2024.
8. Enteral Nutrition – Policy Article (A58833). Original Effective Date: 09/05/2021. Revision Effective Date: 10/01/2023.
9. NEW YORK STATE MEDICAID PROGRAM DURABLE MEDICAL EQUIPMENT, PROSTHETICS, ORTHOTICS, AND SUPPLIES PROCEDURE CODES AND COVERAGE GUIDELINES. (n.d.).
10. State, N. (n.d.). Medicaid Advantage Plus Contract MEDICAID ADVANTAGE PLUS (MAP) MODEL CONTRACT MISCELLANEOUS/CONSULTANT SERVICES. Valid 01/01/2022-12/31/2026.
11. 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.
12. 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.
13. Jaffe, A. C. (2011). Failure to Thrive: Current Clinical Concepts. Pediatrics in Review, 32(3), 100–108.
14. 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 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).	
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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:	**10/01/2024**
Approval Date:	**04/01/2026**
Effective Date:	**06/01/2026**
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.

Initial AND continuation approval duration is for up to 12 months

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

Initial AND continuation approval duration is for up to 12 months

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.
9. 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.
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

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12. Jaffe, A. C. (2011). Failure to Thrive: Current Clinical Concepts. Pediatrics in Review, 32(3), 100–108.

MVP Health Care Medical Policy

Enteral Therapy Vermont
(enteral, modified solid foods and medical foods)

Type of Policy:	**Medical Therapy**
Prior Approval Date:	**10/01/2024**
Approval Date:	**04/01/2026**
Effective Date:	**06/01/2026**
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 BCAD 1 POW BCAD 2 POW CAMINO PRO15 LIQ COMPLEX MSD POW JUNIOR COMPLEX MSD POW VANILLA COMPLEX MSUD BAR AMINO AC COMPLEX MSUD POW CYCLINEX-1 POW CYCLINEX-2 POW GA POW GA DIET POW	PHENYLD GMP POW DHA/FIBR PHENYLD GMP POW DHA/FIBR PHENYLD GMP POW DHA/FIBR PHENYL-FREE POW 1 PHENYL-FREE POW 2 PHENYL-FREE POW 2HP PHLEXY-VITS PKU 2 POW PKU 3 POW PKU COOLER LIQ 15

GLUTAREX-1 POW	PKU COOLR 10 LIQ
GLUTAREX-2 POW	PKU COOLR 15 LIQ
GLYTACTIN POW APPLE	PKU COOLR 20 LIQ
GLYTACTIN POW PUNCH	PKU EXP20 PAK
GLYTACTIN POW TROPICAL	PKU EXPRESS POW
HCY 1 POW	PKU GEL PAK
HCY 1 DIET POW	PKU LOPHLEX LIQ LQ 20
HCY 2 POW	PKU SPHERE LIQ 20 VAN
HOM 2 POW	PKU SPHERE LIQ NEXT 15
HOMINEX-1 POW	PKU START POW
HOMINEX-2 POW	PKU START POW
I-VALEX-1 POW	PKU TRIO POW
I-VALEX-2 POW	PORTAGEN POW
KETONEX-1 POW	PROMACTIN AA PLUS
KETONEX-2 POW	PROPIMEX-1 POW
LANAFLEX PAK	PROPIMEX-2 POW
LMD POW	TYR COOLER LIQ
LMD DIET POW	TYR COOLER LIQ 20
LOPHLEX POW	TYR EXP20 PAK
METHIONAID POW	TYR EXPRESS PAK
MSUD 2 POW	TYR GEL PAK
MSUD AID POW	TYR LOPHLEX LIQ LQ
MSUD ANALOG POW	TYREX-1 POW
MSUD COOLER LIQ	TYREX-2 POW
MSUD COOLER LIQ 20	TYROS 1 POW
MSUD EXP20 PAK	UCD 2 POW
MSUD EXPRESS PAK	UCD ANAMIX POW JUNIOR
MSUD GEL PAK	UCD TRIO POW
MSUD LOPHLEX LIQ LQ	WND POW
MSUD MAXAMAD POW	WND 1 POW
MSUD MAXAMUM POW	WND 2 POW
OA 1 POW	XLEU ANALOG POW
OA 1 DIET POW	XLEU MAXAMAD POW
OA 2 POW	XLEU MAXAMUM POW
OA 2 DIET POW	XLYS XTRP POW ANALOG
OS 2 POW	XLYS-XTRP POW MAXAMAID
PEPTAMEN JR LIQ	XLYS-XTRP POW MAXAMUM
PEPTAMEN JR LIQ PHGG 1.2	XMET ANALOG POW
PERIFLEX POW INFANT	XMET MAXAMAD POW
PERIFLEX POW JUNIOR	XMET MAXAMUM POW
PERIFLEX LQ LIQ PKU	XMTVI ANALOG POW
PFD 1 POW	XMTVI MAXAMD POW
PFD 2 POW	XMTVI MAXAMU POW
PHENEX-1 POW	XPHE MAXAMAD POW
PHENEX-2 POW	XPHE MAXAMUM POW
PHENYLADE	XPHE-XTYR POW ANALOG
PHENYLADE POW ESSNTL	XPHE-XTYR POW MAXAMAID
PHENYLADE POW GMP ULTR	XPTM ANALOG POW
PHENYLADE POW GMP ULTR	
PHENYLADE POW GMP ULTR	
PHENYLADE POW GMP ULTR	
PHENYLADE POW GMP ULTR	

PHENYLADE POW MTE PHENYLADE40 POW PHENYLADE60 POW PHENYLADE60 POW DRNK MIX	

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

- Members 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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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).	
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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:	**11/01/2024**
Approval Date:	**10/01/2025**
Effective Date:	**12/01/2025**

Related Policies:

Experimental or Investigational Procedures

Infliximab,

Certolizumab

Risankizumab

Upadacitinib

Ustekinumab

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/formfile.aspx

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)

      OR

    - 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
        i. 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 or contracted

provider office. Prior Authorization and medical justification are required for Entyvio IV obtained and administered in a non-preferred site of care (i.e. outpatient hospital setting).

A. MVP will allow 60 days after prior authorization approval for members to transfer to a preferred infusion site.
B. This requirement does not apply to MVP Medicare and Medicaid, CHP 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 are 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 members 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/Pneumonitis** 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, colitis, or pneumonitis related to their immunotherapy; AND
• Documented failure, contraindication, or ineffective response to systemic corticosteroids or infliximab.

Entyvio IV for Immune Checkpoint Inhibitor Related Diarrhea/Colitis/ **Pneumonitis** 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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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:	**01/01/2024**
Approval Date:	**10/01/2025**
Effective Date:	**12/01/2025**

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 members should be brought up to date with all immunizations according to current immunization guidelines. ENTYVIO is not recommended in members with active, severe infections until the infections are controlled. Providers should consider withholding treatment in members 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:

- 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.);

- Coverage duration (unless otherwise specified for applicable indication)
    - **Initial coverage up to 6 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 members 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/Pneumonitis**:

- 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, colitis, or pneumonitis related to their immunotherapy; AND

- Documented failure, contraindication, or ineffective response to systemic corticosteroids or infliximab.

Continuation of therapy will require documentation of: May not be renewed for Immune Checkpoint Inhibitor-Related Diarrhea/Colitis/Pneumonitis

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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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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 • 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 • 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
	  ○ May titrate up to 300 units/kg three times weekly or 60,000 units once weekly
	• Pediatric patients (5-18 years): 600 units/kg intravenously or subcutaneously once weekly
	  ○ 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) • 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 • May titrate up to 60,000 units weekly
Anemia due to MDS/MPN	• 150-300 units/kg intravenously or subcutaneously three times weekly • 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

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2. Aranesp [package insert]. Thousand Oaks, CA; Amgen; June 2011. Accessed March 2019.
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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 March 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 Potential for Retrospective Review
MVP Child Health Plus	
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

Etanercept

Type of Policy:	**Drug/Medical Therapy**
Prior Approval Date:	**02/01/2024**
Approval Date:	**11/01/2024**
Effective Date:	**01/01/2026**
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/formfile.aspx

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. Juvenile Psoriatic Arthritis (JPsA)

Etanercept may be considered for coverage for Juvenile Psoriatic Arthritis (JPsA) when:

a. Member has a diagnosis of moderate to severe Juvenile Psoriatic Arthritis
b. Chart notes documenting an inadequate treatment response, intolerance, or contraindication to a 3-month trial of at least ONE conventional disease-modifying antirheumatic drugs (DMARDs)

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. 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.

G. 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
- Members with Sepsis

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1. Enbrel® (etanercept) injection. Prescribing Information. Thousand Oaks, CA: Immunex Corporation; Approved 1998. Revised 10/2024.
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 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.
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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
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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

Etrasimod

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

Prior Approval Date: 10/01/2024

Approval Date: 10/01/2025

Effective Date: 12/01/2025

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 of the following:
    - 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
    - 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.

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

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; Approval 2023. Revised 08/2025.

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 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

Formulary Exception for Non-Covered Drugs

Type of Policy: **Drug Therapy**
Prior Approval Date: **12/01/2024**
Approval Date: **11/01/2025**
Effective Date: **01/01/2026**
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.

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
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MVP DualAccess Plus D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
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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
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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

GABA-Receptor Modulators

Type of Policy: **Drug Therapy**
Prior Approval Date: **11/01/2024**
Approval Date: **08/01/2025**
Effective Date: **10/01/2025**
Related Policies: Quantity Limits for Prescription Drugs

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 is a GABA receptor modulator indicated for the treatment of cataplexey and excessive daytime sleepiness associated with narcolepsy. Xywav is a combination formulation of calcium, magnesium, potassium and sodium oxybates. Xywav is indicated for the treatment of cataplexey and excessive daytime sleepiness associated with narcolepsy as well as the treatment of idiopathic hypersomnia

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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).
- Documentation of a failure, contraindication or intolerance to a 1-month trial of modafinil **and** a formulary methylphenidate product

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

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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. **Maski K, Trotti LM, Kotagal S, Auger RR, Rowley JA, Hashmi SD, Watson NF.** Treatment of central disorders of hypersomnolence: an American Academy of Sleep Medicine clinical practice guideline. *J Clin Sleep Med*. 2021;17(9):1881–1893. doi:10.5664/jcsm.9328^
3. Xyrem® (sodium oxybate) Oral Solution. Prescribing Information. Palto Alto, CA: Jazz Pharmaceuticals Inc.; April 2025
4. 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.
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6. Xywav® calcium, magnesium, potassium, and sodium oxybates solution. Prescribing Information. Palto Alto, CA: Jazz Pharmaceuticals Inc.; April 2023.
7. Arnulf I, Leu-Semenescu S, Dodet P. Precision medicine for idiopathic hypersomnia. *Sleep Med Clin*. 2019;14(3):333-350.

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
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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:	**11/01/2024**
Approval Date:	**08/01/2025**
Effective Date:	**10/01/2025**
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.

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 a 1-month trial to one of the following:
    - Ropinirole
    - Pramipexole
        - A one month trial of ropinirole or pramipexole is not required if one of the following is provided:
            - Member has a contraindication
            - Member has an intolerance
            - Provider attestation that they are not medically appropriate for the member's clinical management.

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

References

1. Horizant® (gabapentin enacarbil). Prescribing Information. Atlanta, GA: Arbor Pharmaceuticals, LLC April 2025.
2. **Winkelman JW, Berkowski JA, DelRosso LM, Koo BB, Scharf MT, Sharon D, Zak RS, Kazmi U, Falck-Ytter Y, Shelgikar AV, Trotti LM, Walters AS.** Treatment of restless legs syndrome and periodic limb movement disorder: an American Academy of Sleep Medicine clinical practice guideline. *J Clin Sleep Med.* 2025;21(1):1–52. doi:10.5664/jcsm.11390 Gralise (gabapentin). Prescribing Information. Newark, CA: Depomed, Inc. April 2020. Revised 04/2023.
3. 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:	**02/01/2024**
Approval Date:	**08/01/2025**
Effective Date:	**10/01/2025**
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

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.

2. Ztalmy [package insert]. Radnor, PA: Marinus Pharmaceuticals, Inc.; Initial U.S. Approval/Publication Year: 2022. Revised: 04/2024.

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 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

Gastric Acid-Related Disorder Agents

Type of Policy:	**Drug Therapy**
Prior Approval Date:	**10/01/2025**
Approval Date:	**06/01/2026**
Effective Date:	**06/01/2026**
Related Policies:	**NA**

Drugs Requiring Prior Authorization under the pharmacy benefit

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.Potassium-competitive acid blockers (PCAB) such as Voquezna, are different from PPIs but ultimately inhibit the same target. It suppresses basal and stimulated gastric acid secretion at the secretory surface of the gastric parietal cell through inhibition of the H^+, K^+-ATPase enzyme system in a potassium competitive manner. This mechanism of action also blocks 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.

Indications/Criteria

Drugs requiring Prior Authorization and/or Quantity limits

Drug Name	Prior Authorization Required*	Quantity Limits
Aciphex (brand name)	Yes	Yes (2 per day)
Dexilant (brand name)	Yes	Yes (2 per day)
dexlansoprazole	No	Yes (2 per day)
esomeprazole	No	Yes (2 per day)
Esomeprazole-naproxen	Yes	Yes (2 per day)
lansoprazole	No	Yes (2 per day)
Nexium (brand name)	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 (brand name)	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

A. For medications that require prior authorization in the chart above, the following criteria must be met:

- Chart notes are provided 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
- For **esomeprazole-naproxen** requests, the criteria above must be met and must include documentation indicating why taking esomeprazole and naproxen separately is medically inappropriate for the member.

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.

B. Quantities of proton pump inhibitors greater than the quantity of 60 doses per month may be considered when the member meets the following criteria in one of the scenarios below:

- Member has a documented diagnosis of 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

- Chart notes are provided documenting the member has a 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.

C. H. pylori with duodenal ulcer disease

- **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

D. Omeprazole + suspension syrspend and First- Lansoprazole

- These products will require prior authorization for members 7 years of age and older. Chart notes must be provided identifying why all commercially available proton pump inhibitors would not be medically appropriate for the member.

Exclusions

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling.
- Esomeprazole Strontium is excluded from coverage.

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
4. Aciphex® (rabeprazole) Tablets. Prescribing Information. Woodcliff Lake, NJ: Eisai Co, Ltd.; Updated 12/2014
5. Nexium® (esomeprazole) Capsules. Prescribing Information. Wilmington, DE: AstraZeneca LP; Updated 08/2021
6. Prevacid® (lansoprazole) Capsules. Prescribing Information. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; Updated 09/2012
7. Prilosec® (omeprazole) Capsules. Prescribing Information. Wilmington, DE: AstraZeneca LP; Updated 06/2018
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).
16. U.S. Food and Drug Administration (FDA). FDA MedWatch Proton Pump Inhibitors (PPIs) - Drug Safety Communication: Clostridium Difficile-Associated Diarrhea (CDAD) Can be Associated with Stomach Acid Drugs. Available: http://www.fda.gov/safety/medwatch/safetyinformation/safetyalertsforhumanmedicalproducts/ucm290838.htm.
17. Katz OP, Gerson LB, Vela MF. Diagnosis and Management of Gastroesophageal Reflux Disease, Am J Gastroenterol 2013; 108:308-328
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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.
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).	
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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:	**07/01/2024**
Approval Date:	**11/01/2025**
Effective Date:	**11/01/2025**
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 autosomal recessive lysosomal storage disorder caused by mutations in the *GBA* gene, which encodes the enzyme β-glucocerebrosidase. Deficiency of this enzyme leads to the accumulation of glucocerebroside within macrophages, forming characteristic "Gaucher cells" that infiltrate various organs. This impacts primarily the spleen, liver and bone marrow which can cause organ inflammation and dysfunction.

There are three different types of disease:

Gaucher disease Type 1: This is the most common. It is characterized by hepatosplenomegaly, anemia, thrombocytopenia, and skeletal involvement. There are no signs of brain involvement.

Gaucher disease 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.

Gaucher disease Type 3: Features progressive neurological involvement with later onset and slower progression than Type 2. Patients may also exhibit visceral and skeletal symptoms

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).

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, Vpriv & Elelyso)

a. Per the MVP Health Care Pharmacy Management Programs policy, Cerezyme, Vpriv and Elelyso are subject to Site of Care requirements and must be obtained through a preferred home infusion vendor, contracted infusion center or contracted provider office. Prior Authorization and medical justification are required for Cerezyme, Vpriv or Elelyso 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 Medicaid, and CHP 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

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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/1.73m^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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10. 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: 02/01/2024
Approval Date: 02/01/2026
Effective Date: 04/01/2026
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

Adlyxin

Ozempic

Rybelsus

Trulicity

Victoza/liraglutide

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.

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 following MVP Health Care pharmacy policies: "Weight loss medications" and "Quantity Limits for Prescription Drugs policy".
- Age, dose, frequency outside of FDA approved labeling

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 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.
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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 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:	**02/01/2024**
Approval Date:	**11/01/2025**
Effective Date:	**01/01/2026**
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/formfile.aspx

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
     a. 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 or contracted provider office. Prior Authorization and medical justification is required for Simponi Aria 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 and Medicaid, CHP 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

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 04/2025.
3. Simponi ARIA (golimumab) injection. Prescribing information. Janssen Biotech, Inc. Horsham, PA. Revised 04/2025.
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

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
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MVP Child Health Plus	Prior Auth
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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.

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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: Golimumab

Type of Policy:	**Medical Therapy**
Prior Approval Date:	**02/01/2024**
Approval Date:	**11/01/2024**
Effective Date:	**01/01/2026**
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

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 04/2025.
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:	**08/01/2024**
Approval Date:	**11/01/2025**
Effective Date:	**01/01/2026**
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. 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.

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: 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
    - Used for the treatment of asymptomatic hyperuricemia
- Krystexxa:
    - 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

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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).	

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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: **12/01/2024**
Approval Date: **12/01/2025**
Effective Date: **02/01/2026**
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

- OTC medications are subject to the member's applicable copayment
- OTC medications must be filled by a participating pharmacy.
- A prescription for an OTC product described below must be written by a practitioner licensed and authorized to prescribe medications.
-
- OTC medication coverage follows the New York State Medicaid NYRX's List of Reimbursable Drugs. For detailed information on covered non-prescription/OTC drugs refer to the New York State Medicaid Pharmacy List of Reimbursable Drugs available at: Medicaid Pharmacy List of Reimbursable Drugs

- Certain over the counter supplies are covered at the pharmacy based on the NYS Medicaid Pharmacy Services DME Fee Schedule. Examples of coverage are listed below and the full list is available at: NYS Medicaid DMEPOS Services Fee Schedule
    - 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 and 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.

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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 NYRX Medicaid Pharmacy Program: Pharmacy Manual Policy Guidelines. October 2025; Version 2025-2. Accessed on October 28, 2025. Available at: Pharmacy_Policy_Guidelines.pdf

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Member Product	Medical Management Requirements*
New York Products	
HMO	Not Covered
PPO in Plan	Not Covered
PPO OOP	Not Covered
POS in Plan	Not Covered
POS OOP	Not Covered
Essential Plan	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 Medicare 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 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 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
USA Care PPO	Refer to the MVP website for the Medicare Part B and Part
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 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:	**12/01/2024**
Approval Date:	**11/01/2025**
Effective Date:	**01/01/2026**
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)

Sogroya (somapacitan)

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.

Sogroya (somapacitan) is a human growth hormone analog indicated for the treatment of pediatric patients aged 2.5 years and older who have growth failure due to inadequate secretion of endogenous growth hormone. It is also indicated for the replacement of endogenous growth hormone in adults with growth hormone deficiency.

Indications/Criteria

Norditropin/Flexpro, Humatrope, Sogroya, Omnitrope 10mg/1.5ml and Omnitrope 5mg/1.5ml 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. **For the following indications**, 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 ≤ - 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	Growth velocity < 25% for bone age and bone age less than 14 years (for growth velocity)	X	

		(for growth velocity)			
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 response to one GH test AND IGF-l and IGF-BP3 levels more than 2 SD below the mean for bone age and gender..	X			X	Normal or elevated growth hormone **AND** basal IGF-1 standard deviation score ≤ - 3.0
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. Dose authorization will be based on the member's weight and the FDA approved maximum dosing limit for the indication and the medication.

  Extension requests will be up to 12 months. Dose increases require a new prior authorization request. Dose authorization will be based on the member's weight and the FDA approved maximum dosing limit for the indication and the medication.

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. Dose authorization will be based on the member's weight and the FDA approved maximum dosing limit for the indication and the medication

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.

Dose authorization will be based on the member's weight and the FDA approved maximum dosing limit for the indication and the medication

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. Dose authorization will be based on the member's weight and the FDA approved maximum dosing limit for the indication and the medication.

Extension requests will be up to 12 months when documentation of prior height and current height with dates is provided. Dose authorization will be based on the member's weight and the FDA approved maximum dosing limit for the indication and the medication.

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;**
- Members 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. Dose authorization will be based on the member's weight and the FDA approved maximum dosing limit for the indication and the medication

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.

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.
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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	Prior Auth
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).

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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

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.

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.

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

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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

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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.

Exclusions

- N/A

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: **10/01/2024**
Approval Date: **07/01/2025**
Effective Date: **09/01/2025**
Related Policies: **Hemophilia Factor**

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

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

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
5.

Member Product	Medical Management Requirements*
New York Products	
HMO	Prior Authorization
PPO in Plan	Prior Authorization
PPO OOP	Prior Authorization
POS in Plan	Prior Authorization
POS OOP	Prior Authorization
Essential Plan	Prior Authorization
MVP Medicaid Managed Care	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 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 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).	
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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: 10/01/2024
Approval Date: 07/01/2025
Effective Date: 09/01/2025
Related Policies: Hemophilia Factor

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

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.

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:	**12/01/2024**
Approval Date:	**12/01/2025**
Effective Date:	**02/01/2026**
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.

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 (chronic)
- **Harvoni**-Genotypes 1, 4, 5, 6 (chronic)
- **Mavyret**-Genotype 1-6 (acute or chronic)
- **Vosevi**-Genotypes 1-6 (chronic)

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
- 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.; Revised 12/2024.
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
5. 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.
6. Epclusa. Prescribing Information. Foster City, CA: Gilead Sciences, Inc. Last updated April 2022Harvoni. Prescribing Information. Foster City, CA: Gilead Science, Inc. Revised 4/2022
7. Solvaldi. Prescribing Information. Foster City, CA: Gilead Science, Inc. Revised 12/2024.
8. Mavyret Tablets. Prescribing Information. North Chicago, IL: AbbVie Inc. Revised 06/2025.
9. Vosevi Tablets. Prescribing Information. Foster City, CA: Gilead Science, Inc. Last updated November 2019
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11. Pegasys®. Prescribing Information. South San Francisco, CA: Hoffmann-La Roche, Inc. c/o Genentech, Inc.. Last updated March 2021
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13. 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
14. 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 Medicare 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 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 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
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 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:	**07/01/2025**
Approval Date:	**04/01/2026**
Effective Date:	**06/01/2026**

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

Andembry (Garadacimab-gxii) – self administered

Ekterly (Sebetralstat)- 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	Chemical Name	Indication (HAE-specific)	Administration	Age Restrictions	Recommended Dose	Initial Auth
Andembry	Garadacimab-gxii	Prophylaxis	SC (self-admin only – RX benefit)	≥ 12 years	400 mg subcutaneously once, then 200 mg subcutaneously once monthly	**3 months [5 doses (5 autoinjectors) per RX]**
Berinert®	C1 esterase inhibitor	Acute abdominal, facial, or laryngeal attacks	IV	≥ 12 years	20 units/kg IV	3 months (1 injection per visit at recommended dose)
Cinryze®	C1 esterase inhibitor	Prophylaxis	IV	≥ 6 years	>12 yrs: 1,000 Units IV q3–4 days 6–11 yrs: 500 Units IV q3–4 days	3 months [10 doses (20 vials)/month for >12 yrs] [10 doses (10 vials)/month for 6–11 yrs]
Firazyr®	icatibant	Acute attacks	SC (self-admin only – RX benefit)	≥ 18 years	30 mg SC x1 MDD = 3 inj/24 hrs	3 months [3 doses (3 prefilled syringes) per RX]

Haegarda	C1 esterase inhibitor	Prophylaxis	SC (self-admin only – RX benefit)	≥ 6 years	60 units/kg SC twice weekly (q3–4 days)	3 months [10 doses/month]
Kalbitor®	ecallantide	Acute attacks	SC (provider-admin only – medical benefit)	≥ 12 years	30 mg SC x1 MDD = 60 mg/24 hrs	3 months (2 doses per visit)
Ruconest	C1 esterase inhibitor	Acute nonlaryngeal attacks	IV	≥ 13 years	<84 kg: 50 units/kg IV >84 kg: 4,200 units IV MDD = 2 inj/24 hrs	3 months (2 doses per visit)
Takhzyro	Lanadelumab-flyo	Prophylaxis	SC (self-admin only – RX benefit)	≥ 2 years	>12 yrs: 300 mg SC q2 weeks Consider q4 weeks if attack-free >6 months 6–11 yrs: 150 mg SC q2 weeks 2–5 yrs: 150 mg SC q4 weeks	3 months [2 doses (4 vials)/month]
Ekterly	Sebetralstat	Acute Attacks	Oral	>12 years	600 mg (2 tablets) PO at first sign of attack; additional 600 mg at least 3 hours after initial dose if needed (max: 1200 mg /24 hrs)	At least enough for 2 attacks [2 doses (8 tablets)]

Cinryze, Berinert, Firazyr, Haegarda, Kalbitor, Takhzyro, Ruconest, Andembry, and Ekterly 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)
- **Short term prophylaxis**
    - Short term prophylaxis has been appropriately used for known triggers (e.g., surgery, major dental procedures), and the member continues to experience severe HAE attacks*; OR
    - The member has a contraindication to attenuated androgens (e.g., pregnancy or lactation) or has demonstrated severe intolerance to attenuated androgens (e.g., danazol).
- **Pregnancy/Lactation**
    - C1 esterase inhibitor therapy is recommended as first line treatment in members who are pregnant or lactating.
    - Pre-procedural prophylaxis with C1 esterase inhibitor therapy is recommended during pregnancy.
- Provide family history of angioedema status
- Provider attestation that medications that trigger HAE should be avoided and prescription history and current prescriptions have been reviewed.
- Provider attestation indicating the provider has individualized treatment plans as needed for long term prophylaxis, short term prophylaxis (ie. prior to medical procedures, high risk events), and acute HAE attacks.
- For Cinryze, Ruconest and Berinert
    - Site of Care

    a. 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 or contracted provider office. Prior Authorization and medical justification is required for Cinryze, Ruconest and Berinert 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 and Medicaid, CHP 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, Haegarda, and Andembry for up to 6 months** 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, Berinert, and Ekterly for up to 6 months** 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
- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling
- Ruconest:
- Member with laryngeal attacks
- Ekterly:
    - Should not be used with strong or moderate CYP3A4 inducers or strong inhibitors as it is a CYP3A4 substrate.

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 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).	

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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

Hetlioz (tasimelteon)

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

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

Drugs Requiring Prior Authorization under the pharmacy benefit

HETLIOZ® (tasimelteon) capsules, for oral use

HETLIOZLQ ™ (tasimelteon) oral suspension

Overview

Tasimelteon is an agonist at melatonin MT_1 and MT_2 receptors. Although the mechanism by which tasimelteon exerts its therapeutic effect is unclear, it is thought that the melatonin MT_1 and MT_2 receptors may be involved in the control of circadian rhythms. Hetlioz capsules are indicated for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24) in adults and nighttime sleep disturbances in Smith-Magenis Syndrome(SMS) in patient 16 years of age or older. Hetlioz LQ is indicated for the treatment of nighttime sleep disturbances in SMS in pediatric patients 3 years to 15.

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

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.

Quantity Limit Exceptions

- Will be reviewed on a case-by-case basis and must meet the MVP Experimental/Investigational (E/I) Policy for use

Exclusions

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

- 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 policies.
MVP Medicare Preferred Gold HMO POS	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
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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

Idiopathic Pulmonary Fibrosis

Type of Policy:	**Drug Therapy**
Prior Approval Date:	**07/01/2024**
Approval Date:	**07/01/2025**
Effective Date:	**09/01/2025**
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. 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. 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. Ofev is a kinase inhibitor, which inhibits multiple receptors implicated in the pathogenesis of IPF.

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
- For brand name Esbriet, member must have a documented failure of generic Esbriet (pirfenidone)

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**

- Prescribed by or in consultation 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

- Dosing, age, and/or frequency outside of the FDA approved package labeling
- Esbriet –
    - Severe hepatic impairment
-
- Ofev –
    - Moderate to severe hepatic impairment
    - Pregnancy
- LFTs greater than 5x ULN
- End stage renal disease requiring dialysis

References

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Member Product	Medical Management Requirements*
New York Products	
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PPO in Plan	Prior Auth
PPO OOP	Prior Auth
POS in Plan	Prior Auth
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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

Immunoglobulin Therapy

Type of Policy: Medical Therapy
Prior Approval Date: 04/01/2024
Approval Date: 08/01/2025
Effective Date: 10/01/2025

Related Policies: Experimental or Investigational Procedures, Behavioral Health Services, Drugs & Treatments, Off-Label use of FDA Approved Drugs, Clinical Trials

Refer to the MVP 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.

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 $\leq$ 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

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 analysis
- Documentation 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/formfile.aspx

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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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: Immunoglobulin Therapy

Type of Policy:	**Medical Therapy**
Prior Approval Date:	**04/01/2024**
Approval Date:	**08/01/2025**
Effective Date:	**10/01/2025**

Related Policies: Experimental or Investigational Procedures, Behavioral Health Services, Drugs & Treatments, Off-Label use of FDA Approved Drugs, Clinical Trials

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

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

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/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

- **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 L33794 for External Infusion Pumps. Please refer to LCD L33794 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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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: **02/01/2025**
Approval Date: **02/01/2026**
Effective Date: **04/01/2026**

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.

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.

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* 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)* Lifetime limit 12 cycles. 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* 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. **All other covered procedures**: Drugs are covered for 9 cycles. Follistim AQ is the preferred recombinant FSH.
GnRH antagonists/GnRH agonists	Antigon/Ganirelix Lupron/Leuprolide kit Cetrotide	**IVF**: Prior authorization is required. Lifetime limit of 3 IVF cycles. **All other covered procedures:** No prior authorization is required for up to 9 cycles per pregnancy No cycle limits for Fertility Preservation.	**IVF**: Drugs are covered for a lifetime limit of 3 IVF cycles (see IVF Variation). **Fertility Preservation**: Drugs are covered with an approved fertility preservation medical procedure case. Follistim AQ is the preferred recombinant FSH. **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, 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
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).	
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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**

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)

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).	
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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: **10/01/2024**
Approval Date: **11/01/2025**
Effective Date: **01/01/2026**

Related Policies: **Experimental or Investigational Procedures, Apremilast, Etanercept, Risankizumab, Adalimumab, Tofacitinib, Upadacitinib, Ustekinumab, Zeposia, Secukinumab**

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)

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
    a. 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 or contracted provider office. Prior Authorization and medical justification is required for Avsola, Inflectra, Remicade and Renflexis 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 and Medicaid, CHP 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. 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 benefit

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.

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. Avsola (infliximab) injection. Prescribing Information. Thousand Oaks, CA: Amgen Inc.; September 2021.
4. 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.
5. 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).
6. 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
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

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: Infliximab

Type of Policy: **Drug/Medical Therapy**
Prior Approval Date: **10/01/2024**
Approval Date: **11/01/2025**
Effective Date: **01/01/2026**
Related Policies: **Experimental or Investigational Procedures, Risankizumab, Ustekinumab, Secukinumab**

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)

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.

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. <u>Plaque Psoriasis</u>

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.

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).

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. 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. Article - Billing and Coding: Infliximab and biosimilars (A52423). (Revised 08/01/2024). Cms.gov.

8. LCD - Drugs and Biologicals, Coverage of, for Label and Off-Label Uses (L33394). (Revised 08/01/2024). Cms.gov.

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

1. Yates J. Traveler's diarrhea. Am Fam Physician. 2005 Jun 1;71(11):2095-2100.
2. Centers for Disease Control and Prevention (CDC). Travelers' Diarrhea. Accessed August 27, 2019. https://wwwnc.cdc.gov/travel/yellowbook/2020/preparing-international-travelers/travelers-diarrhea
3. Dupont H. Bacterial Diarrhea. N Engl J Med 2009; 361(16):1560-9
4. Vilstrup, H., Amodio, P., Bajaj, J, et al. Hepatic encephalopathy in chronic liver disease: 2014 Practice Guidelines by the American Association for the Study of Liver Disease and the European Association for the Study of Liver. Hepatology. 2014 Aug;60(2):715-35
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).	
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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

Irritable Bowel Syndrome

Type of Policy:	**Drug Therapy**
Prior Approval Date:	**12/01/2024**
Approval Date:	**11/01/2025**
Effective Date:	**01/01/2026**
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.

Indications/Criteria

Coverage criteria for **all** medications in this policy:

- Must be prescribed by or in consultation with a gastroenterologist
- 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
    - Conventional therapy includes:
        - Antidiarrheal agents (Loperamide)
        - Antispasmodics (dicyclomine, hyoscyamine)
        - Tricyclic Antidepressants (amitriptyline, nortriptyline, or imipramine)

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

- 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

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References

1. Lacy BE. Diagnosis and treatment of diarrhea-predominant irritable bowel syndrome. Int J Gen Med. 2016; 9:7-17.
2. Viberzi (eluxadoline) tablets. Prescribing Information. Parsippany, NJ: Actavis Pharma, Inc. Revised 07/2024
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4. Pimental, M. Evidence- Based Management of Irritable Bowel Syndrome with Diarrhea. Am J Manag Care. Jan 25, 2018;24: -S0
5. Lacy, Brian E. PhD, MD, FACG[1]; Pimentel, Mark MD, FACG[2]; Brenner, Darren M. MD, FACG[3]; Chey, William D. MD, FACG[4]; Keefer, Laurie A. PhD[5]; Long, Millie D. MDMPH, FACG (GRADE Methodologist)[6]; Moshiree, Baha MD, MSc, FACG[7]. ACG Clinical Guideline: Management of Irritable Bowel Syndrome. The American Journal of Gastroenterology 116(1):p 17-44, January 2021.
6. Rome IV Criteria Section C1 Irritable Bowel Syndrome Diagnostic Criteria. Rome IV Criteria - Rome Foundation (theromefoundation.org). 2021. Accessed 8/8/2023.
7. LOTRONEX (alosetron hydrochloride) Tablets. Prescribing Information. Roswell, GA: Sebela Pharmaceuticals Inc. Revised 4/2019.
8. 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:	04/01/2025
Approval Date:	04/01/2026
Effective Date:	06/01/2026
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

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 are 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 are 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)

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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 8 Aug. 2025; cited 10 Feb. 2026]. 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.
4. Age-related macular degeneration Preferred Practice Pattern 2024. *American Academy of Ophthalmology*. Retrieved February 6, 2026, from https://www.aao.org/education/preferred-practice-pattern/age-related-macular-degeneration-ppp

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).	
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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:	**04/01/2025**
Approval Date:	**04/01/2026**
Effective Date:	**06/01/2026**
Related Policies:	Syfovre

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

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 are met:

- Chart notes confirming a diagnosis of geographic atrophy secondary to age-related macular degeneration

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- 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 are 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 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 8 Aug. 2025; cited 10 Feb. 2026]. Available from: http://online.lexi.com. Subscription required to view.

Classified as Confidential

2. Izervay (avacincaptad pegol intravitreal solution) NDA 217225. FDA. Revised 2/2025. 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.
4. Age-related macular degeneration Preferred Practice Pattern 2024. *American Academy of Ophthalmology*. Retrieved February 6, 2026, from https://www.aao.org/education/preferred-practice-pattern/age-related-macular-degeneration-ppp

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MVP Health Care Medical Policy

Jynarque

Type of Policy:	**Drug Therapy**
Prior Approval Date:	**02/01/2025**
Approval Date:	**02/01/2026**
Effective Date:	**04/01/2026**
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 members 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

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

- Prescribed by or in consult with a nephrologist
- Diagnosis of autosomal dominant polycystic kidney disease (ADPKD) confirmed by ultrasound OR genetic testing when there is limited availability of ultrasound or ultrasound is not adequate for diagnosis of ADPKD
- 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 member 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 . Revised 03.2025
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

4. Chapman AB, Devuyst O, Eckardt KU, et al. Autosomal-dominant polycystic kidney disease (ADPKD): executive summary from a Kidney Disease: Improving Global Outcomes (KDIGO) Controversies Conference. Kidney Int. 2015;88:17-27.
5. Muller RU, Messchendorp AL, Birn H, et al. An update on the use of tolvaptan for autosomal dominant polycystic kidney disease: Consensus statement on behalf of the ERA Working Group on Inherited Kidney Disorders, the European Rare Kidney Disease Reference Network and Polycystic Kidney Disease International. Nephrol Dial Transplant. 2022;37:825-839.

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).	

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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

Lebrikizumab

Type of Policy: Drug Therapy
Prior Approval Date: 10/01/2025
Approval Date: 04/01/2026
Effective Date: 06/01/2026
Related Policies: Dupixent, Upadacitinib

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

Drugs Requiring Prior Authorization under the pharmacy benefit

Ebglyss (lebrikizumab)

Overview

Lebrikizumab (Ebglyss) is a human IgG4 monoclonal antibody that is an interleukin-13 antagonist. It is indicated for the treatment of moderate-to-severe atopic dermatitis (eczema) in adults and pediatric patients 12 years and older weighing at least 40 kg whose disease is not adequately controlled with other topical prescription therapies or when use of those therapies is not advised.

Indications/Criteria

A. Moderate to Severe Atopic Dermatitis

Ebglyss may be considered for moderate to severe atopic dermatitis when the following criteria is met:

- 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).

- Must have at least 10% BSA involvement at baseline documented in chart notes
- Chart notes documenting that symptom control has not been achieved with one of the following after an adequate trial:
    - Medium or high potency topical corticosteroids **OR**
    - Topical calcineurin inhibitors (i.e. tacrolimus ointment, pimecrolimus cream)
- 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.

Exclusions

The use of Ebglyss 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 another monoclonal antibody is not a covered benefit

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References

1. Lebrikizumab (Ebglyss). In: Clinical Pharmacology [database on the Internet]. Tampa (FL): Elsevier. 2025 [July 23, 2025]. Available from: www.clinicalpharmacology.com. Subscription required to view.

2. Ebglyss [package insert]. Indianapolis, IN: Eli Lilly and Company; Revised May 2025.

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 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.
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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).	

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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

Lenmeldy

Type of Policy:	Medical Therapy (administered by the pharmacy department)
Prior Approval Date:	06/01/2024
Approval Date:	08/01/2025
Effective Date:	10/01/2025
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

J3391 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 2.0×10^6 $CD34^+$ 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

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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:	06/01/2024
Approval Date:	08/01/2025
Effective Date:	10/01/2025
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

J3391 Lenmeldy (Atidarsagene Autotemcel)

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.

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 x 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

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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)

MVP Health Care Medical Policy

Luxturna

Type of Policy: **Drug Therapy**
Prior Approval Date: **04/01/2025**
Approval Date: **04/01/2026**
Effective Date: **06/01/2026**
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

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling
- 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.
5. Voretigene Neparvovec: A Review in RPE65 Mutation-Associated Inherited Retinal Dystrophy. Molecular Diagnosis & Therapy. 2020. Kang C, Scott LJ.
6. Voretigene Neparvovec for Inherited Retinal Dystrophy Due to RPE65 Mutations: A Scoping Review of Eligibility and Treatment Challenges From Clinical Trials to Real Practice. Eye. 2024. Testa F, Bacci G, Falsini B, et al.

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).	
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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:	**04/01/2025**
Approval Date:	**04/01/2026**
Effective Date:	**06/01/2026**
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 relevant CMS LCDs/NCDs/Policy Articles for most up to date Medicare Part B guidance if available.

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

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling
- 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.
4. Voretigene Neparvovec: A Review in RPE65 Mutation-Associated Inherited Retinal Dystrophy. Molecular Diagnosis & Therapy. 2020. Kang C, Scott LJ.
5. Voretigene Neparvovec for Inherited Retinal Dystrophy Due to RPE65 Mutations: A Scoping Review of Eligibility and Treatment Challenges From Clinical Trials to Real Practice. Eye. 2024. Testa F, Bacci G, Falsini B, et al.

MVP Health Care Medical Policy

Lyfgenia (Lovotibeglogene Autotemcel)

Type of Policy:	Drug Therapy (administered by the pharmacy department)
Prior Approval Date:	07/01/2025
Approval Date:	02/01/2026
Effective Date:	01/01/2026
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

J3394 Lyfgenia (Lovotibeglogene Autotemcel)

Overview

Lyfgenia (Lovotibeglogene Autotemcel) 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

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)

Classified as Confidential

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.

B. Medicaid Variation

In addition to the criteria above, Lyfgenia will be considered for coverage for Medicaid members when the following additional criteria is met:

- The treatment center participates with the Center for International Blood & Marrow Transplant Research- CIBMTR. The list of participating centers may be found here: CIBMTR Participating Centers.
- Provider attestation that the member will have provider access for at least one year after receiving Lyfgenia therapy.

Lyfgenia 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. Lyfgenia (the medication only) is **reviewed** by MVP Health Care and **billed** through the member's NYRX Medicaid benefit.

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	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
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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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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
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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:	06/01/2024
Approval Date:	07/01/2025
Effective Date:	09/01/2025
Related Policies:	Casgevy, Adakveo

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 Lyfgenia (Lovotibeglogene Autotemcel)

Overview

Lyfgenia (Lovotibeglogene Autotemcel) 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

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phases including cell mobilization and apheresis to collect CD34+ cells for manufacturing, myeloablative conditioning, and finally the modified cells are returned to 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.

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- Current documentation that the member does not have any active bacterial, viral, fungal, or parasitic infection(s)

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.

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.).

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https://classic.clinicaltrials.gov/ct2/show/NCT02140554?term=02140554&draw=2&rank=1

MVP Health Care Medical Policy

Lyme Disease/IV Antibiotic Treatment

Type of Policy: **Medical Therapy**
Prior Approval Date: **12/01/2024**
Approval Date: **12/01/2025**
Effective Date: **02/01/2026**
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: eMedNY Medicaid Pharmacy List of Reimbursable Drugs

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.)

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
4. Halperin, J.J. et.al. Report of the Quality Standards Subcommittee of the American Academy of Neurology. "Practice Parameter: Treatment of Nervous System Lyme Disease (an evidence-based review). Practice parameter: treatment of nervous system Lyme disease (an evidence-based review): report of the Quality Standards Subcommittee of the American Academy of Neurology [RETIRED] - PubMed
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
6. Lantos PM, Rumbaugh J, Bockenstedt LK, et al. Clinical Practice Guidelines by the Infectious Diseases Society of America, American Academy of Neurology, and American College of Rheumatology: 2020 Guidelines for the Prevention, Diagnosis, and Treatment of Lyme Disease. Neurology. 2021 Feb 9;96(6):262-273. doi: 10.1212/WNL.0000000000011151. Epub 2020 Nov 30. Erratum in: Neurology. 2021 Feb 9;96(6):296. PMID: 33257476.
7. Treatment of Lyme Disease. Centers for Disease Control and Prevention (CDC). Updated August 16, 2024. Available at: Treatment of Lyme Disease | Lyme Disease | CDC.
8. Paul M Lantos, Jeffrey Rumbaugh, Linda K Bockenstedt, Yngve T Falck-Ytter, Maria E Aguero-Rosenfeld, Paul G Auwaerter, Kelly Baldwin, Raveendhara R Bannuru, Kiran K Belani, William R Bowie, John A Branda, David B Clifford, Francis J DiMario, John J Halperin, Peter J Krause, Valery Lavergne, Matthew H Liang, H Cody Meissner, Lise E Nigrovic, James (Jay) J Nocton, Mikala C Osani, Amy A Pruitt, Jane Rips, Lynda E Rosenfeld, Margot L Savoy, Sunil K Sood, Allen C Steere, Franc Strle, Robert Sundel, Jean Tsao, Elizaveta E Vaysbrot, Gary P Wormser,

Lawrence S Zemel, 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*, Volume 72, Issue 1, 1 January 2021, Pages e1–e48, https://doi.org/10.1093/cid/ciaa1215

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
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 Medicare WellSelect 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
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 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: **12/01/2024**
Approval Date: **12/01/2025**
Effective Date: **02/01/2026**
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)

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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: eMedNY Medicaid Pharmacy List of Reimbursable Drugs

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.)

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
4. Halperin, J.J. et.al. Report of the Quality Standards Subcommittee of the American Academy of Neurology. "Practice Parameter: Treatment of Nervous System Lyme Disease (an evidence-based review). Practice parameter: treatment of nervous system Lyme disease (an evidence-based review): report of the Quality Standards Subcommittee of the American Academy of Neurology [RETIRED] - PubMed
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6. Lantos PM, Rumbaugh J, Bockenstedt LK, et al. Clinical Practice Guidelines by the Infectious Diseases Society of America, American Academy of Neurology, and American College of Rheumatology: 2020 Guidelines for the Prevention, Diagnosis, and Treatment of Lyme Disease. Neurology. 2021 Feb 9;96(6):262-273. doi: 10.1212/WNL.0000000000011151. Epub 2020 Nov 30. Erratum in: Neurology. 2021 Feb 9;96(6):296. PMID: 33257476.
7. Treatment of Lyme Disease. Centers for Disease Control and Prevention (CDC). Updated August 16, 2024. Available at: Treatment of Lyme Disease | Lyme Disease | CDC.

8. Paul M Lantos, Jeffrey Rumbaugh, Linda K Bockenstedt, Yngve T Falck-Ytter, Maria E Aguero-Rosenfeld, Paul G Auwaerter, Kelly Baldwin, Raveendhara R Bannuru, Kiran K Belani, William R Bowie, John A Branda, David B Clifford, Francis J DiMario, John J Halperin, Peter J Krause, Valery Lavergne, Matthew H Liang, H Cody Meissner, Lise E Nigrovic, James (Jay) J Nocton, Mikala C Osani, Amy A Pruitt, Jane Rips, Lynda E Rosenfeld, Margot L Savoy, Sunil K Sood, Allen C Steere, Franc Strle, Robert Sundel, Jean Tsao, Elizaveta E Vaysbrot, Gary P Wormser, Lawrence S Zemel, 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*, Volume 72, Issue 1, 1 January 2021, Pages e1–e48, https://doi.org/10.1093/cid/ciaa1215

MVP Health Care Medical Policy

Mail Order

Type of Policy:	**Drug Therapy**
Prior Approval Date:	**02/01/2025**
Approval Date:	**02/01/2026**
Effective Date:	**04/01/2026**

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: **02/01/2025**
Approval Date: **02/01/2026**
Effective Date: **04/01/2026**
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.

Drugs Requiring Prior Authorization under the Medical Benefit. (See Medicaid)

J3145 Aveed (Testosterone undecanoate 750mg/3ml)

J1072 Azmiro (testosterone cypionate, 1mg)

Drugs Requiring Prior Authorization under the Medical Benefit when quantity limits are exceeded. (See Medicaid Variation- prior authorization is required regardless of quantity)

J1073 Testopel (Testosterone pellet, 75 mg)

Drugs Requiring Prior Authorization under the Pharmacy Benefit

- All products require prior authorization when quantity limit is exceeded.
- Non-Preferred products require prior authorization regardless of quantity
- For Medicaid, medications that are a pharmacy benefit are covered and billed to New York State Fee-For-Service (FFS) program. Please 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	testosterone	30 patches	Yes

2mg/24 HR *4mg/24 HR*			
Androgel 1% Topical Gel Packets *25mg testosterone in 2.5g gel* *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 *100mg/mL* *200mg/mL*	testosterone cypionate	10 mL	Yes (brand name only)
Fortesta Gel *10mg/act*	testosterone	60 grams	Yes (brand name only)
Kyzatrex Capsules 100mg 150mg 200mg	Testosterone undecanoate	120 capsules	Yes
Jatenzo Capsules *158mg* *198mg* *237mg*	testosterone undecanoate	120 capsules	Yes
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

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

1. Drugs requiring prior authorization per this policy will be considered for coverage when the criteria below is met. Please see Medicaid Variation for Medicaid members.
    - The member is biologically male; **AND**
    - Chart notes document a current 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**
    - Chart notes document a current 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**
    - Chart notes document 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**
    - Chart notes document:

- 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**

- Requests for non-preferred/non-formulary products require a documented trial, failure or contraindication to formulary products testosterone cypionate/enanthate injection and Androgel/testosterone td gel.

  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).

2. Medicaid Variation

- Azmiro, Testopel pellets (regardless of quantity) and Aveed require prior authorization for Medicaid.
- Azmiro, Testopel pellets and Aveed require a trial of self-administered testosterone products and member must meet the diagnostic criteria in the policy above.
- 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

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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

References

1. 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.
2. Androgel® (testosterone gel) package insert. North Chicago, IL: AbbVie Inc.; 2022 Nov.
3. Androgel 1.62% (testosterone gel) package insert. North Chicago, IL: AbbVie Inc.: 2022 Nov.
4. Androderm (testosterone transdermal system) package insert. Madison, NJ: Allergan USA, Inc.; 2020 Aug.
5. Android (methyltestosterone) package insert. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; 2015 Apr.
6. Axiron (testosterone) topical solution, package insert. Indianapolis, IN: Lilly USA, LLC: 2017 July.
7. Delatesteryl (testosterone cypionate), Chadds Ford, PA: Endo Pharmaceuticals, Inc.; 2010 Dec.
8. DEPO-TESTOSTERONE (testosterone cypionate) injection, package insert. New York, NY: Pharmacia & Upjohn Co.; 2018 Aug.

9. Fortesta (testosterone) gel, package insert, Malvern, PA: Endo Pharmaceuticals Inc.; 2017 Jul.
10. Striant (testosterone buccal system) package insert. Chesterbrook, PA; Actient Pharmaceuticals LLC; 2015 May.
11. Testim (testosterone gel) package insert. St-Laurent, Quebec; Paladin Labs, Inc. ; 2017 Feb.
12. Testopel (testosterone pellets) package insert. Malvern, PA: Endo Pharmaceuticals Inc.; 2024 Mar.
13. Dandona P, Rosenberg MT, A practical guide to male hypogonadism in the primary care setting. *Int J Cli Pract*. 2010. 2010;64(6);682-696.
14. Natesto (testosterone nasal gel) package insert. Bavaria, Germany; Haupt Pharma Amareg GmbH; 2016 Oct.
15. 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.
16. Xyosted (testosterone enanthate) package insert. Ewing, NJ. Antares Pharma, Inc. 2019 November.
17. Vogelxo (testosterone) package insert. Maple Grove, MN. Upsher-Smith Laboratories, LLC.; 2019 May.
18. Androxy (fluoxymesterone) package insert. Maple Grove, MN. Upsher-Smith Laboratories, LLC.; 2017 Sep.
19. Aveed (testosterone undecanoate) package insert. Malvern, PA. Endo Pharmaceuticals Inc.; 2021 Aug.
20. Methyltestosterone Capsules package insert. Bridgewater, NJ. Amneal Pharmaceuticals LLC; 2019 May.
21. 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 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).	

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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:	**02/01/2025**
Approval Date:	**02/01/2026**
Effective Date:	**04/01/2026**
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.**

Drugs Requiring Prior Authorization under the Medical Benefit

J3145 Aveed (Testosterone undecanoate 750mg/3ml)

J1072 Azmiro (testosterone cypionate, 1mg)

Drugs Requiring Prior Authorization under the Medical Benefit when quantity limits are exceeded. Quantities greater than 10 pellets.

J1073 Testopel (testosterone pellet, 75mg)

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**
- The member is biologically Male; **AND**
- Chart notes document a current 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**
- Chart notes document a current confirmation of early morning serum total testosterone level **on a separate occasion** OR if the member 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**
- Chart notes document 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**
- Chart notes document:
    - 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

References

1. 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.
2. 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.
3. Testopel (testosterone pellets) package insert. Malvern, PA: Endo Pharmaceuticals Inc.; 2024 Mar.

4. Aveed (testosterone undecanoate) package insert. Malvern, PA. Endo Pharmaceuticals Inc.; 2021 Aug.

Medical Drug List

Revised: **06/01/2026**

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	
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
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 (Injection, coagulation factor Xa (recombinant), inactivated (andexxa), 10 mg)	J7169	
Anktiva (nogapendekin alfa inbakicept, intravesical))	J9028	See Optum List if treatment is being used for a cancer diagnosis
Aphexda	J2277	

(motixafortide)		
Aponvie (aprepitant,fosaprepitant)	J8502	
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
Aurlumyn (Injection, iloprost, 0.1 mcg)	J1749	
Avastin (bevacizumab)	C9257, J9035	See Optum List if treatment is being used for a cancer diagnosis
Avlayah (tividenofusp alfa)	J3590	Subject to 6-month new drug. Prior authorization required.
Avsola (Infliximab, 10mg)	Q5121	Subject to Infliximab policy and may be subject to Site of Care
Avtozma (Injection, tocilizumab-anoh (**avtozma**), biosimilar, 1 mg)	Q5156	Subject to Tocilizumab policy and see Optum List if treatment is being used for a cancer diagnosis
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 (amisulpride, injection for intravenous use)	J0184	See Optum List if treatment is being used for a cancer diagnosis
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
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	
Byooviz (ranibizumab-nuna)	Q5124	
Cabenuva (cabtegravir, rilpivirine)	J0741	
Caldolor (ibuprofen, inj)	J1741	
Camcevi (Leuoprolide inj 1mg)	J1952	See Optum List if treatment is being used for a cancer diagnosis

Caspofungin (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 (imiglucerase, 10 units)	J1786	Subject to Gaucher Disease Type 1 Treatment policy and may be subject to Site of Care
Cimerli (ramibizumab)	Q5128	
Cinryze (Injection, C1 esterase inhibitor (human), 10 units)	J0598	Subject to Hereditary Angioedema policy and may be subject to Site of Care
Cinvanti (aprepitant)	J0185	See Optum List if treatment is being used for a cancer diagnosis
Contepo (fosfomycin, powder for solution for injection)	J3490	Subject to 6-month new drug. Prior authorization required.
Columvi (glofitamab)	J9286	See Optum List if treatment is being used for a cancer diagnosis
Cosela (Trilaciclib)	J1448	See Optum List if treatment is being used for a cancer diagnosis
Crysvita (inj, burosumab-twza 1 mg)	J0584	Subject to Orphan Drug(s) and Biologicals policy and may be subject to Site of Care
Cyramza (Injection, ramucirumab)	J9308	See Optum List if treatment is being used for a cancer diagnosis
Dalvance (Injection, dalbavancin)	J0875	
Danyelza (injection, naxitamab)	J9348	Prior Authorization per Orphan Drug and Biologicals Policy. See Optum List if treatment is being used for a cancer diagnosis
Darzalex (Injection, daratumumab)	J9145	See Optum List if treatment is being used for a cancer diagnosis
Darzalex Faspro (subcutaneous inj, daratumumab and hyaluronidase-fihj)	J9144	
Datroway (datopotamab deruxtecan)	J9011	See Optum List if treatment is being used for a cancer diagnosis

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	
Dihydroergotamine mesylate 1mg (DHE), injection	J1110	
Diphenhydramine (Injection, diphenhydramine HCl, up to 50 mg)	J1200	
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
Eligard (Leuprolide acetate (for depot suspension)	J9217	See Optum List if treatment is being used for a cancer diagnosis
Elrexfio (elranatamab, injection)	J1323	See Optum List if treatment is being used for a cancer diagnosis
Emblaveo (aztreonam and avibactam)	J0458	

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)	J9326	See Optum List if treatment is being used for a cancer diagnosis
Entyvio (vedolizumab, injection 1mg)	J3380	Subject to Entyvio policy and may be subject to Site of Care
Epioxa HD/Kit	J3590	Excluded per Phototherapeutic Keratectomy (PTK) and Refractive Surgery medical policy
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
Exdensur (depemokimab)	J3590	Subject to 6-month new drug. Prior authorization required.
Exparel (injection, bupivacaine)	J0666	Excluded
Eylea HD (aflibercept)	J0177	
Eylea (aflibercept)	J0178	
Famotidine (Injection, famotidine, 0.25 mg)	J1308	
Fensolvi (leuprolide acetate for depot suspension 0.25 mg)	J1951	
Feraheme (Injection, ferumoxytol)	Q0138, Q0139	
Ferrlecit	J2916	

(Injection, sodium ferric gluconate complex in sucrose injection)		
Fetroja (cefiderocol, IV)	J0693	
Firmagon (Injection, degarelix)	J9155	See Optum List if treatment is being used for a cancer diagnosis
Focinvez (fosasprepitant)	J1434	See Optum List if treatment is being used for a cancer diagnosis
Furoscix (furosemide controlled release on body infuser)	J1941	
Fyarro (Injection, nanoparticle albumin-bound sirolimus)	J9331	See Optum List if treatment is being used for a cancer diagnosis
Gazyva (Injection, obinutuzumab)	J9301	See Optum List if treatment is being used for a cancer diagnosis
Glassia (Injection, alpha 1 proteinase inhibitor (human))	J0257	
Gleolan	J8499	
Grafapex (treosulfan)	J0614	
Granix (Injection, tbo-filgrastim)	J1447	See Optum List if treatment is being used for a cancer diagnosis
Herceptin (trastuzumab)	J9355	See Optum List if treatment is being used for a cancer diagnosis
Herceptin Hylecta (trastuzumab)	J9356	See Optum List if treatment is being used for a cancer diagnosis
Hercessi (trastuzumab-strf (hercessi), biosimilar, 10 mg)	Q5146	See Optum List if treatment is being used for a cancer diagnosis
Halaven (Injection, eribulin mesylate)	J9179	See Optum List if treatment is being used for a cancer diagnosis
Herzuma (Injection, traztuzumab-pkrb)	Q5113	See Optum List if treatment is being used for a cancer diagnosis
Hyaluronic Acid Derivatives	J7318 J7320 J7321	Not covered for MVP Medicaid Managed Care Products when billed with diagnosis codes for osteoarthritis of the knee as Listed

	J7322 J7323 J7324 J7325 J7326 J7327 J7328 J7329 J7331 J7332	in the Viscosupplementation of the knee: Non-Coverage for Medicaid Managed Care Plans Payment Policy
IDose TR (travoprost implant)	J7355	Excluded Please refer to Surgical Procedures for Glaucoma for Medicare coverage.
Iheezo gel (chloroprocaine)	J2403	
Ilumya (Injection, tildrakizumab, 1mg)	J3245	Excluded
Iluvien (Injection, fluocinolone acetonide, intravitreal implant)	J7313	
Imdelltra (tarlatamab, injection)	J9026	See Optum List if treatment is being used for a cancer diagnosis
Imfinzi (Injection, durvalumab)	J9173	See Optum List if treatment is being used for a cancer diagnosis
Imjudo (Injection, tremelimumab)	J9347	See Optum List if treatment is being used for a cancer diagnosis
Imlygic (Injection, talimogene laherparepvec)	J9325	See Optum List if treatment is being used for a cancer diagnosis
Inflectra (Injection, infliximab, 10mg)	Q5103	Subject to Infliximab policy and may be subject to Site of Care
Injectafer (Injection, ferric carboxymaltose)	J1439	
Inlexzo (gemcitabine intravesical system)	J9183	See Optum List if treatment is being used for a cancer diagnosis
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
Jobevne (bevacizumab)	Q5160	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
Kepivance (Injection, palifermin, 50 micrograms)	J2425	
Keytruda (pembrolizumab)	J9271	See Optum List if treatment is being used for a cancer diagnosis
Keytruda QLEX (pembrolizumab; berahyaluronidase alfa)	J9277	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 (Levonorgestrel-releasing intrauterine contraceptive system)	J7296	
Kyprolis (carfilzomib)	J9047	See Optum List if treatment is being used for a cancer diagnosis
Kyxata (carboplatin)	J9278	See Optum List if treatment is being used for a cancer diagnosis

Lartruvo (olaratumab)	J9285	See Optum List if treatment is being used for a cancer diagnosis
Lasix Onyu (Furosemide pre-filled cartridge solution for subcutaneous infusion kit)	J3490	Subject to 6-month new drug. Prior authorization required.
Leqvio (injection, inclisiran, 1mg)	J1306	Excluded for Medicare For other lines of business, refer to the MVP PCSK9 Inhibitors clinical policy
Libtayo (cemiplimab-rwlc)	J9119	See Optum List if treatment is being used for a cancer diagnosis
Liletta (Levonorgestrel-releasing intrauterine contraceptive system)	J7297	
Loargys (pegzilarginase, solution for injection)	J3590	Subject to 6-month new drug. Prior authorization required.
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)	J9601	See Optum List if treatment is being used for a cancer diagnosis
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	J9371	

(Injection, vincristine sulfate liposome)		
Mirena (Levonorgestrel-releasing intrauterine contraceptive system)	J7298	
Monoferric (injection, ferric derisomaltose, 10mg)	J1437	
Monjuvi (tafasitamab)	J9349	See Optum List if treatment is being used for a cancer diagnosis
Mvasi (bevacizumab)	Q5107	See Optum List if treatment is being used for a cancer diagnosis;
Mylotarg (Injection, gemtuzumab ozogamicin)	J9203	See Optum List if treatment is being used for a cancer diagnosis
Myobloc (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 (insulin human in sodium chloride injection), for intravenous use	J3590	
Naglazyme (Inj, galsulfase, 1 mg)	J1458	Subject to Orphan Drug(s) and Biologicals policy and may be subject to Site of Care
Nexobrid (anacaulase)	J7353	
Nexplanon (Etonogestrel (contraceptive) implant system)	J7307	
Nivestym IV (Injection, filgrastim-aafi)	Q5110	See Optum List if treatment is being used for a cancer diagnosis
Nplate (Injection, romiplostim)	J2802	See Optum List if treatment is being used for a cancer diagnosis
Nulojix (Injection, belatacept)	J0485	
Nuzyra IV	J0121	

(Injection, omadacycline)		
Nypozi (Injection, filgrastim-txid (nypozi), biosimilar)	Q5148	Excluded. See Optum List if treatment is being used for a cancer diagnosis
Ogivri (Trastuzumab)	Q5114	See Optum List if treatment is being used for a cancer diagnosis
Olinvyk (oliceridine)	J3490	
Omvoh (mirikizumab, solution for injection, IV)	J2267	Exclude
Ondansetron (Injection, ondansetron hydrochloride, per 1 mg)	J2405	
Onivyde (Injection, irinotecan liposome)	J9205	See Optum List if treatment is being used for a cancer diagnosis
Onpattro (patisiran), injection 0.1 mg	J0222	Subject to Transthyretin-Mediated Amyloidosis Therapy policy and may be subject to Site of Care
Ontruzant (Injection, trastuzumab-dttb)	Q5112	See Optum List if treatment is being used for a cancer diagnosis
Opdivo (Injection, nivolumab)	J9299	See Optum List if treatment is being used for a cancer diagnosis
Opdivo Qvantig (Nivolumab + hyaluronidase-nvhy)	J9289	See Optum List if treatment is being used for a cancer diagnosis
Opdualag (injection, nivolumab, relatlimab)	J9298	See Optum List if treatment is being used for a cancer diagnosis
Opuviz (Injection, aflibercept-yszy biosimilar, 1 mg)	Q5153	
Orbactiv (Injection, oritavancin)	J2407	
Orencia (abatacept, 10mg (Orencia IV)	J0129	Subject to Abatacept policy and may be subject to Site of Care
Osenvelt (denosumab solution for injection)	Q5157	See Optum List if treatment is being used for a cancer diagnosis
Otiprio (Installation, ciprofloxacin otic suspension)	J7342	

Ozurdex (Injection, dexamethasone, intravitreal implant)	J7312	
Padcev (enfortumab vedotin-ejfv) for injection, for intravenous use	J9177	
Paragard (Intrauterine copper contraceptive)	J7300	
Pavblu (aflibercept)	Q5147	
Pedmark (sodium thiosulfate)	J0208	
Pemfexy (pemetrexed)	J9304	See Optum List if treatment is being used for a cancer diagnosis
Perjeta (Injection, pertuzumab)	J9306	See Optum List if treatment is being used for a cancer diagnosis
Perseris (Injection, risperidone)	J2798	
Pemetrexed ditromethamine	J9305	See Optum List if treatment is being used for a cancer diagnosis
Phesgo (pertuzumab/trastuzumab hyaluronidase-zzxf)	J9316	See Optum List if treatment is being used for a cancer diagnosis
Portrazza (Injection, necitumumab)	J9295	See Optum List if treatment is being used for a cancer diagnosis
Praxbind (idarucizumab)	J3590	
Prevduo (neostigmine, glycopyrrolate, solution for injection)	J2711	
Prevymis IV (letermovir, IV)	J3490	Prior authorization required per Pharmacy Programs Administration Policy
Probuphine (Buprenorphine implant)	J0570	
Progesterone (injection, progesterone, per 50mg)	J2675	
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	S1091	Excluded per UM E/I List

(Mometasone furoate sinus implant)		
Qivigy (Immune Globulin (IVIG, IMIG, SCIG))	J1599	Subject to 6-month new drug. Prior authorization required.
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	
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
Rolvedon (eflapegrastim)	J1449	See Optum List if treatment is being used for a cancer diagnosis
Ruxience (Injection, rituximab-pvvr, biosimilar, (ruxience), 10 mg)	Q5119	See Optum List if treatment is being used for a cancer diagnosis
Rybrevant (amivantamab)	J9061	See Optum List if treatment is being used for a cancer diagnosis
Rybrevant Faspro (Amivantamab; Hyaluronidase)	J9999	

Rykindo (risperidone, injection)	J2801	
Rylaze (asparaginase erwinia chrysanthemi [recombinant]-rywn)	J9021	See Optum List if treatment is being used for a cancer diagnosis
Rytelo (Imetelstat)	J0870	
Ryzneuta (efbemalenograstim alfa-vuxw)	J9361	See Optum List if treatment is being used for a cancer diagnosis
Sandostatin LAR (Injection, octreotide)	J2353	See Optum List if treatment is being used for a cancer diagnosis
Sarclisa (intravenuous, isatuximab-irfc)	J9227	See Optum List if treatment is being used for a cancer diagnosis
Sezaby (phenobarbital, injection)	J2561	
Signifor LAR (Injection, pasireotide long acting)	J2502	
Simponi Aria (injection, golimumab)	J1602	Subject to Golimumab policy and may be subject to Site of Care
Skyla (Levonorgestrel-releasing intrauterine contraceptive system)	J7301	
Soliris (Injection, eculizumab 300 mg/30 mL solution for injection)	J1300	Subject to Eculizumab policy and may be subject to Site of Care
Stoboclo Denosumab solution for injection	Q5157	
Sublocade (Injection, buprenorphine extended-release)	Q9991, Q9992	
Sunlenca (lenacapavir, injection)	J1961	
Supprelin-LA (Histrelin implant)	J9226	
Sustol (Injection, granisetron, extended-release)	J1627	See Optum List if treatment is being used for a cancer diagnosis
Synribo	J9262	See Optum List if treatment is being used for a cancer diagnosis

(Injection, omacetaxine mepesuccinate)		
Talvey (injection, talquetamab-tgvs)	J3055	See Optum List if treatment is being used for a cancer diagnosis
Tecentriq (Injection, atezolizumab)	J9022	See Optum List if treatment is being used for a cancer diagnosis
Tecentriq Hybreza (Injection, atezolizumab)	J9024	See Optum List if treatment is being used for a cancer diagnosis
Tecvayli (Injection, tecListamab)	J9380	See Optum List if treatment is being used for a cancer diagnosis
Teflaro (Injection, ceftaroline fosamil)	J0712	
Temodar IV (Injection, temozolomide)	J9328	See Optum List if treatment is being used for a cancer diagnosis
Tepadina (thiopeta, injection)	J9342	See Optum List if treatment is being used for a cancer diagnosis
Tepezza (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 (Thiotepa)	J9341	See Optum List if treatment is being used for a cancer diagnosis
Terlivaz (Injection, terlipressin)	J3490	
Tevimbra (tislelizumab-jsgr)	J9329	See Optum List if treatment is being used for a cancer diagnosis
Tivdak (tisotumab vedotin)	J9273	See Optum List if treatment is being used for a cancer diagnosis
Tofidence (Injection, tocilizumab-bavi (tofidence), biosimilar, 1 mg)	Q5133	Subject to Tocilizumab policy and see Optum List if treatment is being used for a cancer diagnosis
Torisel (Injection, temsirolimus)	J9330	See Optum List if treatment is being used for a cancer diagnosis
Treanda (Injection, bendamustine)	J9033	See Optum List if treatment is being used for a cancer diagnosis
Trelstar (Injection, triptorelin pamoate)	J3315	See Optum List if treatment is being used for a cancer diagnosis
Triferic (Injection, ferric pyrophosphate citrate solution)	J1443	
Triptodur (Injection, triptorelin)	J3316	

Trodelvy (intravenous, sacituzumab govitecan-hziy)	J9317	See Optum List if treatment is being used for a cancer diagnosis
Trogarzo (Injection, ibalizumab-uiyk)	J1746	
Truxima (Injection, rituximab-abbs)	Q5115	See Optum List if treatment is being used for a cancer diagnosis
Tyruko (natalizumab-szt)	Q5134	Subject to 6-month new drug. Prior authorization required
Tyenne (Injection, tocilizumab-aazg (**tyenne**), biosimilar, 1 mg)	Q5135	Subject to Tocilizumab policy and see Optum List if treatment is being used for a cancer diagnosis
Ultomiris (Injection, rivulizumab)	J1303	Subject to Ravulizumab-cwvz policy and may be subject to Site of Care
Unloxcyt	J9275	See Optum List if treatment is being used for a cancer diagnosis
Uzedy (risperidone) suspension for injection	J2799	Exclude
Vabysmo (faricimab-svoa)	J2777	
Vantas (Histrelin implant)	J9225	
Varubi (rolapitant)	J2797	
Vegzelma (injection, bevacizumab-adcd, biosimilar, 10mg)	Q5129	See Optum List if treatment is being used for a cancer diagnosis
Venofer (Injection, iron sucrose, 1 mg)	J1756	
Vibativ (Injection, telavancin)	J3095	
Vivitrol (Injection, naltrexone)	J2315	
Voraxaze (Injection, glucarpidase)	J3590	
Vyloy (zolbetuximab)	J1326	See Optum List if treatment is being used for a cancer diagnosis
Vyxeos	J9153	See Optum List if treatment is being used for a cancer diagnosis

(Injection, liposomal, 1 mg daunorubicin and 2.27 mg cytarabine)		
Wyost (Injection, denosumab-bbdz, biosimilar, 1 mg)	Q5136	See Optum List if treatment is being used for a cancer diagnosis
Xacduro (inj, sulbactum, durlobactum)	J3490	
Xenpozyme (olipudase alfa)	J0218	Prior Authorization per the Orphan Drug Policy and may be subject to Site of Care
Xeomin (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 (Injection, eravacycline)	J0122	
Xgeva (Injection, denosumab)	J0897	See Optum List if treatment is being used for a cancer diagnosis
Xiaflex (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 (meloxicam, solution for injection)	J1737	
Xipere (triamcinolone acetonide injection)	J3299	Excluded
Xofigo (Radium Ra-223 dichloride)	A9606	
Yervoy (Injection, ipilimumab)	J9228	See Optum List if treatment is being used for a cancer diagnosis
Yeztugo Injection, lenacapavir, 1 mg, fda approved prescription, only for use as hiv pre-exposure prophylaxis (not for use as treatment for hiv)	J0738	

Yimmugo Injection, immune globulin, intravenous, non-lyophilized (e.g. liquid)	J1599	Subject to 6-month new drug. Prior authorization required.
Yondelis (Injection, trabectedin)	J9352	See Optum List if treatment is being used for a cancer diagnosis
Yutiq (Injection, fluocinolone acetonide, intravitreal implant)	J7314	
Zaltrap (Injection, ziv-aflibercept)	J9400	See Optum List if treatment is being used for a cancer diagnosis
Zemaira (Injection, alpha 1-proteinase inhibitor)	J0256	
Zemdri (Injection, plazomicin)	J0291	
Zepzelca (lurbinectedin)	J9223	See Optum List if treatment is being used for a cancer diagnosis
Zerbaxa (Injection, ceftolozane)	J0695	
Zevtera (ceftobiprole, powder for injection)	J06811	
Ziihera (zanidatamab)	J9276	See Optum List if treatment is being used for a cancer diagnosis
Zilretta (Injection, triamcinolone acetonide, preservative-free, extended-release,)	J3304	
Zirabev (bevacizumab-bvzr, IV)	Q5118	See Optum List if treatment is being used for a cancer diagnosis
Zoladex (Goserelin acetate implant)	J9202	Zoladex requires a prior authorization for **Medicaid** effective 05/14/2022; **See Optum List if treatment is being used for a cancer diagnosis**
Zoledronic acid	J3489	
Zusduri (mitomycin)	J9282	See Optum List if treatment is being used for a cancer diagnosis
Zynrelef (Instillation, bupivacaine and meloxicam, 1 mg/0.03 mg)	J0668	

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
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
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
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
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
Oncaspar	Pegaspargase	J9266
Taxol®	Paclitaxel	J9267
Nipent	Pentostatin	J9268
Elzonris	Tagraxofusp-erzs	J9269
Keytruda	Pembrolizumab	J9271

Keytruda QLEX	Pembrolizumab abd berahyaluronidase alfa-phph	J9277
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
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
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 & trade;	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
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
Datroway	datopotamab deruxtecan-dlnk	J9011
Avtozma	tocilizumab -anoh biosimilar (Avtozma)	Q5156
Stoboclo/Osenvelt	denosumab biosimilar	Q5157
Bomyntra/Conexxence	denosumab biosimilar	Q5158
Ospomyv/Xbryk	denosumab biosimilar	Q5159
Ryzneuta	(efbemalenograstim alfa-vuxw)	J9361
Zusduri	Mitomycin intravesical Instillation	J9282
Emrelis	telisotuzumab vedotin-tllv	J9326
Gemcitabine	Gemcitabine	J9184
Camcevi ETM	leuprolide mesylate 21 mg	J9003
Aukelso	Denosumab-kyqq	Q5161
Bosaya	Denosumab-kyqq	Q5161
Bildyos	Denosumab-nxxp	Q5162
Bilprevda	Denosumab-nxxp	Q5162
Tyenne	Tocilizumab-aazg	Q5135

MVP Health Care Medical Policy

Medicare Part B Drug Therapy

Type of Policy:	**Drug/Medical Therapy**
Prior Approval Date:	**11/01/2024**
Approval Date:	**08/01/2025**
Effective Date:	**10/01/2025**
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.

References

1. Medicare Benefit Policy Manual. Chapter 15. Covered Medical and Other Health Services. Revised 01/16/2025. 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

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 Mvasi	Avastin Alymsys Vegzelma
Herceptin Trazimera Herceptin Hylecta	Kanjinti Ogivri Ontruzant Herzuma Hercessi
Neulasta Udenyca	Fulphila Ziextenzo Fylnetra Rolvedon Stimufend Nyvepria
Nivestym Releuko	Zarxio Neupogen Granix
Ruxience Rituxan Rituxan Hycela	Truxima Riabni
Gemcitabine	Infugem
leucovorin	levoleucovorin
Aranesp Retacrit Procrit/Epogen	N/A
Aloxi Emend Fosaprepitant	Akynzeo Cinvanti 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:	**11/01/2024**
Approval Date:	**08/01/2025**
Effective Date:	**10/01/2025**
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 DME approved 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- refer to LCD for Nebulizers (L33370) for specific criteria

Exclusions Under Part B benefit (see Policy Article for Nebulizers (A52466))

- If a nebulizer that is FDA-approved for administration of a certain inhaled drug solution is not sufficiently durable to meet the DME statutory requirements for coverage, the inhaled drug solution will be denied as noncovered under the Medicare Part B DME benefit
    - May be eligible for coverage under the Medicare Part D benefit
        - Cayston (aztreonam lysine): indicated for members with cystic fibrosis with chronic Pseudomonas aeruginosa infection
        - Arikayce (amikacin liposome) indicated for adults with refractory Mycobacterium avium complex (MAC) lung disease

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 additional and specific coverage details.

Infusion Pump Drugs-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
- Administration of chemotherapy for the treatment of primary hepatocellular carcinoma or Duke's Class D colorectal cancer, in a member whom the metastases are limited to the liver, where this disease is unresectable or where the beneficiary refuses surgical excision of the tumor
- Blinatumomab
- Deferoxamine for the treatment of chronic iron overload
- Continuous subcutaneous insulin (used with an approved durable external or ambulatory insulin infusion pump)
    - Insulin used with a disposable insulin pump would be considered a Medicare part D benefit
- Morphine for the treatment of intractable pain caused by cancer
- Opioid drugs (e.g., morphine) intrathecally or epidurally for treatment of severe chronic intractable pain of malignant or nonmalignant origin in member who

have a life expectancy of at least 3 months, and who have proven unresponsive to less invasive medical therapy
- Narcotic analgesics (except meperidine) for the treatment of severe intractable cancer pain 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
- Anti-spasmodic drugs for severe spasticity, intrathecally (e.g., baclofen) to treat chronic intractable spasticity in patients who have proven unresponsive to less invasive medical therapy
- 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) s, LCD for External Infusion Pumps (L33794), Article for Implantable Infusion Pumps (A56695), and Article for External Infusion Pumps (A52507) for coverage details

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.

Refer to LCD for Immunosuppressive Drugs (L33824), Article for Immunosuppressive Drugs (A52474), and Chapter 15 Section 50.5.1 of the Medicare Benefit Policy Manual for coverage details

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 AND other approved indications
- Refer to Chapter 15 Section 50.5.2 of the Medicare Benefit Policy Manual NCD for Erythropoiesis Stimulating Agents (ESAs) in Cancer and Related Neoplastic

Conditions (110.21), LCD for Erythropoiesis Stimulating Agents (L39237), and Policy Artic for Billing and Coding: Erythropoiesis Stimulating Agents- Policy Article (A52509) for coverage guidance.

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
- 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),the accompanying Policy Article (A52479), and Chapter 15 Section 50.5.3 of the Medicare Benefit Policy Manual 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), the accompanying Policy Article (A52480), and Chapter 15 Section 50.5.4 of the Medicare Benefit Policy Manual for coverage guidance.

Immunizations-covered under Part B

- Hepatitis B vaccines- when administered to member who:
    - Is at high or intermediate risk of contracting hepatitis B
        - High risk groups include:
            - Members with ESRD;
            - Hemophiliacs who receive Factor VIII or IX concentrates;
            - Clients of institutions for individuals with intellectual disabilities;
            - Members who live in the same household as a hepatitis B virus (HBV) carrier;
            - Homosexual men;
            - Illicit injectable drug abusers;

        - Members diagnosed with diabetes mellitus;
        - Pacific Islanders (that is, those Medicare beneficiaries who reside on Pacific islands under U.S. jurisdiction, other than residents of Hawaii);
    - Intermediate risk groups include:
        - Staff in institutions for individuals with intellectual disabilities and classroom employees who work with individuals with intellectual disabilities;
        - Workers in health care professions who have frequent contact with blood or blood-derived body fluids during routine work (including workers who work outside of a hospital and have frequent contact with blood or other infectious secretions);
        - Heterosexually active members with multiple sexual partners (that is, those Medicare beneficiaries who have had at least two documented episodes of sexually transmitted diseases within the preceding 5 years);
        - Members who have not previously received a complete hepatitis B vaccination series OR those whose vaccination history is unknown
- Pneumococcal vaccines
- Tetanus vaccines-when administered directly related to the treatment of an injury
- Influenza vaccines
- COVID-19 vaccines
- Mpox vaccines

Parenteral Nutrition- Must be covered under the prosthetic devices benefit when criteria are met

Refer to LCD for Enteral Nutrition (LCD L38955) accompanying Policy Article(A58833), and Medicare Part B Enteral Nutrition Policy

- Therapy is being provided because of a non-functioning digestive tract
- Intraperitoneal Nutrition is considered a Part B compound

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

Refer to Immunoglobulin Therapy policy and applicable LCDs, NCDs, and policy articles for coverage criteria which may include LCD L39314- Off-Label Use of Intravenous Immune Globulin (IVIG), Policy Article A59105-Billing and Coding: Off-Label Use of Intravenous Immune Globulin (IVIG), LCD L33610 for Intravenous Immune Globulin and the accompanying Policy Article A52509

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.

References

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 10/04/2024. Available: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf
3. Medicare Local Coverage Determination for Nebulizers- LCD (L33370), Original Effective Date 10/01/2015. Revision Effective Date: 01/01/2024
4. Centers of Medicare & Medicaid Services. National Coverage Determination for Infusion Pumps (280.14). Effective Date 12/17/2004.
5. Medicare Prescription Drug Benefit Manual, Chapter 6. Revised 01/19/2016.

6. Intravenous Immune Globulin- Policy Article (A52509)- Original Effective Date: 10/01/2015. Revision Effective Date: 04/01/2025.
7. Medicare Local Coverage Determination for Enteral Nutrition (L38955). Original Effective Date: 09/05/2021. Revision Effective Date: 01/01/2024.
8. Medicare Local Coverage Determination for Oral Anticancer Drugs (L33826). Original Effective Date: 10/01/20215. Revision Effective Date: 01/01/2024.
9. Medicare Local Coverage Article Oral Anticancer Drugs – Policy Article (A52479). Original Effective Date: 10/01/2015. Revision Effective Date: 10/01/2024.
10. External Infusion Pumps - Policy Article (A52507)- Original Effective Date: 10/01/2015. Revision Effective Date: 01/01/2024.
11. Local Coverage Determination for External Infusion Pumps (L33794). Original Effective Date: 10/01/2015. Revision Effective Date: 01/01/2025
12. Implantable Infusion Pumps - Policy Article (A56695)- Original Effective Date: 07/11/2019. Revision Effective Date: 10/01/2024.
13. Preexposure Prophylaxis (PrEP) Using Antiretroviral Therapy to Prevent Human Immunodeficiency Virus (HIV) Infection. Effective Date 9/30/2024
14. PrEP for HIV & Related Preventive Services. CMS.gov. Page Last Modified 10/01/2024
15. Medicare Benefit Policy. Chapter 11. End Stage Renal Disease (ESRD). Last Revised 03/01/2019.
16. Centers of Medicare & Medicaid Services. National Coverage Determination for Erythropoiesis Stimulating Agents (ESAs) in Cancer and Related Neoplastic Conditions (110.21). Effective Date 07/30/2007.
17. Medicare Local Coverage Determination for Erythropoiesis Stimulating Agents (L39237). Original Effective Date: 07/24/2022. Revision Effective Date: 03/13/2025.
18. Medicare Benefit Policy Manual Chapter 15 – Covered Medical and Other Health Services 50.4.4.2 – Immunizations. Rev 13248; Issued:05-29-25; Effective:01-01-25 ; Implementation: 10-06-25.
19. Medicare Local Coverage Determination for Immunizations (L34596). Original Effective Date: 10/01/2015. Revision Effective Date: 10/26/2023.
20. Centers for Medicare & Medicaid Services, Department of Health and Human Services. 42 Code of Federal Regulations (CFR), Chapter IV, Subchapter B, Section 410.63. Last amended 4/15/2025.
21. Centers for Medicare & Medicaid Services. Local Coverage Determination (LCD) for Intravenous Immune Globulin (L33610) Original Effective Date 10/01/2015. Revision Effective Date 01/01/2025.

MVP Health Care Medical Policy

Metformin ER

Type of Policy: **Drug Therapy**
Prior Approval Date: **02/01/2025**
Approval Date: **02/01/2026**
Effective Date: **04/01/2026**

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 members with type 2 diabetes mellitus. Clinical data suggests that members receiving extended release formulations of metformin experience less gastrointestinal upset than those receiving immediate release formulations. Through increased glucose control, members 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%.

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 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).	
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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:	**08/01/2024**
Approval Date:	**11/01/2025**
Effective Date:	**01/01/2026**

Related Policies:

Experimental or Investigational Policy

Drug Requiring Prior Authorization under the Pharmacy Benefit

Otrexup® (methotrexate autoinjector) for subcutaneous injection

Rasuvo® (methotrexate autoinjector) 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 below are met. Claims

coding will allow coverage if there is at least one claim of generically available injectable methotrexate ('vial & syringe') and an appropriate diagnosis code in the medical record.

- Otrexup or Rasuvo are prescribed by or in consultation with a rheumatologist, immunologist or dermatologist
- Member has a documented failure, contraindication or intolerance to generically available injectable methotrexate ('vial & syringe')

Initial authorizations and extension requests, if approved, will be approved for 12 months.

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. Otrexup® (Methotrexate) injection, for subcutaneous use. Prescribing Information. Ewing, NJ: Antares Pharma; April 2014. Revised December 2019.
2. 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.
3. Rasuvo (methotrexate) injection.. Chicago (IL). Medexus Pharma; 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 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

Monoclonal Antibodies for Alzheimer's Disease

Type of Policy: Drug Therapy
Prior Approval Date: 08/01/2025
Approval Date: 12/01/2025
Effective Date: 12/01/2025

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 under the medical benefit

J0172 Aduhelm (aducanumab-avwa)

J0174 Leqembi (lecanemab-irmb)

J0175 Kisunla (donanemab-azbt)

Drugs Requiring Prior Authorization under the pharmacy benefit)

Leqembi IQLIK

Overview

Aduhelm, Kisunla and 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

Indications/Criteria

Aduhelm, Kisunla, Leqembi IV and Leqembi IQLIK 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.
5. For Leqembi IV, after the member has completed 18 months of infusion, rationale and documentation are provided identifying why the member or caregiver are unable to self-administer Leqembi SQ.
6. Leqembi IQLIK
    a. The member has completed at least 18 months of Leqembi IV infusion
    b. Provider attestation that the member or caregiver can administer Leqembi IQLIK and that self-administration is reassessed with extension requests.

Initial authorization for 6 months

Extension requests may be approved up to 6 months when accompanied by a provider attestation that the member's score remained stable or improved, utilizing the same baseline assessment tool as outlined for initiation of therapy.

Medicaid Variation for Aduhelm

Before initiating aducanumab-avwa (Aduhelm®), prescribers must attest that the member 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 member 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 member 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.

Initial authorization for 6 months

Extension requests may be approved up to 6 months when accompanied by a provider attestation 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.
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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)
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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. Leqembi [package insert]. Nutley, NJ: Eisai Inc. and Biogen; Revised August 2025.
12. Kisunla [package insert]. Indianapolis, IN: Eli Lilly; Revised July 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
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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
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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
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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: **11/01/2024**

Approval Date: **08/01/2025**

Effective Date: **10/01/2025**

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)

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.

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

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. Leqembi [package insert]. Nutley, NJ: Eisai Inc. and Biogen; Revised January 2025.

12. Kisunla [package insert]. Indianapolis, IN: Eli Lilly; Revised July 2024.

MVP Health Care Medical Policy

Movement Disorders

Type of Policy: **Drug Therapy**
Prior Approval Date: **10/01/2024**
Approval Date: **07/01/2025**
Effective Date: **10/01/2025**
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.

Indications/Criteria

A. Huntington's disease

Xenazine (brand and generic), Austedo/XR 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 testingDocumentation 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).
- 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.

B. Tardive Dyskinesia

Austedo/XR and 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
- If the member is on a first-generation antipsychotic, a switch to a second-generation antipsychotic should be attempted unless clinically inappropriate.
- Documentation of baseline Abnormal Involuntary Movement Scale (AIMS)-items 1 to 8 scores

- 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. 02/2025
6. Ingrezza (valbenazine) capsules. Prescribing Information. San Diego, CA. Neurocrine Biosciences, Inc. October 2017. Revised 04/2024.
7. Xenazine (tetrabenazine) tablets. Prescribing Information. Deerfield, IL. Valeant Pharmaceuticals North America LLC. Revised 11/2019.
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

9. Chorea & Huntington's Disease. (2013). Movementdisorders.org. https://www.movementdisorders.org/MDS/About/Movement-Disorder-Overviews/Chorea--Huntingtons-Disease.htm

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

Mulpleta/Doptelet

Type of Policy: **Drug Therapy**
Prior Approval Date: **12/01/2024**
Approval Date: **07/01/2025**
Effective Date: **09/01/2025**
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 50,000mm^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 should not be administered to members with chronic immune thrombocytopenia 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
- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling

References

1. Mulpleta [package insert]. Florham Park, NJ: Shionogi Pharmaceuticals, Inc; April 2020.

2. Doptelet [package insert]. Durham, NC: AkaRx, Inc.; Revised July 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
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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: **08/01/2025**
Approval Date: **02/01/2026**
Effective Date: **02/01/2026**
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.

Drugs 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)

J2350 Ocrevus (ocrelizumab injection, 1mg)*****

J2351 Ocrevus Zunovo (ocrelizumab, subcutaneous infusion)*****

*****Prior Authorization is not required for Medicaid, Medicare and CHP members for Ocrevus and Ocrevus Zunovo

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)

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.

Aubagio:

- Is a pyrimidine synthesis inhibitor indicated for the treatment of members with relapsing forms of 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.

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.

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.

Ocrevus:

- Is a CD20-directed cytolytic antibody indicated for the treatment of members with relapsing or primary progressive forms of MS
    - See exclusions

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.

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.

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.

Indications/Criteria

1. **Ocrevus and Ocrevus Zunovo**
   Ocrevus or Ocrevus Zunovo may be considered for coverage when all of the following criteria is met:
    - Treatment is being used for an FDA- approved indication
    - Per the MVP Health Care Pharmacy Management Programs policy, Ocrevus and Ocrevus Zunovo are subject to Site of Care requirements and

must be obtained through a participating home infusion provider/specialty pharmacy, a participating MVP Provider Office or participating MVP Infusion Center. 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

- Prior authorization for Ocrevus and Ocrevus Zunovo is **not** required for Medicaid, Medicare and CHP members

2. **Non-Preferred Agents (prior authorization required):**

   Non-Preferred Agents may be considered for coverage when all of the following criteria is met:

   - See Medicaid Variation (Section 6) for Tysabri, Briumvi and Lemtrada coverage
   - See Tysabri (Section 3)
   - See Lemtrada (Section 4)
   - See Briumvi (Section 5)

- Medication is prescribed by a neurologist.
- Monitoring and REMS requirements per the prescribing information are met.
- Documentation of neurology chart notes for the past 2 years are included. Chart notes includes radiologic reports that substantiate MS diagnosis consistent with prescribing information
- Chart notes documenting previous MS treatment including timeframe used.
- Chart notes documenting a contraindication, failure or adverse effects to all preferred agents
  - Failure is defined as:
    - At least 2 relapses within the past 12 months, AND
    - MRI identifying lesion progression.
- **Initial approval** for up to 6 months
- **Extension requests** will be approved up to 12 months if the member has a continued benefit to therapy (decrease in number of relapses).
-

3. **Tysabri** (natalizumab)

Tysabri (natalizumab) may be considered for coverage when the following criteria is met:

- Provider attestation that Tysabri will be used as monotherapy
- Member meets the criteria in Section 2.
- A baseline MRI scan must be obtained prior to natalizumab and documentation must be provided with the request.
- Members must be evaluated at 3 and 6 months after the first infusion and every 6 months thereafter.
- 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
- **Initial approval** will be up to 3 infusions in 3 months.
- **Extension requests** will be approved up to 6 months if the member has a continued benefit to therapy (decrease in number of relapses).

4. **Lemtrada** (alemtuzumab)

   Lemtrada (alemtuzumab)may be considered for coverage when the following criteria is met:

   - Member meets the criteria in Section 2.
   - Documentation that the member does not have Human Immunodeficiency Virus (HIV)
   - Documentation that the member does not have an active infection.
   - **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

5. **Briumvi** (ublituximab)

   Briumvi (ublituximab) may be considered for when all the following criteria is met:

   - Member meets criteria in Section 2
   - Hepatitis B virus screening and quantitative serum immunoglobulin screening required prior to first dose
   - Documentation that the member does not have an active infection.
   - For female members of reproductive potential, a negative serum pregnancy test must be confirmed

- Provider attestation that the member has 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 participating home infusion provider/specialty pharmacy, a participating MVP Provider Office or participating MVP Infusion Center.
  i. Prior Authorization and medical justification is required for Briumvi 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, CHP and Medicaid members
- **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

6. **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 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.

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 Medicare 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 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 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
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 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:	**04/01/2025**
Approval Date:	**08/01/2025**
Effective Date:	**10/01/2025**
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.

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)

J2351 Ocrevus Zunovo (ocrelizumab, subcutaneous infusion)

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 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.

Ocrevus and Ocrevus Zunovo:

- Is a CD20-directed cytolytic antibody indicated for the treatment of members with relapsing or primary progressive forms of MS

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.

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) – see exclusion criteria
Ocrevus Zunovo

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 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.

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 approva**l 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

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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9. ECRI Health Technology Assessment Information Service. Natalizumab (Tysabri) for the Treatment of Multiple Sclerosis available at: http://www.ta.ecri. 2006.
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14. FDA Website. Available at: http://www.fda.gov/bbs/topics/NEWS/2006/NEW01380.html. Accessed on 6/6/2006.
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16. Goodin DS, Cohen BA, O'Connor P, et al. Assessment: The use of natalizumab (Tysabri) for the treatment of multiple sclerosis (an evidence-based review) : Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. *Neurology* 2008;71;766
17. Ocrevus™ (ocrelizumab) injection. Prescribing Information. South San Francisco, CA. May 2017
18. Briumvi (ublituximab). Prescribing Information. Morrisville, NC. TG Therapeutics. Revised: December 2022
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MVP Health Care Medical Policy

Cancer Guidance Program-Oncology Medication Coverage and Review

Type of Policy: **Drug/Medical Therapy**
Prior Approval Date: **11/01/2025**
Approval Date: **02/01/2026**
Effective Date: **01/01/2026**

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

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: **12/01/2025**
Approval Date: **02/01/2026**
Effective Date: **01/01/2026**

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

	Focinvez Posfrea

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

Exclusions: N/A

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

Niktimvo (axatilimab-csfr)

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

Prior Approval Date: N/A

Approval Date: 10/01/2025

Effective Date: 11/01/2025

Related Policies N/A

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

J9038 Niktimvo Solution Injection for intravenous use, axatilimab-csfr, 0.1 mg

Overview

Niktimvo is a colony stimulating factor-1 receptor (CSF-1R)-blocking antibody indicated for the treatment of chronic graft-versus-host disease (cGVHD). For adult and pediatric patients weighing ≥ 40kg, after failure of at least two prior lines of systemic therapy. Niktimvo is dosed at 0.3 mg/kg, up to a maximum dose of 35 mg, as an intravenous infusion over 30 minutes every 2 weeks until progression or unacceptable toxicity.

Indications/Criteria

A. Chronic graft-versus-host disease (cGVHD)

- Niktimvo may be considered for coverage when all of the following criteria are met:
    - Prescribed by, or in consult with an oncologist, hematologist, or another applicable specialized physician
    - Chart notes documenting the following:
        1. Confirmed diagnosis of cGVHD
        2. Weight of ≥ 40kg
        3. At least 2 prior lines of systemic therapy for cGVHD that failed to produce the desired response
    - Provider attestation indicating monitoring of aspartate aminotransferase (AST), alanine aminotransferase (ALT), alkaline phosphatase (ALP), creatine phosphokinase (CPK), amylase, and lipase prior to initiation of therapy, every 2 weeks for the first month, and every 1 to 2 months thereafter until abnormalities are resolved

Initial approval will be for up to 12 months.

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

Exclusions

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

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

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References

1. Niktimvo Prescribing Information. Wilmington, DE: Incyte Corporation; Approved 2024. Revised 01/2025.

2. Axatilimab-NIKTIMVO. In: Clinical Pharmacology [database on the Internet]. Tampa (FL): Elsevier. publication year [2025]. Available from: www.clinicalpharmacology.com. Subscription required to view.

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.
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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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MVP Health Care Medical Policy

Nuedexta

Type of Policy: **Drug Therapy**
Prior Approval Date: **11/01/2024**
Approval Date: **08/01/2025**
Effective Date: **10/01/2025**

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

- 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
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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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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

Onychomycosis

Type of Policy:	**Drug Therapy**
Prior Approval Date:	**04/01/2025**
Approval Date:	**04/01/2026**
Effective Date:	**06/01/2026**
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.

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; Initial approval 1992. Revised 03/2019.
2. Sporanox® (itraconazole) Capsules/Oral Solution. Prescribing Information. Raritan, NJ: Ortho-McNeil-Janssen Pharmaceuticals, Inc.; Revised 12/2024.
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, Revised 07/2025
5. Kerydin® (tavaborole) topical solution, 5%. Prescribing Information. Palo Alto, CA: Anacor Pharmaceuticals, Inc; Revised 04/2023.
6. Tolsura (itraconazole capsules). Prescribing Information. Greenville, NC: Maybe Pharma; Revised 10/2024.
7. 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
8. Onychomycosis: A Review. Journal of the European Academy of Dermatology and Venereology : JEADV. 2020. Gupta AK, Stec N, Summerbell RC, et al.
9. Oral Medications to Treat Toenail Fungal Infection. The Journal of the American Medical Association. 2018. Kreijkamp-Kaspers S, Hawke KL, van Driel ML.

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 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).	
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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:	02/01/2024
Approval Date:	08/01/2025
Effective Date:	10/01/2025
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 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: 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 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.

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 04/29/2025. Accessed July 6, 2025.

2. Prescribing Information. Omisirge. Gamida Cell, Inc. Boston, MA. Initial Approval 2023. Revised 01/2025. Omisirge-final-PI.pdf (gamida-cell.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
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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
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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: Omidubicel

Type of Policy:	Medical Therapy (administered by the pharmacy department)
Prior Approval Date:	02/01/2024
Approval Date:	08/01/2025
Effective Date:	10/01/2025
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

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: 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 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.

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 04/29/2025. Accessed July 6, 2025.
2. Prescribing Information. Omisirge. Gamida Cell, Inc. Boston, MA. Initial Approval 2023. Revised 01/2025. Omisirge-final-PI.pdf (gamida-cell.com)

MVP Health Care Medical Policy

Oral Allergen Immunotherapy Medications

Type of Policy: **Drug Therapy**
Prior Approval Date: **11/01/2024**
Approval Date: **08/01/2025**
Effective Date: **10/01/2025**
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.

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	5 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 December 2019.
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 2021.
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 February 2025.
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:	**08/01/2024**
Approval Date:	**07/01/2025**
Effective Date:	**09/01/2025**

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)
Adzynma (J7171, ADAMTS13, Recombinant-krhn)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)
Imaavy (nipocalimab-aahu IV)
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)
Piasky (J1307, crovalimab-akkz)
Pombiliti (J1203, cipaglucosidase alfa, powder for injection)
Poteligeo (J9204) Inj. mogamulizumab-kpkc)
Reblozyl (J0896, luspatercept-aamt, SQ injection)
Retisert® (J7311 fluocinolone acetonide, intravitreal implant)
Rivfloza Vials (C9399, J3490, nedosiran)
Rystiggo (J9333, Rozanolixizumab SQ infusion)
Scenesse (J7352, afamelanotide implant 16mg)
Sylvant (J2860 Inj, siltuximab, 10mg)
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*

***Drugs Requiring Prior Authorization (covered under the pharmacy benefit)**
Apokyn® (J0364 SQ Injection, apomorphine hydrochloride, 1 mg)
Aqneursa (levacetylleucine)
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)
Gattex® (teduglutide)
Givlaari (givosiran,189mg/mL solution for subcutaneous injection)
Gomekli (mirdametinib)
Harliku (nitisinone)
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)
Livdelzi® (seladelpar)
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)
Onapgo (apomorphine)
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)
Rivfloza Pre-Filled Syringes (nedosiran)
Rozlytrek® (entrectinib)
Ruzurgi (Amifampridine)
Signifor (SQ Injection pasireotide)
Skyclarys (omaveloxolone capsules)
Sohonos (palovarotene, oral capsules)
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)
Vonjo™ (pacritinib)
Vykat (diazoxide choline ER)
Xolremdi (mavorixafor oral capsules)
Xospata® (gilteritinib oral tablets)
Xpovio (Selinexor)
Xuriden (uridine triacetate, oral granules)
Zilbrysq (zilucoplan, subcutaneous injection)
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.

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].

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 or contracted provider office. Prior Authorization and medical justification is required for Aldurazyme, Crysvita, Elaprase, Lumizyme, Naglazyme and Xenpozyme 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/fullform.pdf

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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.

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: Orphan Drug(s) and Biologicals

Type of Policy:	**Drug/Medical Therapy**
Prior Approval Date:	**08/01/2024**
Approval Date:	**07/01/2025**
Effective Date:	**09/01/2025**

Related Policies: **Experimental or Investigational Procedures, Behavioral Health Services, Drugs & Treatments, Off-Label use of FDA Approved Drugs, Clinical Trials**

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)**

Adagen® (J2504 Inj, pegademase bovine, 25 IU)
Adzynma (J7171, ADAMTS13, Recombinant-krhn)
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)
Imaavy (nipocalimab-aahu IV)

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)
Piasky (J1307, crovalimab-akkz)
Pombiliti (J1203, cipaglucosidase alfa, powder for injection)
Poteligeo (J9204) Inj. mogamulizumab-kpkc)
Reblozyl (J0896, luspatercept-aamt, SQ injection)
Retisert® (J7311 fluocinolone acetonide, intravitreal implant)
Rivfloza Vials (C9399, J3490, nedosiran)
Rystiggo (J9333, Rozanolixizumab SQ infusion)
Scenesse (J7352, afamelanotide implant 16mg)
Sylvant (J2860 Inj, siltuximab, 10mg)
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*

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

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].

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.

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

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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.

MVP Health Care Medical Policy

Ozanimod

Type of Policy: **Drug/Medical Therapy**
Prior Approval Date: **11/01/2024**
Approval Date: **08/01/2025**
Effective Date: **10/01/2025**
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.

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
- Used in combination with immunomodulators, biologic therapy, or targeted synthetic drugs
- Myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or NYHA Class III or IV heart failure experienced in the last 6 months
- Concomitant use of a MAOI (monoamine oxidase inhibitor)
- Severe untreated sleep apnea
- Presence of Mobitz type II second-degree or third degree atrioventricular (AV) block, sick sinus syndrome, or sino-atrial block, unless the member has a functioning pacemaker

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References

1. Clinical Pharmacology

2. Zeposia (ozanimod). Prescribing Information. Summit, NJ. Celgene Corporation. Approved 2020. Revised 08/2024..

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).	
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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

Pain Medications

Type of Policy: **Drug Therapy**
Prior Approval Date: **08/01/2024**
Approval Date: **11/01/2025**
Effective Date: **01/01/2026**
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 under the Pharmacy Benefit

Additional quantities exceeding the amounts identified in the chart below will require prior authorization. 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 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.

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:

- Must have current provider- patient opioid treatment agreement
- Must have a documented pain management treatment plan that addresses taper
- Must have documented verification of Prescription Monitoring Program Registry (if available)
- Must have addressed opioid overdose risk management if MME >90
- 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:

- 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
- 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
- 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:

- Moderate to severe pain post-surgery requiring analgesia at the opioid level
- Not able to take oral medications including liquids, sublingual, etc
- Approval will be for a maximum of 5 days per surgery
- 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,
- 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

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling
- Fentanyl oral transmucosal, buccal, sublingual tablets, sublingual spray, or nasal spray dosage forms used as monotherapy
- Extended release narcotic formulations in opioid naive members or for short-term/acute use (excluding Xartemis XR).
- "As needed use" (also known as PRN) of an extended release opioid since the delivery mechanism is insufficient to treat pain immediately

- Coverage for concomitant use of long-acting pain medications without documented failure of single agents at maximal doses.
- 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.
- Combination of buprenorphine medications with opioids

References

1.
2. Actiq® (fentanyl citrate) lozenges. Prescribing Information. Salt Lake City, UT: Cephalon, Inc.; June 2012.
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.
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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).	
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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

Palforzia

Type of Policy:	**Drug Therapy**
Prior Approval Date:	**11/01/2024**
Approval Date:	**08/01/2025**
Effective Date:	**10/01/2025**
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
- 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
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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 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

Palivizumab

Type of Policy: Medical *(administered by the pharmacy department)*
Prior Approval Date: **11/01/2025**
Approval Date: **08/01/2025**
Effective Date: **10/01/2025**
Related Policies: **Immunizations Childhood, Adolescent and Adults**

Codes Requiring Prior Authorization under the Medical Benefit

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 10^{th} 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

1. Updated guidance for palivizumab prophylaxis among infants and young children at increased risk of hospitalization for respiratory syncytial virus infection. Pediatrics. 2014;134(2):415-20.
2. American Academy of Pediatrics, Respiratory Syncytial Virus. In: Pickering LK, ed. *Red Book: 2009 Report of the Committee on Infectious Diseases.* 28th ed. Elk Grove Village, IL: American Academy of Pediatrics; 2012:609-618. Available at: http://aapredbook.aappublications.org/cgi/content/full/2009/1/3.110. Accessed May 23, 2014.
3. Allen, J.: Zwerdling, et al., (2003) American Thoracic Society Documents: Statements: Statement on the care of the child with chronic lung disease of infancy and childhood. *American Journal of Respiratory Care Medicine.* 168: 356-296.
4. Synagis® (palivizumab injection). Prescribing Information. Gaithersburg, MD: Medimmune, LLC; March 2014.
5. Feltes, T.F., Cabalka, A.K., Meissner, H.C., Piazza, F.M., Carlin, D.A., Connor, E.M. Sondheimer, H.M. (2003). Palivizumab prophylaxis reduces hospitalizations due to respiratory synctial virus in young children with hemodynamically significant congenital heart disease. Journal of Pediatrics. 143(4). 532-544.
6. Robinson, R.F., Nahata, M.C. (2000) Respiratory syncytial virus (RSV) immune globuline and palivizumab for prevention of RSV infection. *Am J Health-Syst Pharm_Am J, Health-yst Pharm*_57: 259-264.
7. American Academy of Pediatrics (1998) Policy Statement: Prevention of respiratory syncytial virus infections: Indications for the use of Palivizumab and update on the use of RSV-IGIV. Pediatrics, 102(5)1211-16.
8. The Impact RSV Study Group (1988) Palivizumab, a humanized respiratory syncytial virus monoclonal antibody, reduces hospitalization from respiratory syncytial virus infection in high-risk infants. *Pediatrics,* 102(3), 531-37.
9. Interim Guidance for the Use of Palivizumab Prophylaxis to Prevent Hospitalizations From Severe Respiratory Syncytial Virus Infection During the Current Atypical Interseasonal RSV Spread. American Academy of Pediatrics. September 23, 2021. Interim Guidance for Use of Palivizumab Prophylaxis to Prevent Hospitalization from Severe Respiratory Syncytial Virus Infection During the Current Atypical Interseasonal RSV Spread (aap.org).

10. AAP releases nirsevimab guidance, calls for continued access to palivizumab. Accessed October 10, 2023. 25400.pdf (silverchair-cdn.com)
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
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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

- 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
- 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
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Student Health Plans	Prior Auth
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Vermont Products	
POS in Plan	Prior Auth
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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:	**04/01/2025**
Approval Date:	**04/01/2026**
Effective Date:	**06/01/2026**

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

- 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 01/2025.
2. 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.
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4. Etelcalcetide Utilization, Dosing Titration, and Chronic Kidney Disease-Mineral and Bone Disease (CKD-MBD) Marker Responses in US Hemodialysis Patients. American Journal of Kidney Diseases : The Official Journal of the National Kidney Foundation. 2022. Karaboyas A, Muenz D, Fuller DS, et al.

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
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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:	**12/01/2024**
Approval Date:	**12/01/2025**
Effective Date:	**02/01/2026**
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 • Excessive Duration • Refill Too Soon
Misuse	• Drug-Drug Interactions • Drug-Disease Interactions • Drug-Age Interactions • Drug-Gender Interaction
Under Use	• Under Minimum Daily Dose • 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:	**04/01/2025**
Approval Date:	**11/01/2025**
Effective Date:	**01/01/2026**

Related Policies: Orphan Drug Policy

Drugs Requiring Prior Authorization (covered under the pharmacy benefit)

Praluent (alirocumab)

Drugs Requiring Prior Authorization (covered under the medical benefit)

J1306 Leqvio (injection, inclisiran, 1mg)

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
- For Leqvio requests, members must meet the criteria in Section A, the specific applicable diagnosis criteria below and chart notes must be provided indicating the member has had a trial of self-administered PCSK9 therapy such as Praluent. Claims history will be verified.

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 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

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
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

Pharmacy Management Programs

Type of Policy: **Administrative**
Prior Approval Date: **11/01/2024**
Approval Date: **1001/2025**
Effective Date: **01/01/2026**
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.

- 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.

A. Formulary and Drug Coverage

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.

Medical benefit drugs

MVP maintains a published Medical Drug List which includes but not limited to:

- Medications that do not have utilization management requirements
- Medications with miscellaneous codes
- Medications that are excluded from the medical benefit
- New medications that have recently been introduced to the market.
- Medications that are part of the Cancer Guidance Program.

The Medical Drug list is not all inclusive of medications available for coverage on the medical benefit.

The list is reviewed, updated and published on an ongoing basis. A printed list is published after changes are approved by the P&T Committee and available on the MVP website. Medical benefit drugs that require a prior authorization are housed in their specific clinical policy rather than this list.

Medical drugs when used for an off-label use are 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.

Medical drugs that are excluded require prior authorization. For coverage determinations, requests must include documentation indicating that all other medications available through the members' pharmacy and/or medical benefit meet the following:

- Are not medically appropriate OR
- The member tried and failed all other medications OR
- The member has a contraindication to other medications.

B. 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.
- MVP Step Therapy policy has additional information regarding State specific criteria and parameters for review.

- 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

- The following applies to NY Commercial (Lg Group), NY Exchange (Small Group, Individual, Essential Plan), and VT Exchange
- Please see Government Variations section for NY CHP, Medicaid and Medicare
- 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 a contracted provider office or 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:
    - Outpatient hospital cannot buy and bill
    - Outpatient hospital cannot obtain from specialty for hospital administration

- Site of Care program excludes 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.

C. Government Programs Variations

1. 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.

2. NYS Child Health Plus (CHP)
    a. Medication request review for coverage (PA, ST, formulary exception) will be made within 24 hours of the receipt of the request.

3. 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.

Exclusions

None

MVP Health Care Medical Policy

Phenylketonuria Agents

Type of Policy:	**Drug Therapy**
Prior Approval Date:	**02/01/2025**
Approval Date:	**02/01/2026**
Effective Date:	**04/01/2026**
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
Sephience (sepiapterin) oral powder

Overview

Kuvan™ (sapropterin dihydrochloride) is indicated to reduce blood phenylalanine (Phe) levels in members with hyperphenylalaninemia (HPA) due to tetrahydrobiopterin (BH4)-responsive Phenylketonuria (PKU). Approximately 25-50% of members 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 members 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 members.

Palynziq™ is indicated in adult members 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 members with phenylketonuria. **It is only available through a REMS program.**

Sephience is a phenylalanine hydroxylase (PAH) activator indicated for the treatment of hyperphenylalaninemia (HPA) in adult and pediatric patients 1 month of age and older with sepiapterin-responsive phenylketonuria (PKU).

Indications/Criteria

For all indications, the following criteria must be met in addition to the specific drug criteria below:

- The drug must be prescribed by a specialist or prescriber with experience in the intensive management of PKU members
- Member, parents, and caregivers (if minor) are motivated to control PKU and maintain dietary restrictions
- Member 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:
- 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 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

Kuvan may be considered for initial coverage if **all** the above and following criteria are met:

- Diagnosis of phenylketonuria and current mean blood phenylalanine concentration above the upper limit of the recommended ranges which are:
  - <12 years: ≥360 µmol/L;
  - ≥12 years: ≥600 µmol/L;
  - pregnancy: ≥360 µmol/L.
- If the member 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:

- Member, including parents and caregivers (if minor), continue to be motivated to control PKU and maintain dietary restrictions
- Member adheres to follow-up appointments, 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
- Positive response with at least a 30% percent decrease of blood Phe from mean pretreatment levels continues OR Phe maintained within goal range (120–360 µmol/L for children and adults)
- Maintenance of diet which is at least as stringent as the pretreatment diet unless the dietary needs of the member have changed
- While on the sapropterin and diet, adherence was substantiated by the availability of diet logs or FFQs prior to a minimum of three (3) lab measurements within the past 6 months

Sephience may be considered for initial coverage if **all** the above and following criteria are met:

- Member has a history of failure, contraindication, or intolerance to Kuvan
- Member was adherent to both diet and previous therapy
- Diagnosis of phenylketonuria and current mean blood phenylalanine concentration above the upper limit of the recommended ranges which are:
    - ≥1 month; Phe ≥360 µmol/L within the prior 90 days

Initial authorization will be considered up to 6 months.
Continued authorization up to 12 months will be considered if documentation supports:

- Positive response with at least a 20% reduction in blood phenylalanine levels from pre-treatment baseline OR a Phe level below threshold (≤600 micromol/L)
- Member must maintain current diet and remain consistent while on therapy

Palynziq may be considered for initial coverage if **all** the above and following criteria are met:

- Member is 18 years of age or older
- Member has a history of failure, contraindication, or intolerance to Kuvan and Sephience

- Member has uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on existing management
- Member was adherent to both diet and previous therapy

Initial authorization will be considered up to 6 months.

Continued authorization up to 12 months will be considered if documentation supports:

- Positive response with at least a 20% reduction in blood phenylalanine levels from pre-treatment baseline OR a level less than 600 micromol/L
- Member must maintain current diet and remain consistent while on therapy

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Exclusions

- **Age, dose**, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling
- Concurrent PKU agent use unless during transition per package label Non-compliance or nonresponse to therapy per renewal criteria

Kuvan

- Neonates less than 1 month of age or infants < 2 years of age with blood Phe <360µmol per L
- Non-responders (i.e. do not have a decrease in blood Phe with sapropterin treatment after one month of treatment at the maximum dose)
- Previous failure of Kuvan

Palynziq

- Does not respond to a trial of 60 mg daily for 16 weeks or Phe levels above 600 micromol/L despite therapy

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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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5. Cunningham A, Bausell B, Brown M, Chapman M, DeFouw K, Ernst S, et al. Recommendations for the use of sapropterin in phenylketonuria. Mol Genet and Metab 2012;106:269-76.
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7. Palynziq™ (pegvaliase-pqpz). Prescribing Information. Novato, CA: BioMarin Pharmaceutical Inc; Approved 2018. Revised 10/2025.
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
9. Sephience (sepiapterin) [package insert]. Warren, NJ: PTC Therapeutics, Inc; Initial U.S. Approval/Publication Year: 2025. Revised: 07/2025.

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).	
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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:	**02/01/2025**
Approval Date:	**02/01/2026**
Effective Date:	**04/01/2026**
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 prescription drug coverage.

References None

MVP Health Care Medical Policy

Prademagene Zamikeracel

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

Prior Approval Date: 10/01/2025

Approval Date: 04/01/2026

Effective Date: 06/01/2026

Related Policies: Orphan Drugs 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

J3389 Zevaskyn, Topical administration, prademagene zamikeracel, per treatment

Overview

Prademagene zamikeracel is an autologous cell sheet-based gene therapy indicated for the treatment of wounds in individuals with recessive dystrophic epidermolysis bullosa (RDEB). RDEB is characterized by widespread blistering and scarring of the skin and mucosal membranes, which can lead to significant deformities and major extracutaneous involvement. Prademagene zamikeracel is composed of autologous cells from skin punch biopsies of individuals with mutations in the collagen type VII alpha 1 chain (COL7A1) gene. These cells have been modified ex vivo using a replication-incompetent retroviral vector (RVV) that carries the complete COL7A1 gene. The resulting gene-modified cell sheets express functional collagen VII (C7) protein.

Indications/Criteria

A. Recessive Dystrophic Epidermolysis Bullosa (RDEB)

Zevaskyn may be considered for coverage when all of the following criteria is met:

- Zevaskyn is prescribed by or in consultation with a dermatologist or wound care specialist
- Member is at least 6 years of age or older
- Chart notes documenting a confirmed diagnosis of recessive DEB established by genetic testing. Genetic testing must confirm two (biallelic) pathogenic mutations in the collagen type alpha 1 chain (COL7A1) gene.
    - Note: If unable to confirm a biallelic mutation with member, documentation which confirms that BOTH parents do not have any evidence of dominant disease is also acceptable.
- Chart notes documenting clinical manifestations of the RDEB which includes would location and size
- Chart notes indicating that the member has current cutaneous wound(s) which are adequate for treatment (e.g., stage 2 wounds that have an area ≥20 cm) and have been present for at least 6 months
- Chart notes indicating that the member does not have an active infection with human immunodeficiency virus (HIV), hepatitis B or hepatitis C
- Provider attestation that Zevaskyn will not be used concurrently for the same would with another disease-modifying agents indicated for DEB (e.g. birch triterpenes, beremagene geperpavecetc).
    - Please note that this does NOT include disease/wound management incidentals such as topicals, dressings, antibiotics, etc).
- Documentation that the member does not show current evidence or have a history of squamous cell carcinoma (SCC) in the area to be treated
- Provider attestation that the member has not received prior Zevaskyn treatment.
- Zevaskyn must be administered in a qualified treatment center: Find a ZEVASKYN Qualified Treatment Center

Zevaskyn will be approved as a one-time procedure per lifetime 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 Zevaskyn will not be covered for the following situations:

- Age, dose, frequency of dosing and/or duration of therapy outside of the FDA approved package labeling
- Retreatment with Zevaskyn for previously treated wounds

- More than one Zevaskyn procedure per lifetime
- Active infection with human immunodeficiency virus (HIV), hepatitis B or hepatitis C

References

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2. Zevaskyn [package insert]. Cleveland, OH: Abeona Therapeutics Inc; April 2025 Available from: ZEVASKYN_Final_Label_30Apr2025.pdf

3. Abeona Therapeutics Inc. Phase 3, Open-label Clinical Trial of EB-101 for the Treatment of Recessive Dystrophic Epidermolysis Bullosa (RDEB). December 22, 2022. Available from: Study Details | NCT04227106 | Phase 3, Open-label Clinical Trial of EB-101 for the Treatment of Recessive Dystrophic Epidermolysis Bullosa (RDEB) | ClinicalTrials.gov

Member Product	Medical Management Requirements*
New York Products	
HMO	Prior Auth
PPO in Plan	Prior Auth
PPO OOP	Prior Auth
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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).	
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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

Prescribers Treating Self or Family Members

Type of Policy:	**Drug Therapy**
Prior Approval Date:	**02/01/2025**
Approval Date:	**02/01/2026**
Effective Date:	**04/01/2026**
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.

Exclusions

None

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: **04/01/2025**
Approval Date: **05/01/2026**
Effective Date: **06/01/2026**

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: • Persons who are at high risk for preeclampsia after 12 weeks of gestation. • 81mg per day	• Age limit 12 years-59 years (preeclampsia) • Quantity Limit of 100 units/fill • Generics only • Single ingredient OTC dosages of 81mg
Folic Acid	• Daily supplement recommended for persons who are planning or capable of pregnancy. • Dose 0.4 to 0.8 mg per day	• Age limit ≤ 55 years • Quantity Limit of 100 units/fill • Generics only • 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 • Brand and generics • 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 • 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 • Generic only nicotine replacement products • Generic only bupropion • 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 years through 75 years • Rx products only • 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 • Generics and single source brands • Quantity Limit for injectable products (1/75 days, 4/300 days) • Quantity Limit for implantable=1/300 days • Quantity Limit for IUD (1/300 days) • Quantity Limit for vaginal ring (13/300 days) • 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 years and older • 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 years to 75 years • Generics only: Atorvastatin 10-20mg Fluvastatin 20-40mg Fluvastatin ER 80mg Lovastatin 10-40mg Pravastatin 10-80mg

		Rosuvastatin 5-10mg 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: o Emtricitabine/tenofovir disoproxil fumarate (generic Truvada) o Truvada (brand name requires prior authorization) o Descovy 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 years to 70 years old • Metformin 850mg (generic) • 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

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.

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MVP Health Care Medical Policy

Pulmonary Hypertension (Advanced Agents) Commercial

Type of Policy:	**Drug/Medical Therapy**
Prior Approval Date:	06/01/2025
Approval Date:	04/01/2026
Effective Date:	04/01/2026
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)
Yutrepia (Treprostinil)

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, Tadliq are 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
Yutrepia is indicated for the treatment of pulmonary arterial hypertension (PAH; WHO Group 1) to improve exercise ability and pulmonary hypertension associated with interstitial lung disease (PH-ILD; WHO Group 3) to improve exercise ability	treprostinil inhalation powder, for oral inhalation	Prostacyclin mimetic

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, Yutrepia
    - Documentation that Tyvaso, Yutrepia are 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.

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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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	Prior Auth
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).	

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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) 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.

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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14. Tyvaso® (treprostinil) inhalation solution. Prescribing Information. Research Triangle Park, NC: United Therapeutics Corp.; Apr 2013.
15. Badesch DB, Champion HC, Gomez Sanchez MA, et. al. Diagnosis and assessment of pulmonary arterial hypertension. J Am Coll Cardiol 2009;54:S55–66.
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22. Opsumit (macitentan) tablets. Prescribing Information. South San Francisco, CA: Actelion Pharmaceuticals US, Inc.; Oct 2013.

23. Orenitram (treprostinil) extended release tablets. Prescribing Information. Research Triangle Park, NC: United Therapeutics Corp; Oct 2014.
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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: **04/01/2026**

Approval Date: **06/09/2026**

Effective Date: **06/01/2026**

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.

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.**

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

ANOREXIANTS NON-AMPHETAMINE (365 days per lifetime)

- **ANTIDEMENTIA AGENTS** Zunveyl- 60 tablets per 30 days

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

- **ANTI-INFECTIVE AGENTS - MISC.** 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
- 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 - 120 capsules per 365 days

ANTI-CATAPLECTIC AGENTS (540 ML every 30 days)

- Sodium oxybate oral solution 500 mg/ml
- 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**
Aralen	Chloroquine 250mg & 500mg	16 tablets per 365 days
Coartem	Artemether/lumefantrine	24 tablets per 365 days
Krintafel	Tafenoquine succinate	2 tablets per 180 days
Malarone	Atovaquone/proguanil	42 tablets per 365 days
Mefloquine	Mefloquine	14 tablets per 365 days
Primaquine	Primaquine phosphate	46 tablets per 365 days
Qualaquin	Quinine	84 capsules per 365 days

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

Hypnotics

Name	Quantity Limit per 30 days
Doral/quazepam	30 tablets
Eszopiclone	30 tablets
Flurazepam	30 tablets
Halcion/ triazolam	30 tablets
Prosom/estazolam	30 tablets
Ramelteon	30 tablets
Restoril/temazepam	30 tablets
Doxepin 3mg, 6mg	30 tablets
Zaleplon	30 tablets
Zolpidem	30 tablets
Zolpidem ER	30 tablets

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 – 16 tablets per 30 days
- Ubrelvy – 16 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
- Ajovy- 4.5ml per 84 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

Pain Medications

Journavx- 30 tablets per 90 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

Diclofenac sodium gel 3% (actinic keratoses)	100 grams per 365 days
Diflorasone 0.05% ointment/cream	60 grams per 30 days
DOVONEX CREAM 0.005%	60 grams per 30 days
Doxepin 5%, Zonalon, Prudoxin cream	45 grams per 365 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

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 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).**
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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

Radicava

Type of Policy: **Medical Therapy** (administered by the pharmacy department)
Prior Approval Date: **11/01/2024**
Approval Date: **08/01/2025**
Effective Date: **10/01/2025**
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/formfile.aspx

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.
- 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
    a. 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 or contracted provider office. Prior Authorization and medical justification is required for Radicava obtained and administered in a non-preferred site of care (i.e. outpatient hospital setting).

        - 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)**

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. Amyotrophic lateral sclerosis (ALS). Mayo Clinic. Accessed July 2 2025. Amyotrophic lateral sclerosis (ALS) - Diagnosis and treatment - Mayo Clinic
3. ALS Functional Rating Scale Revised Guide: *Measuring progression of disability in people with ALS 1*. (n.d.). https://alspathways.com/wp-content/themes/alspathways/assets/pdf/ALS-Functional-Rating-Scale-Revised-Guide.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 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: **11/01/2024**
Approval Date: **08/01/2025**
Effective Date: **10/01/2025**
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.

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 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.
- 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. Amyotrophic lateral sclerosis (ALS). Mayo Clinic. Accessed July 2 2025. Amyotrophic lateral sclerosis (ALS) - Diagnosis and treatment - Mayo Clinic

3. ALS Functional Rating Scale Revised Guide: *Measuring progression of disability in people with ALS 1*. (n.d.). https://alspathways.com/wp-content/themes/alspathways/assets/pdf/ALS-Functional-Rating-Scale-Revised-Guide.pdf

MVP Health Care Medical Policy

Ravulizumab-cwvz

Type of Policy:	**Drug/Medical Therapy**
Prior Approval Date:	**10/01/2024**
Approval Date:	**08/01/2025**
Effective Date:	**10/01/2025**
Related Policies:	Orphan Drug(s) and Biologicals, Eculizumab

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 Ultomiris, IV Injection, ravulizumab-cwvz 300 mg/3 mL solution

J1303 Ultomiris, IV Injection, ravulizumab-cwvz 1,100 mg/11 mL solution

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 as appropriate
    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 or contracted provider office. Prior Authorization and medical justification is required for Ultomiris obtained and administered in a non-preferred site of care (i.e. outpatient hospital setting).
        1. MVP will allow 60 days after prior authorization approval for members to transfer to a preferred infusion site.
        2. 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 ≥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 show **no evidence of disease progression** while **on current regimen AND documentation of positive response** to therapy, which may include the following per applicable indication:

PNH

- Reduction in blood transfusions, stabilization in hemoglobin concentrations, reduction of exacerbations, improved quality of life scores/fatigue, and/or normalization of LDH levels

aHUS

- Normalization of LDH levels, platelet counts, improvement in renal function from baseline

gMG

- Improvement in MG-ADL score, changes compared to baseline in Quantitative Myasthenia Gravis (QMG) total score

NMOSD

- Improvement in EDSS score, decreased hospitalizations, improvement in stability, reduced plasma exchange treatments

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Exclusions

- Treatment of members with Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS)
- 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

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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. Sanders D, Wolfe G, Benatar M et al. International consensus guidance for management of myasthenia gravis. Neurology. 2021; 96 (3) 114-122.
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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	
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

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.
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MVP DualAccess D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
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UVM Health Advantage Select 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
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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: 10/01/2024
Approval Date: 10/01/2025
Effective Date: 12/01/2025

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, hepatologist, or endocrinologist
- 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.

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

5. REZDIFFRA [package insert]. West Conshohocken, PA: Madrigal Pharmaceuticals, Inc.; Initial U.S. Approval/Publication Year: 2024. Revised: 03/2024.

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 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

Revakinagene Taroretcel

Type of Policy: Drug/Medical therapy (administered by the pharmacy department)
Prior Approval Date: 08/01/2025
Approval Date: 04/01/2026
Effective Date: 06/01/2026
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 medical benefit

J3403 Encelto (Revakinagene Taroretcel, ophthalmic implant)

Overview

Revakinagene Taroretcel (Encelto) is an encapsulated cell-based gene therapy indicated for one time use. It is approved for adults with idiopathic macular telangiectasia type 2 (MacTel). It is a small capsule, about the size of a grain of rice, that is placed inside the eye to release a protein called recombinant human ciliary neurotrophic factor (rhCNTF) that can directly reach the retina, the light sensitive part of the eye. The capsule contains living cells that have been genetically modified to continuously produce and release rhCNTF. This protein helps protect certain cells in the retina, supporting their health and reducing the loss of light-sensing cells known as photoreceptors.

Indications/Criteria

A. Idiopathic Macular Telangiectasia Type 2 (MacTel)

Encelto may be considered for coverage when all of the following criteria is met:

- Chart notes documenting a confirmed diagnosis of MacTel type 2 in at least one eye. Examination and diagnostic imaging results supporting the

diagnosis must be included (i.e. Optical Coherence Tomography (OCT), OCT angiography, Fluorescein Angiography, Fundus Autofluorescence)
- Chart notes documenting photoreceptor inner segment/outer segment 395 (IS/OS PR) break (loss) in ellipsoid zone (EZ) between 0.16 and 2.00 mm2
- Current chart notes documenting that the member has a best corrected visual acuity (BCVA) of 54-letter score or better using the Early Treatment Diabetic Retinopathy Study (ETDRS) charts OR member has best corrected visual acuity (BVCA) of 20/80 or better using the Snellen chart.
- Provider attestation that the member does not have current ocular or periocular infections
- Documentation that Encelto is prescribed and administered by an ophthalmologist
- Provider attestation that the member will be monitored post administration for the following:
    - Infectious endophthalmitis
    - Retinal tear and detachment
    - Vitreous hemorrhage
    - Implant extrusion

Encelto will be approved as a one-time dose per affected eye 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 implantation.

Exclusions

The use of Encelto will not be covered for the following situations:
- Members with neovascular MacTel
- Member is currently receiving intravitreal anti-VEGF therapy
- Retreatment of Encelto for a previously treated eye
- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling

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References

1. Sadeghi E, Venkatesh R, Chhablani J. Diagnostic pearls for MacTel type 2. *Retina Today*. 2025 Apr. Available from: Diagnostic Pearls for MacTel Type 2 - Retina Today

2. Encelto™ intravitreal implant [prescribing information]. Cumberland, RI: Neurotech; March 2025

3. Turbert D. What is macular telangiectasia? *American Academy of Ophthalmology*. 2024 Sep 23 [cited 2025 Jul 7]. Available from: https://www.aao.org/eye-health/diseases/macular-telangiectasia

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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USA Care PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
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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).	

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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:	**10/01/2024**
Approval Date:	**10/01/2025**
Effective Date:	**12/01/2025**
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.

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.

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 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 are 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 are 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 are 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

1. Skyrizi (risankizumab) injection package insert. North Chicago, IL: AbbVie Inc.; Approved 2019. Revised 05/2025.

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)

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: Risankizumab

Type of Policy:	**Drug/Medical Therapy**
Prior Approval Date:	**10/01/2024**
Approval Date:	**10/01/2025**
Effective Date:	**12/01/2025**
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 are 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 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.

C. Plaque Psoriasis

Risankizumab may be considered for coverage for Plaque Psoriasis when the following criteria are 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 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 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.

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:	**04/01/2025**
Approval Date:	**04/01/2026**
Effective Date:	**06/01/2026**
Related Policies:	Cosmetic Drug Agents, 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.

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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2. National Institute of Arthritis and Musculoskeletal and Skin Diseases. Alopecia Areata - Hair loss Causes & Living With It | NIAMS (nih.gov). Last reviewed 8/2024. Accessed 02/27/2026.
3. American Academy of Dermatology Association. Revised 08/22/2024. Accessed 02/27/2026. Hair loss types: Alopecia areata diagnosis and treatment (aad.org)
4. Litfulo. Prescribing Information. Pfizer Labs. Division of Pzifer Inc. New York, NY. Initial approval: 2023 Revised June 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 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).	
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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

Secukinumab

Type of Policy:	**Drug/Medical Therapy**
Prior Approval Date:	**10/01/2024**
Approval Date:	**10/01/2025**
Effective Date:	**12/01/2025**
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 indications including ankylosing spondylitis, psoriasis, psoriatic arthritis, enthesitis-related arthritis (ERA), and hidradenitis suppurativa (HS). 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 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 NSAID 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 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

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) **AND**
- Failure or contraindication to clinically appropriate antibiotic **OR**
- Failure or contraindication to clinically appropriate TNF inhibitor

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. Approved 2015. Revised 08/2025.
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

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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
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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

Medicare Part B: Secukinumab

Type of Policy:	**Drug/Medical Therapy**
Prior Approval Date:	**02/01/2024**
Approval Date:	**10/01/2025**
Effective Date:	**12/01/2025**

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 NSAID 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.

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. Secukinumab. Revised 11/02/2023. Accessed 01/04/2024.
2. Cosentyx (secukinumab) injection. Prescribing Information. East Hanover, NJ. Novartis Pharmaceuticals Corporation. Approved 2015. Revised 08/2025.
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: **12/01/2024**
Approval Date: **07/01/2025**
Effective Date: **09/01/2025**

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

- 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
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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 Immunomodulating Agents

Type of Policy:	**Drug Therapy**
Prior Approval Date:	**07/01/2025**
Approval Date:	**06/01/2026**
Effective Date:	**04/01/2026**
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) pre-filled syringe
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 and Fasenra are also indicated for adult patients with eosinophilic granulomatosis with polyangiitis (EGPA). Nucala is also indicated for add-on maintenance treatment of adult patients with chronic rhinosinusitis with nasal polyps

(CRSwNP), add-on maintenance treatment of adult patients with inadequately controlled chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype, and patients with hypereosinophilic syndrome (HES) for greater than or equal to 6 months without an identifiable non-hematologic secondary cause.

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 and for the add-on maintenance treatment of adult and pediatric patients aged 12 years and older with inadequately controlled chronic rhinosinusitis with nasal polyps (CRSwNP)

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: NYRX: Medicaid Pharmacy List of Reimbursable Drugs . 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:Member must have a peripheral blood eosinophil count of at least 400 cells/microliter in the past 30 days **OR**
- Memberis 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 asthma control 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 **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 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.

B. Eosinophilic Granulomatosis with Polyangiitis

Nucala or Fasenra 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 may be considered for coverage when:
- 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 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.

C. Chronic Rhinosinusitis with Nasal Polyps

Nucala or Tezspire 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 irrigationsor antileukotriene agents (montelukast, zafirlukast, zileuton).
- Documentation of prior oral corticosteroid therapy and/or sinus surgery
- Nucala or Tezspire will be add on maintenance in combination with an intranasal corticosteroid
- 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 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 immunologist
- Member has 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
- 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 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.

E. Chronic Obstructive Pulmonary Disease (COPD) with an eosinophilic phenotype

Nucala will be considered for the coverage of adults **inadequately controlled** chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype when all of the following are met:

- Confirmed diagnosis of COPD
- Member is followed by an allergist, immunologist or pulmonologist
- Member has eosinophilic phenotype with eosinophil count ≥300 cells/microliter
- 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)

- Provider attestation that Nucala will be add on maintenance treatment
- 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 12 months

Continued authorization for up to 3 years will be considered if there is a documented decrease in symptoms and exacerbations, continued eosinophilic phenotype, and ongoing adherence to maintenance therapy

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
-
- Age, dose, frequency of dosing, and/or duration of therapyoutside of 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
- 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. August 2007.

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4. Nucala (mepolizumab) for injection. Prescribing Information. Philadelphia, PA. GlaxoSmith Kline LLC. Revised 08/2025.
5. Cinqair (reslizumab) injection. Prescribing Information. West Chester, PA. Teva Respiratory LLC. Revised 02/2020.
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.
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9. Global Strategy for Asthma Management and Prevention. 2023 Update. GINA Main Report 2023 Front Cover (ginasthma.org). 2023 GINA Main Report - Global Initiative for Asthma - GINA
10. Prescribing Information. Tezspire (Tezepelumab-ekko). Thousand Oaks, CA. AstraZeneca and Amgen. Revised 10/2025.
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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 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).	
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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: Select Immunomodulating Agents

Type of Policy: **Drug Therapy**
Prior Approval Date: **07/01/2025**
Approval Date: **06/01/2026**
Effective Date: **04/01/2026**
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) auto injector

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

Refer to relevant CMS LCDs/NCDs/Policy Articles for most up to date Medicare Part B guidance if available

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 and Fasenra are also indicated for adult patients with eosinophilic granulomatosis with polyangiitis (EGPA). Nucala is also indicated for add-on maintenance treatment of adult patients with chronic rhinosinusitis with nasal polyps (CRSwNP), add-on maintenance treatment of adult patients with inadequately controlled chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype, and patients with hypereosinophilic syndrome (HES) for greater than or equal to 6 months without an identifiable non-hematologic secondary cause.

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 **drug specific 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

Nucala, Cinqair, 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 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 or Fasenra 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 may be considered for coverage when:

- 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 symptoms and exacerbations

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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 surgeryNucala will be add on maintenance in combination with an intranasal corticosteroid

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 12 months 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 has 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 12 months will be based upon a positive clinical response including a decrease in HES flares as well as documentation of decreasing eosinophil count from baseline.

E. Chronic Obstructive Pulmonary Disease (COPD) with an eosinophilic phenotype

Nucala will be considered for the coverage of adults **inadequately controlled** chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype when all of the following are met:

- Confirmed diagnosis of COPD
- Member is followed by an allergist, immunologist or pulmonologist
- Member has eosinophilic phenotype with eosinophil count ≥300 cells/microliter
- 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)
- Provider attestation that Nucala will be add on maintenance treatment

Provider administered medications under the medical benefit may be considered for coverage when:

- 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 12 months

Continued authorization for up to 12 months will be considered if there is a documented decrease in symptoms and exacerbations, continued eosinophilic phenotype, and ongoing adherence to maintenance therapy

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Exclusions

- Nucala
    1. For hypereosinophilic syndrome (HES):
        - Members with non-hematologic secondary HES or FIP1L1-PDGFRα kinase positive HES
- Age, dose, frequency of dosing, and/or duration of therapy outside of 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
- 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. August 2007. Available at: Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma
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. Revised 08/2025.
5. Cinqair (reslizumab) injection. Prescribing Information. West Chester, PA. Teva Respiratory LLC. Revised 02/2020.
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. Revised 09/2024.

8. Global Strategy for Asthma Management and Prevention. 2023 Update. GINA Main Report 2023 Front Cover (ginasthma.org). 2023 GINA Main Report - Global Initiative for Asthma - GINA
9. Keating MK, Phillips JC, Phillips J. Chronic Rhinosinusitis. Am Fam Physician. 2023 Oct;108(4):370-377. PMID: 37843944.

MVP Health Care Medical Policy

Skysona

Type of Policy:	**Drug/Medical Therapy**
Prior Approval Date:	**12/01/2024**
Approval Date:	**12/01/2025**
Effective Date:	**02/01/2026**
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 a one time 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) without an available human leukocyte antigen (HLA)-matched donor for allogeneic hematopoietic stem cell transplant. 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.

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:
    - No human leukocyte antigen (HLA)-matched donor for allogeneic hematopoietic stem cell transplant available
    - 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 biological 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
- Confirmation that member has not received any vaccinations at least 6 weeks prior to the start of myeloablative conditioning
- Confirmation that member has been assessed for hepatic and renal impairment to ensure hematopoietic stem cell (HSC) transplantation is appropriate
    - Can be confirmed by recent bloodwork (review LFTs, total bilirubin, eGFR)
- Provider attestation that full myeloablative and lymphodepleting conditioning would be administered prior to infusion of Skysona.
- Provider attestation that member will be monitored closely for evidence of malignancy through complete blood counts at least every 3 months and through assessments for evidence for clonal expansion or predominance at least twice in the first year after Skysona administration and annually thereafter
- 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
- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling
- For treatment of CALD secondary to head trauma
- For treatment or prevention of adrenal insufficiency
- 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)

References

1. Skysona (elivaldogene autotemcel) suspension for intravenous infusion. Prescribing Information. Somerville, MA: Bluebird Bio, Inc; 2022. Revised August 2025.

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 Medicare 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 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 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
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 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:	**12/01/2024**
Approval Date:	**12/01/2025**
Effective Date:	**02/01/2026**
Related Policies:	**N/A**

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 Skysona (elivaldogene autotemcel)

Overview/Summary of Evidence

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) without an available human leukocyte antigen (HLA)-matched donor for allogeneic hematopoietic stem cell transplant. 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.

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:
    - No human leukocyte antigen (HLA)-matched donor for allogeneic hematopoietic stem cell transplant available
    - 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 biological 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
- Confirmation that member has not received any vaccinations at least 6 weeks prior to the start of myeloablative conditioning
- Confirmation that member has been assessed for hepatic and renal impairment to ensure hematopoietic stem cell (HSC) transplantation is appropriate
    - Can be confirmed by recent bloodwork (review LFTs, total bilirubin, eGFR)
- Provider attestation that full myeloablative and lymphodepleting conditioning would be administered prior to infusion of Skysona.
- Provider attestation that member will be monitored closely for evidence of malignancy through complete blood counts at least every 3 months and through assessments for evidence for clonal expansion or predominance at least twice in the first year after Skysona administration and annually thereafter
- 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
- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling
- For treatment of CALD secondary to head trauma
- For treatment or prevention of adrenal insufficiency
- 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)

References

1. Skysona (elivaldogene autotemcel) suspension for intravenous infusion. Prescribing Information. Somerville, MA: Bluebird Bio, Inc; 2022. Revised August 2025.
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

Spesolimab

Type of Policy:	**Drug Therapy**
Prior Approval Date:	**04/01/2025**
Approval Date:	**04/01/2026**
Effective Date:	**06/01/2026**
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

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) in adults and pediatric patients 12 years of age and older and weighing at least 40 kg. Intravenous (IV) Spesolimab is used for treatment of acute GPP flares, and subcutaneous (SC) Spesolimab is used for treatment of GPP when not experiencing a flare, including prevention of future flares. The IV dosage form 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 immunological and infectious disease prior to initiating therapy including TB screening. Members must 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

IV 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
- Chart notes are provided documenting all of the following:
  - Current acute GPP flare
    - Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) score of at least 3-[GPPPGA scores range from 0 (clear) to 4 (severe)]
    - At least 5% of body surface area covered with erythema and presence of pustules
    - 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
- Medication is ordered by or with consult from a dermatologist or rheumatologist
- 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 IV **Spevigo for GPP Flare** above are met
- 4 weeks have passed since treatment with loading dose of 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

    - 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**

Exclusions

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

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

References

1. Spesolimab. Clinical Pharmacology. Revision date 10/23/2025. Accessed on 03/2026.
2. Spevigo (spesolimab-sbzo) injection, for subcutaneous or intravenous use. Prescribing Information. Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT. Revised 10/2025.
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.
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6. Spesolimab for Generalized Pustular Psoriasis: A Review of Two Key Clinical Trials Supporting Initial US Regulatory Approval. Frontiers in Immunology. 2024. Gwillim EC, Nichols AJ.

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).	
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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: Spesolimab

Type of Policy:	**Drug Therapy**
Prior Approval Date:	**04/01/2025**
Approval Date:	**04/01/2026**
Effective Date:	**06/01/2026**

Related Policies: N/A

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

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) in adults and pediatric patients 12 years of age and older and weighing at least 40 kg. Intravenous (IV) Spesolimab is used for treatment of acute GPP flares, and subcutaneous (SC) Spesolimab is used for treatment of GPP when not experiencing a flare, including prevention of future flares. The IV dosage form 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 immunological and infectious disease prior to initiating therapy including TB screening. Membersavoid 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

IV 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
- Chart notes are provided documenting all of the following:
  - Current acute GPP flare
    - Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) score of at least 3- [GPPPGA scores range from 0 (clear) to 4 (severe)]
    - At least 5% of body surface area covered with erythema and presence of pustules
    - 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
- Medication is ordered by or with consult from a dermatologist or rheumatologist
- 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 IV **Spevigo for GPP Flare** above are met
- 4 weeks have passed since treatment with loading dose of 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

    - 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**

Exclusions

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

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

References

1. Spesolimab. Clinical Pharmacology. Revision date 10/23/2025. Accessed on 02/26/2026.
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MVP Health Care Medical Policy

Spinal Muscular Atrophy

Type of Policy:	**Medical Therapy *(administered by the pharmacy department)***
Prior Approval Date:	**04/01/2026**
Approval Date:	**05/01/2026**
Effective Date:	**05/01/2026**
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 medical benefit

J2326 Spinraza (Nusinersen) 12mg, 28mg, 50mg

J3399 Zolgensma (Onasemnogene abeparvovex-xioi)

J3590 Itvisma (Onasemnogene Abeparvovec, Suspension for injection, intrathecal)

Drugs Requiring Prior Authorization 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

Spinal Muscular Atrophy (SMA) is a progressive genetic disorder that causes the loss of nerve cells called motor neurons in the spinal cord. The muscles, in turn, do not receive signals from the motor neurons which leads to muscle atrophy (wasting). The most common form of SMA is chromosome 5-related SMA which is caused for a deficiency of a motor neuron protein called SMN. The gene affected by SMA is SMN (SMN1 and SMN2). SMN1 produces the majority of SMN protein. SMN2 produces a small amount of

functional SMN protein. There are several therapies that target the SMN1 and SMN2 genes for the treatment of SMA

Spinraza is an intrathecally administered survival motor neuron-2 (SMN2)-directed antisense oligonucleotide. It is approved for both pediatric and adult patients. Nusinersen is the first drug to be approved to treat pediatric and adult patients with spinal muscular atrophy (SMA). It is designed to treat spinal muscular atrophy (SMA) caused by mutations in chromosome 5q that lead to SMN protein deficiency. Nusinersen increases exon 7 inclusion in SMN2 messenger ribonucleic acid (mRNA) transcripts and production of full-length SMN protein

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. 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 survival. Zolgensma (Onasemnogene abeparvovex-xioi) was granted breakthrough therapy and priority review by the FDA.

Itvisma is the intrathecal formulation of Onasemnogene Abeparvovec. It is indicated in a wider patient population of patients 2 years old and older including adult patients.

Patients who were previously treated with Zolgensma (intravenuous formulation) should not be treated with the intrathecal formulation (Itvisma).

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.

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 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)
- Chart notes documenting previous SMN- targeting treatments such as Evrysdi, Zolgensma or Itvisma

    - For members aged 2 years old to less than 18 years old, Spinraza therapy **prior** to Itvisma therapy is acceptable for coverage criteria based on the STRENGTH study (NCT05386680).
    - For all members regardless of age, Spinraza therapy **after** Zolgensma or Itvisma therapy has not been studied and is excluded from coverage unless there are current chart notes documenting functional decline.
    - Combination therapy with Evrysdi is excluded from coverage

For Spinraza 12mg (low dose regimen), initial approval will be for 3 months, 4 doses to determine the efficacy of the treatment. Coverage of lost, damaged, or mishandled product will not be covered.

For Spinraza 28mg, 50mg (high dose regimen), initial approval will be for 3 months, 2 doses to determine the efficacy of the treatment. Coverage of lost, damaged, or mishandled product will not be covered.

Extension requests for Spinraza (both low dose and high dose regimens) 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)
- Coverage of lost, damaged, or mishandled product will not be covered.

B. ZOLGENSMA

Zolgensma will be considered for coverage when the following criteria is met:

- Member is < 2 years old
- Chart notes documenting previous SMN- targeting treatments such as Evrysdi, Spinraza, or Itvisma:

  - Zolgensma therapy is excluded from coverage when the member has had prior therapy with Itvisma.

- Chart notes documenting the member has a confirmed diagnosis of SMA

- Chart notes are provided documenting 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. Coverage of lost, damaged, or mishandled product will not be covered.

C. Itvisma

Itvisma will be considered for coverage when all the following criteria is met:

- Member is within the age requirement of 2 years of age or older.
- Chart notes documenting the member has a confirmed diagnosis of SMA
- Chart notes documenting previous SMN- targeting treatments such as Evrysdi, Spinraza, or Zolgensma
    - For members aged 2 years old to less than 18 years old, Spinraza or Evrysdi therapy **prior** to Itvisma therapy is acceptable for coverage criteria based on the STRENGTH study (NCT05386680).
    - For all members regardless of age, Spinraza or Evrysdi therapy **after** Itvisma therapy has not been studied and is excluded from coverage unless there are current chart notes documenting functional decline.
    - Itvisma therapy is excluded from coverage when the member has had prior therapy with Zolgensma.
- Chart notes indicating that the member can sit independently
- Chart notes are provided documenting genetic testing that indicates:
    - Bi-allelic gene mutation of *SMN1*
- Itvisma is prescribed by a neurologist or geneticist
- Member 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

Itvisma will be approved as a **one-time dose** and will not need to be continued for maintenance. Coverage of lost, damaged, or mishandled product will not be covered.

D. EVRYSDI

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)
- Chart notes documenting previous SMN- targeting treatments such as Spinraza, Zolgensma or Itvisma
  - For members aged 2 years old to less than 18 years old, Evrsydi therapy **prior** to Itvisma therapy is acceptable for coverage criteria based on the STRENGTH study (NCT05386680).
  - For all members regardless of age, Evrsydi therapy **after** Zolgensma or Itvisma therapy has not been studied and is excluded from coverage unless there are current chart notes documenting functional decline.
  - Combination therapy with Spinraza is excluded from coverage

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
- Combination therapy with Evrysdi

II. **Zolgensma and Itvisma (onasemnogene abeparvovex-xioi)**-are 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 or Evrsydi
- 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 member 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

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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
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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).**
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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
J0013, 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.

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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
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: 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
J0013 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

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- 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.

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.
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MVP Health Care Medical Policy

Step Therapy

Type of Policy: Drug therapy (administered by the pharmacy department)
Prior Approval Date: NA
Approval Date: 10/01/2025
Effective Date: 01/01/2026
Related Policies: Pharmacy Programs Management

This policy applies to the following:

Drugs with a "ST" designation on the MVP Commercial, Self-Funded and MVP Marketplace formularies

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

Overview

The Plan is committed to offering a comprehensive, cost-effective pharmacy benefit to those members and employer groups that elect prescription drug coverage. MVP may require the member to try select medications prior to approval of other medications to treat the medical condition (a step therapy protocol). We will use recognized evidence-based and peer reviewed clinical review criteria that is appropriate for the medical condition. The criteria outlined in this policy are based on current State regulations governing step therapy protocols. This policy will be reviewed annually by the Pharmacy & Therapeutics (P&T) committee. This policy will apply to the MVP Commercial, Marketplace and Self-Funded formularies.

Step Therapy Criteria

A. New York

A step therapy protocol override request will be granted when it includes supporting rationale and documentation from a requesting health care professional. Step therapy protocol override requests are reviewed within the following parameters:

- Trial and failure on up to two (2) prescription drugs to treat the member's medical condition or disease.
- Medications required within a step therapy protocol will be FDA approved or supported by current evidence-based guidelines for the member's medical condition.
- The step therapy protocol will not apply if a therapeutic equivalent to the requested Prescription Drug is not available.
- The step therapy protocol will not apply if the requested Prescription Drug has been covered by the member's plan within the last 365 days.
- The step-therapy protocol will not apply for more than thirty days, or the duration of treatment supported by current evidence-based treatment guidelines for the member's medical condition
- For members new to the plan who completed step therapy protocol with a previous health plan within the last 365 days, the step-therapy protocol will not apply for the requested Prescription Drug. Documentation demonstrating previous step therapy use must be submitted.
- If a step therapy override is granted and the Plan implements a formulary or utilization management change that impacts the step therapy protocol, no changes to the previously approved authorization will be allowed until the override authorization expires unless there is a specifically identified and current evidence based safety concerns and a therapeutic alternative Prescription Drug exists

Requests are approved for 12 months or treatment duration based on current evidence-based guidelines

B. Vermont

Per Vermont H.766, a step therapy protocol override prior authorization request will be granted when it includes supporting rationale and documentation from a requesting health care professional, demonstrating that:

- The member is stable on a prescription drug
- Failure, including discontinuation due to lack of efficacy or effectiveness, diminished effect, or an adverse event, on the same medication on more than one occasion for members who are continuously enrolled in a plan will not be required.
- The member has already tried the prescription drugs on the step therapy protocol, or other medications in the same pharmacologic class or with the same mechanism of action, which have been discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event.
- The medication required under the step-therapy protocol is contraindicated or will likely cause an adverse reaction or physical or mental harm.
- The medication required under the step-therapy protocol is expected to be ineffective based on the member's known clinical history, condition, and prescription drug regimen.
- The step-therapy protocol or a prescription drug required under the protocol is not in the member's best interests because it will: (I) pose a barrier to adherence; (II) likely worsen a comorbid condition; or (III) likely decrease the member's ability to achieve or maintain reasonable functional ability.

Initial requests and extensions are approved for 12 months or treatment duration based on current evidence-based guidelines

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References

1. **New York State Senate.** Senate Bill S1267A: An act to amend the insurance law and the public health law, in relation to requiring a utilization review agent to follow certain rules when establishing a step therapy protocol. Albany (NY): New York State Senate; 2023 [cited 2025 Jul 29]. Available from: https://legislation.nysenate.gov/pdf/bills/2023/S1267A
2. **Vermont General Assembly.** House Bill H0766: An act relating to prior authorization and step therapy requirements, health insurance claims, and provider contracts. Montpelier (VT): Vermont General Assembly; 2023 [cited 2025 Jul 29]. Available from: https://legiscan.com/VT/text/H0766/2023

MVP Health Care Medical Policy

Syfovre

Type of Policy:	**Medical Therapy**
Prior Approval Date:	**04/01/2025**
Approval Date:	**04/01/2026**
Effective Date:	**06/01/2026**

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.

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 10/14/2025. Accessed 02/26/2026.
2. Syfovre (pegcetacoplan). Prescribing Information. Apellis Pharmaceuticals, Inc. Waltham, MA. Revised 07/2025. PI_SYFOVRE.pdf (apellis.com).
3. Prevent Blindness (n.d.). *Eye Diseases & Conditions*. Retrieved 02/26/2026, from https://preventblindness.org/geographic-atrophy/
4. Age-related macular degeneration Preferred Practice Pattern 2024. *American Academy of Ophthalmology*. Retrieved February 6, 2026, from https://www.aao.org/education/preferred-practice-pattern/age-related-macular-degeneration-ppp

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
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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 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
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MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
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ASO	See SPD
Vermont Products	
POS in Plan	Prior Auth
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MVP VT HDHP HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
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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

Medicare Part B: Syfovre

Type of Policy:	**Medical Therapy**
Prior Approval Date:	**04/01/2026**
Approval Date:	**04/01/2026**
Effective Date:	**06/01/2026**

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 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

J2781 Syfovre (pegcetacoplan) solution for injection

Overview

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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 10/14/2025. Accessed 02/26/2026.
2. Syfovre (pegcetacoplan). Prescribing Information. Apellis Pharmaceuticals, Inc. Waltham, MA. Revised 07/2025. PI_SYFOVRE.pdf (apellis.com).
3. Prevent Blindness (n.d.). *Eye Diseases & Conditions*. Retrieved 02/26/2026, from https://preventblindness.org/geographic-atrophy/
4. Age-related macular degeneration Preferred Practice Pattern 2024. *American Academy of Ophthalmology*. Retrieved February 6, 2026, from https://www.aao.org/education/preferred-practice-pattern/age-related-macular-degeneration-ppp

MVP Health Care Medical Policy

Tadalafil for BPH

Type of Policy:	Drug Therapy
Prior Approval Date:	08/01/2024
Approval Date:	11/01/2025
Effective Date:	01/01/2026
Related Policies:	Quantity Limit for Prescription Drugs Pharmacy Programs Administration 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.

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	

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 member 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
- Brand Cialis 2.5mg or 5mg requires failure or intolerance to an adequate trial of generic tadalafil

Initial authorization will be for 12 months

Extension requests will be approved for 12 months if the member has a continued benefit to therapy and there is 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)
- 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
- Greater than a 30-day supply per fill

References

1. Cialis® (tadalafil). Prescribing Information. Indianapolis, IN: Eli Lilly and Company; April 2023.
2. Sandhu JS, Bixler BR, Dahm P, et al. Management of lower urinary tract symptoms attributed to benign prostatic hyperplasia (BPH): AUA Guideline amendment 2023. J Urol. 2023;10.1097/JU.0000000000003698. https://doi.org/10.1097/JU.0000000000003698
3. Lerner LB, McVary KT, Barry MJ, Bixler BR, Dahm P, Das AK, Gandhi MC, Kaplan SA, Kohler TS, Martin L, Parsons JK, Roehrborn CG, Stoffel JT, Welliver C, Wilt TJ. Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia: AUA GUIDELINE PART I-Initial Work-up and Medical Management. J Urol. 2021 Oct;206(4):806-817. doi: 10.1097/JU.0000000000002183. Epub 2021 Aug 13. Erratum in: J Urol. 2021 Nov;206(5):1339. PMID: 34384237.

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

TECELRA® (afamitresgene autoleucel)

Type of Policy:	Drug/Medical Therapy (administered by the pharmacy department)
Prior Approval Date:	12/01/2024
Approval Date:	08/01/2025
Effective Date:	10/01/2025
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. 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

- 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
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	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.
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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.
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MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	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	

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: TECELRA® (afamitresgene autoleucel)

Type of Policy:	Drug/Medical Therapy (administered by the pharmacy department)
Prior Approval Date:	12/01/2024
Approval Date:	08/01/2025
Effective Date:	10/01/2025
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).

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. 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

- 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:	**02/01/2025**
Approval Date:	**02/01/2026**
Effective Date:	**04/01/2026**
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 members 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 members 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 members, 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.
- Site of Care

    a. 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 or contracted provider office. Prior Authorization and medical justification is required for Tepezza 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 and Medicaid, CHP 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.

Exclusions

- Prior surgical treatment for Thyroid Eye Disease
- Age, dose, frequency of dosing and/or duration of therapy outside of FDA approved labeling.

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

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).	

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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:	**02/01/2025**
Approval Date:	**02/01/2026**
Effective Date:	**04/01/2026**
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 members 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 members 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 members, 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.

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

MVP Health Care Medical Policy

Teplizumab-mzwv

Type of Policy:	**Drug Therapy**
Prior Approval Date:	**02/01/2025**
Approval Date:	**02/01/2026**
Effective Date:	**04/01/2026**
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 members 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 members with active serious infection or chronic infection, other than localized skin infections, or in members 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.; Approved 2022. Revised 04/2025.
2. Berold KC, Bundy BN, Long SA, et al. An Anti-CD3 Antibody, Teplizumab, in Relatives at Risk for Type 1 Diabetes [published correction appears in N Engl J Med. 2020 Feb 6;382(6):586]. N Engl J Med. 2019;381(7):603-613. doi:10.1056/NEJMoa1902226.

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
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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.
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).	

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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:	**02/01/2025**
Approval Date:	**02/01/2026**
Effective Date:	**04/01/2026**
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 members 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 members with active serious infection or chronic infection, other than localized skin infections, or in members 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.
2. Berold KC, Bundy BN, Long SA, et al. An Anti-CD3 Antibody, Teplizumab, in Relatives at Risk for Type 1 Diabetes [published correction appears in N Engl J Med. 2020 Feb 6;382(6):586]. N Engl J Med. 2019;381(7):603-613. doi:10.1056/NEJMoa1902226.

MVP Health Care Medical Policy

Tocilizumab

Type of Policy:	**Medical Therapy**
Prior Approval Date:	**02/01/2024**
Approval Date:	**02/01/2026**
Effective Date:	**04/01/2026**
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

Tyenne SQ is non-preferred under the pharmacy benefit

Drugs Requiring Prior Authorization under the medical benefit

J3262 tocilizumab, 1mg injection (Actemra injection)

Q5133 Injection, tocilizumab-bavi, biosimilar, 1 mg (Tofidence)

Q5135 Injection, tocilizumab-aazg, biosimilar, 1 mg (Tyenne)

Q5156 Injection, tocilizumab-anoh, biosimilar, 1 mg (Avtozma)

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.

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, Tyenne) 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

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.

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 12/12/2025. Accessed 12/23/2025
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 2025.
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. Tyenne (tocilizumab-aazg). Prescribing Information. Fresenius Kabi, Lake Zurich, IL. Revised February 2025.
6. Tofidence (tocilizumab-bavi). Prescribing Information. Biogen MA Inc. Cambridge, MA. Revised March 2025.
7. Avtozma. Celltrion. Prescribing Information. Incheon, Republic of Korea. Revised July 2025.

8. Maz, M., Chung, S. A., Abril, A., Langford, C. A., Gorelik, M., Guyatt, G., ... & Mustafa, R. A. (2021). *2021 American College of Rheumatology/Vasculitis Foundation guideline for the management of giant cell arteritis and Takayasu arteritis*. **Arthritis Care & Research, 73**(8), 1071–1087. https://doi.org/10.1002/acr.24632

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).	
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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: Tocilizumab

Type of Policy:	**Medical Therapy**
Prior Approval Date:	**02/01/2024**
Approval Date:	**02/01/2026**
Effective Date:	**04/01/2026**
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)

Q5133 Injection, tocilizumab-bavi, biosimilar, 1 mg (Tofidence)

Q5135 Injection, tocilizumab-aazg, biosimilar, 1 mg (Tyenne)

Q5156 Injection, tocilizumab-anoh, biosimilar, 1 mg (Avtozma)

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.

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 12/12/2025. Accessed 12/23/2025
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 2025.
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. Tyenne (tocilizumab-aazg). Prescribing Information. Fresenius Kabi, Lake Zurich, IL. Revised February 2025.
6. Tofidence (tocilizumab-bavi). Prescribing Information. Biogen MA Inc. Cambridge, MA. Revised March 2025.
7. Avtozma. Celltrion. Prescribing Information. Incheon, Republic of Korea. Revised July 2025.
8. Maz, M., Chung, S. A., Abril, A., Langford, C. A., Gorelik, M., Guyatt, G., ... & Mustafa, R. A. (2021). *2021 American College of Rheumatology/Vasculitis Foundation guideline for the management of giant cell arteritis and Takayasu arteritis*. **Arthritis Care & Research, 73**(8), 1071–1087. https://doi.org/10.1002/acr.24632

MVP Health Care Medical Policy

Tofacitinib

Type of Policy:	**Drug Therapy**
Prior Approval Date:	**10/01/2024**
Approval Date:	**10/01/2025**
Effective Date:	**12/01/2025**
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.

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 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 are 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, renal disease, or if clinically inappropriate **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 are 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.

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. Approved 2012. Revised 02/2025.
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

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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
8. AGA Living Clinical Practice Guideline on Pharmacological Management of Moderate-to-Severe Ulcerative Colitis. Singh, Siddharth et al. Gastroenterology, Volume 167, Issue 7, 1307 – 1343. December 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 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

Tofersen

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

Prior Approval Date: 10/01/2024

Approval Date: 08/01/2025

Effective Date: 10/01/2025

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.

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 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

Transgender Hormone Policy (Commercial/Exchange/Child Health Plus)

Type of Policy: Drug Therapy
Prior Approval Date: 08/01/2024
Approval Date: 11/17/2025
Effective Date: 11/17/2025
Related Policies:

Gender Affirming Treatment
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]

The *World Professional Association for Transgender Health (WPATH) Standards of Care- Eighth edition (SOC-8)* was developed as a clinical guideline for transgender and gender diverse individuals. The guidelines address both physical and mental health for children, adolescents, and adults. WPATH guidance includes ensuring capacity to consent to treatment, well-documented gender dysphoria per current DSM diagnostic criteria, ensuring that other possible causes of gender incongruence have been identified and excluded, that mental health and physical conditions that could negatively impact the outcome of treatment have been discussed and informing individuals of reproductive effects due to treatment.

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.

A. Hormone therapy (testosterone (injectable and topical), conjugated estrogens or estradiol) for **adolescents** may be considered medically necessary when the following criteria are met:
    - Adolescence is defined as the start of puberty to 18 years of age
    - Documentation of an assessment for gender dysphoria treatment:
        - The customer has a diagnosis of gender dysphoria
        - The customer has reached Tanner stage 2
        - The experience of gender incongruence/diversity is marked and sustained over time
        - The customer demonstrates the emotional and cognitive maturity required to provide informed consent for the treatment
        - The customer has been informed of the reproductive effects on fertility (see Fertility Preservation Medical Policy for coverage criteria)
        - Customer does not suffer from psychiatric comorbidity that interferes with diagnostic work- up or treatment
        - 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)
        - A comprehensive biopsychosocial assessment is completed by a mental health professional who has training and expertise in general child, adolescent, and family mental health across the developmental spectrum;

as well as expertise in gender identity development and gender diversity in children and adolescents in a collaborative and supportive manner; and
- Customer has adequate home support and involvement of parent(s)/guardian(s) in the assessment process, unless their involvement is determined to be harmful to the adolescent or not feasible; and
- The customer has been evaluated for safety and is not requesting surgery as an initial response to gender dysphoria puberty.

Approvals will be for a period of one year.

B. Hormone therapy (testosterone (injectable and topical), conjugated estrogens or estradiol) for **adults** (customer's 18 years of age and older) may be considered medically necessary when the following criteria are met:
    - Documentation of assessment for gender dysphoria:
        i. The customer has persistent, well-documented gender dysphoria per DSM-5-TR diagnostic criteria, is associated clinically with significant distress or problems functioning and lasts at least six months' duration.
        ii. The customer has received mental health screening and assessment with documentation from a qualified medical or mental health professional as part of a multi-disciplinary team for gender affirming care and with experience in diagnosing and treating gender dysphoria.
        iii. Prescribed by a licensed health care professional who has a minimum of a masters-level qualification in a clinical field related to transgender health or equivalent further clinical training; (e.g., mental health professionals, general medical practitioner, or other qualified health care professional); and has sufficient expertise to identify gender incongruence, recognize mental health concerns, distinguish between these concerns and gender dysphoria, incongruence, and diversity; assist a transgender and gender diverse (TGD) person in care planning and preparation for gender-affirming medical and surgical treatments (GAMSTs), and refer to a mental health professional (MHP), if needed.
        iv. If significant medical or mental health concerns are present, they must be reasonably well controlled or under treatment so that gender-affirming medical treatment can be provided optimally; and
    - 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)

Approvals will be for a period of one year.

C. Gonadotropin-releasing hormone agents (pubertal suppressants) are subject to retro-review and will be approved if all the following criteria are met:
   - Customer has a diagnosis of gender dysphoria;
   - Customer has experienced puberty to at least Tanner stage 2, and pubertal changes have resulted in an increase in gender dysphoria;
   - Customer does not suffer from psychiatric comorbidity that interferes with a diagnostic work-up or treatment
   - The customer demonstrates the emotional and cognitive maturity required to provide informed consent for the treatment
   - The customer has been informed of the reproductive effects on fertility
   - Customer has adequate psychological and social support during treatment
   - Customer 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.

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)
8. E. Coleman, A.E Radix, et al. Standard of Care for the Health of Transgender and Gender Diverse People, Version 8, International Journal of Transgender Health, 23:sup1, S1-S259, DOI: 10.1080/26895269.2022.2100644
9. New York State Office of Mental Health Memorandum. May 14, 2024. Clinical Review Criteria for the Treatment of Gender Dysphoria: New Standards of Care for Transgender Health.
10. American Psychiatric Association. (2022). *Diagnostic and statistical manual of mental disorders* (5th ed., text rev.). https://doi.org/10.1176/appi.books.9780890425787

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
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).	
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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: **02/01/2025**
Approval Date: **02/01/2026**
Effective Date: **04/01/2026**
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 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 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.

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 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	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 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: 08/01/2024
Approval Date: 12/01/2025
Effective Date: 02/01/2026
Related Policies: NA

Drugs Requiring Prior Authorization (covered under the medical benefit)
J0222- Onpattro™ (patisiran)
J0225- Amvuttra (vutrisiran)

Drugs Requiring Prior Authorization (covered under the pharmacy benefit)
Tegsedi™ (inotersen)
Vyndamax (tafamidis)
Vyndaqel (tafamidis meglumine)
Wainua (eplontersen sodium)
Attruby (acoramidis HCL)

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 polyneuropathy in hereditary transthyretin-mediated amyloidosis in adults. In March 2025, Amvuttra received a new indication for the treatment of wild type or hereditary transthyretin amyloid cardiomyopathy for the reduction of cardiovascular mortality, cardiovascular-related hospitalization, and urgent heart failure visits. 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.

Wainua is a subcutaneous, transthyretin-directed antisense oligonucleotide indicated for the treatment of the polyneuropathy of hereditary transthyretin-mediated (hATTR) amyloidosis.

Attruby is a selective transthyretin stabilizer, is indicated for the treatment of cardiomyopathy of the wild-type or variant transthyretin-mediated amyloidosis (ATTR-CM) to reduce cardiovascular death and cardiovascular-related hospitalization in adults.

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 in Appendix A)
    - Baseline FAP (familial amyloid polyneuropathy) Stage 1 or 2 (see reference table in Appendix A)
- Documentation indicating a 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, geneticist, 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, contracted infusion center or contracted provider office. Prior Authorization and medical justification is required for Onpattro 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 and Medicaid, CHP members

Initial approval will be for 6 months

Extension requests will be approved up to 6 months if current documentation indicates 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

For all Amvuttra indications, the following Site of Care requirement applies:

- 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, contracted infusion center or contracted provider office. Prior Authorization and medical justification is required for Amvuttra 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 and Medicaid, CHP members

Amvuttra will be considered 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:

- Chart notes documenting a failure or contraindication to Onpattro
- 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 in Appendix A)
    - Baseline FAP (familial amyloid polyneuropathy) Stage 1 or 2 (see reference table in Appendix A)
- Documentation indicating a 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, geneticist, cardiologist, immunologist, or physician who specializes in the treatment of amyloidosis
- **Initial approval** will be for 6 months
- **Extension requests** will be approved up to 6 months if current documentation indicates 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)

Amvuttra will be considered will be considered medically necessary for the treatment of wild type or hereditary transthyretin amyloid cardiomyopathy for the reduction of cardiovascular mortality, cardiovascular-related hospitalization, and urgent heart failure visits when all the following criteria is met:

- Chart notes documenting a failure or contraindication to self-administered options Vyndaqel, Vyndamax and Attruby

- 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.
    - Member must not have NYHA class IV disease
- 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
- Prescribed by or in consultation with a geneticist, cardiologist or physician specializing in the treatment of amyloidosis

Initial approval will be for 6 months

Extension requests will be approved up to 6 months if current documentation indicates disease stability or improvement in symptoms (e.g., quality of life assessment, decrease cardiac related hospitalizations)

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 in Appendix A)
    - Baseline FAP (familial amyloid polyneuropathy) Stage 1 or 2 (see reference table in Appendix A)
- Documentation indicating a 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

Extension requests will be approved up to 6 months if current documentation indicates 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

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
- Prescribed by or in consultation with a geneticist, cardiologist or physician specializing in the treatment of amyloidosis

Initial approval will be for 6 months

Extension requests will be approved up to 6 months if current documentation indicates disease stability or improvement in symptoms (e.g., quality of life assessment, decrease cardiac related hospitalizations)

E. Wainua will be considered medically necessary for the treatment of hereditary transthyretin amyloidosis-associated polyneuropathy in adults who meet all the following criteria:

- Chart notes documenting the following:
  - A diagnosis of hereditary transthyretin amyloidosis-associated polyneuropathy AND
  - Documentation that the member has a TTR gene mutation confirmed with genetic testing AND
  - A contraindication, intolerance or failure of Onpattro

- Chart notes documenting 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 in Appendix A)
  - Baseline FAP (familial amyloid polyneuropathy) Stage 1 or 2 (see reference table in Appendix A)
- Provider attestation that the member has not had a liver transplant
- Member does not have Type 1 or Type 2 diabetes
- Member does not have New York Heart Association (NYHA) functional classification of ≥3

- Prescribed by or in consultation with a neurologist, immunologist, geneticist or physician who specializes in the treatment of amyloidosis

Initial approval will be for 6 months

Extension requests will be approved up to 6 months if current documentation indicates disease stability or improvement in symptoms.

F. Attruby will be considered medically necessary for the treatment of cardiomyopathy of wild type or variant transthyretin mediated amyloidosis (ATTR-CM) in adults who meet all the following criteria:

- Chart notes documenting a diagnosis of wild type or variant 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

Appendix A:

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
- 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

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4. 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.

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14. Wainua. Study Details | NCT04136184 | NEURO-TTRansform: A Study to Evaluate the Efficacy and Safety of Eplontersen (Formerly Known as ION-682884, IONIS-TTR-LRx and AKCEA-TTR-LRx) in Participants With Hereditary Transthyretin-Mediated Amyloid Polyneuropathy | ClinicalTrials.govWainua. Prescribing Information. Wilmington, DE. AstraZeneca. April 2025
15. Hereditary Transthyretin-Mediated Amyloidosis (hATTR) Clinical Clues and Diagnostic Testing Quick Reference Guide

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
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 Medicare WellSelect 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
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 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:
Transthyretin-Mediated Amyloidosis Therapy

Type of Policy: **Drug Therapy**
Prior Approval Date: **08/01/2024**
Approval Date: **12/01/2025**
Effective Date: **02/01/2026**
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.

DrugsRequiring Prior Authorization (covered under the medical benefit)
J0222- Onpattro™ (patisiran)
J0225 Amvuttra (vutrisiran)

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. In March 2025, Amvuttra received a new indication for the treatment of wild type or hereditary transthyretin amyloid cardiomyopathy for the reduction of cardiovascular mortality, cardiovascular-related hospitalization, and urgent heart failure visits.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.

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 in Appendix A)
    - Baseline FAP (familial amyloid polyneuropathy) Stage 1 or 2 (see reference table in Appendix A)
- Documentation indicating a 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, geneticist or physician who specializes in the treatment of amyloidosis

Initial approval will be for 6 months

Extension requests will be approved up to 6 months if current documentation indicates 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:

- Chart notes documenting a failure or contraindication to OnpattroMember 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 in Appendix A)
    - Baseline FAP (familial amyloid polyneuropathy) Stage 1 or 2 (see reference table in Appendix A)
- Documentation indicating a 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, geneticist, cardiologist, or physician who specializes in the treatment of amyloidosis

- **Initial approval** will be for 6 months, continuation requests up to 6 months.
- **Extension requests** will be approved up to 6 months if current documentation indicates 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

Amvuttra will be considered will be considered medically necessary for the treatment of wild type or hereditary transthyretin amyloid cardiomyopathy for the reduction of cardiovascular mortality, cardiovascular-related hospitalization, and urgent heart failure visits when all the following criteria is met:

- Chart notes documenting a failure or contraindication to self-administered medications for the diagnosis

- 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.

    - Member must not have NYHA class IV disease
- 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
- Prescribed by or in consultation with a geneticist, cardiologist or physician specializing in the treatment of amyloidosis

Initial approval will be for 6 months

Extension requests will be approved up to 6 months if current documentation indicates disease stability or improvement in symptoms (e.g., quality of life assessment, decrease cardiac related hospitalizations)

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Appendix A:

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 of Tegsedi with Amvuttra, Onpattro, or tafamidis
- Concurrent use of Vyndaqel and Vyndamax
- 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

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16. Vyndaqel and Vyndamax Prescribing Information. New York, NY: Division of Pfizer, Inc.; 10/2023

MVP Health Care Medical Policy

Tryngolza (olezarsen)

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

Prior Approval Date: N/A

Approval Date: 10/01/2025

Effective Date: 11/01/2025

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 pharmacy benefit

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

Overview

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). 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 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
    - An inadequate response, intolerance, or contraindication to conventional therapy including:
        - Fibrates, high dose omega-3s
- 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	+1

• <10 years	+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 up to 12 months if the member has a continued benefit to therapy and the following is met:

- Member continues to meet the criteria above **AND**
- Chart notes are provided identifying a positive clinical response (e.g. reduction of episodes of acute pancreatitis from baseline, reduction in TG level from baseline)

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

Exclusions

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

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

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Journal of Clinical Lipidology, Volume 19, Issue 1, 83 – 94. January-February, 2025.

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

Upadacitinib

Type of Policy: Drug Therapy
Prior Approval Date: 10/01/2024
Approval Date: 10/01/2025
Effective Date: 12/01/2025
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 the following indications:

- the treatment of adults with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to one or more TNF blockers
- the treatment of adults and pediatric patients 2 years of age and older with active psoriatic arthritis who have had an inadequate response or intolerance to one or more TNF blockers.
- the treatment of adults and pediatric patients 12 years of age and older with refractory, moderate to severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies are inadvisable.
- the treatment of adults with moderately to severely active ulcerative colitis who have had an inadequate response or intolerance to one or more TNF blockers.
- the treatment of adults with moderately to severely active Crohn's disease who have had an inadequate response or intolerance to one or more TNF blockers.
- the treatment of adults with active ankylosing spondylitis who have had an inadequate response or intolerance to one or more TNF blockers.
- the treatment of adults with active nonradiographic axial spondyloarthritis with objective signs of inflammation who have had an inadequate response or intolerance to TNF blocker therapy.
- the treatment of patients 2 years of age and older with active polyarticular juvenile idiopathic arthritis who have had an inadequate response or intolerance to one or more TNF blockers.
- the treatment of adults with giant cell arteritis

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.

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.

J. Giant Cell Arteritis

Updacitinib may be considered for coverage for Giant Cell Arteritis when the following criteria is met:

- 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 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

    - The dosing Rinvoq 45mg once daily is indicated for short term induction for Crohn's Disease and Ulcerative Colitis
- 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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Member Product	Medical Management Requirements*
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HMO	Prior Auth
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PPO OOP	Prior Auth
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POS OOP	Prior Auth
Essential Plan	
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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

Ustekinumab

Type of Policy: Drug/Medical Therapy
Prior Approval Date: 10/01/2024
Approval Date: 10/01/2025
Effective Date: 01/01/2026
Related Policies: Adalimumab
Apremilast
Etanercept
Infliximab
Risankizumab
Secukinumab
Tofacitinib
Upadacitinib
Zeposia

Drugs Requiring Prior Authorization under the pharmacy benefit

J3357 Stelara, Ustekinumab, subcutaneous, prefilled syringe (ustekinumab)

Q9996 Pyzchiva, ustekinumab-ttwe, subcutaneous, 1 mg

Q5100 Yesintek, ustekinumab-kfce, subcutaneous, biosimilar, 1 mg

Drugs Requiring Prior Authorization under the medical benefit

J3358 Stelara (ustekinumab intravenous injection, 1mg)
Q9994 Pyzchiva, ustekinumab-ttwe, intravenous, 1 mg
Q5100 Yesintek, ustekinumab-kfce 130mg/26ml, intravenous, biosimilar, 1 mg

Overview

Ustekinumab 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.

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.

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

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

9. 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)

10. Ustekinumab (Pyzchiva). In: Clinical Pharmacology [database on the Internet]. Tampa (FL): Elsevier. publication year [September 4, 2025]. Available from: www.clinicalpharmacology.com. Subscription required to view.

11. Ustekinumab (Yesintek). In: Clinical Pharmacology [database on the Internet]. Tampa (FL): Elsevier. publication year [September 4, 2025]. Available from: www.clinicalpharmacology.com. Subscription required to view.

12. Pyzchiva [package insert]. Princeton, NJ: Sandoz; December 2024. Available from: Pyzchiva Package Insert

13. Yesintek [package insert]. Cambridge, MA: Biocon Biologics Inc.; November 2024. Available from: Yesintek 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 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: Ustekinumab

Type of Policy:	Drug/Medical Therapy
Prior Approval Date:	10/01/2024
Approval Date:	10/01/2025
Effective Date:	01/01/2026
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)
Q9994 Pyzchiva, ustekinumab-ttwe, intravenous, 1 mg
J3590 Yesintek, ustekinumab-kfce 130mg/26ml, intravenous, biosimilar, 1 mg

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.

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

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10. Ustekinumab (Yesintek). In: Clinical Pharmacology [database on the Internet]. Tampa (FL): Elsevier. publication year [September 4, 2025]. Available from: www.clinicalpharmacology.com. Subscription required to view.

11. Pyzchiva [package insert]. Princeton, NJ: Sandoz; December 2024. Available from: Pyzchiva Package Insert

12. Yesintek [package insert]. Cambridge, MA: Biocon Biologics Inc.; November 2024. Available from: Yesintek Package Insert

MVP Health Care Medical Policy

Valchlor

Type of Policy:	**Drug Therapy**
Prior Approval Date:	**04/01/2025**
Approval Date:	**04/01/2026**
Effective Date:	**06/01/2026**
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.

Exclusions

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

References

1. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) Primary Cutaneous Lymphomas, Version 2.2026. Available at https://www.nccn.org/professionals/physician_gls/pdf/primary_cutaneous.pdf
2. Valchlor (mechlorethamine) gel. Prescribing Information. South San Francisco, CA. Actelion Pharmaceuticals, Inc. Revised January 2020.
3. Kim YH, Martinez G, Varghese A, Hoppe RT. Topical nitrogen mustard in the management of mycosis fungoides: update of the Stanford experience. Arch Dermatol 2003; 139:165–73. Available at: http://www.ncbi.nlm.nih.gov/pubmed/12588222.
4. NCCN Guidelines for Patients. Mycosis Fungoides/Sezary Syndrome. 2024. 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 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).	

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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

Vimseltinib

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

Prior Approval Date: NA

Approval Date: 11/01/2025

Effective Date: 11/01/2025

Related Policies: Orphan Drugs and Biologicals

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

Drugs Requiring Prior Authorization under the pharmacy benefit

Romvimza

Overview

Vimseltinib is an oral switch-control colony stimulating factor 1 receptor (CSF1R) kinase inhibitor approved for adult patients with symptomatic tenosynovial giant cell tumor (TGCT) for which surgical resection will potentially cause worsening functional limitation or severe morbidity.

Tenosynovial giant cell tumor is a disease in which the tissue lining the joints and tendons in the body (synovium) grows abnormally. It is characterized by a noncancerous mass or tumor. There are two types of Tenosynovial giant cell tumor: the local or nodular form (where the tumor involves the tendons that support the joint, or in one area of the joint) and the diffuse form (where the entire lining of the joint is involved). Symptoms might include: pain, limitation of movement, and locking of the joint. In some cases, the normal joint structure can be destroyed. The knee is most commonly affected

by this condition, though it can occur in other joints such as the hip, shoulder, elbow, ankle, wrist, and rarely the jaw. The cause of Tenosynovial giant cell tumor is unknown.

Indications/Criteria

A. Tenosynovial giant cell tumor (TGCT)

Romvimza may be considered for coverage when all of the following criteria is met:

- Chart notes confirming that the member has a diagnosis of tenosynovial giant cell tumor (TGCT) AND
- Provider attestation that surgical resection would potentially cause worsening of functional limitation or severe morbidity
- 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 will be for 12 months

Extension requests will be approved for up to 12 months if documentation is provided indicating that the member has a continued benefit to therapy and does not show disease progression while on Romvimza. Extension requests where Romvimza did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

Exclusions

The use of Romvimza 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. Tenosynovial giant cell tumor, diffuse type | About the Disease | GARD
2. Clinical Pharmacology

3. Romvimza (vimseltinib). Package Insert. Deciphera Pharmaceuticals; Waltham (MA). February 2025.

4. **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 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.
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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

Vyepti

Type of Policy:	Drug Therapy
Prior Approval Date:	10/01/2024
Approval Date:	11/01/2025
Effective Date:	01/01/2026
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 its binding to the receptor.

Indications/Criteria

- Vyepti may be considered for coverage for migraine prophylaxis when all the following are met:
    - For chronic migraines:
        - Confirmed diagnosis of 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, beta blockers (i.e.

propranolol, timolol, atenolol, nadolol), candesartanamitriptyline, nortriptyline, verapamil, venlafaxine, duloxetine, rimegepant (Nurtec), atogepant (Qulipta), Erenumab (Aimovig), Fremanezumab (Ajovy), Galcanezumab (Emgality) at maximally tolerated doses

- For episodic migraines:
  - Confirmed diagnosis of 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, beta blockers (i.e. propranolol, timolol, atenolol, nadolol), candesartan, amitriptyline, nortriptyline, verapamil, venlafaxine, duloxetine, rimegepant (Nurtec), atogepant (Qulipta), Erenumab (Aimovig), Fremanezumab (Ajovy), Galcanezumab (Emgality)) at maximally tolerated doses.

  - Documentation identifying medical necessity, and why the member is unable to use a self-administered CGRP product indicated for migraine prevention (such as 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 CGRP product indicated for migraine prevention

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.

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

- 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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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

MVP Health Care Medical Policy

Medicare Part B: Vyepti

Type of Policy:	Drug Therapy
Prior Approval Date:	08/01/2024
Approval Date:	10/01/2025
Effective Date:	01/01/2026
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.

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 its binding to the receptor.

Indications/Criteria for prophylaxis for Vyepti

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

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For chronic migraine:

- Confirmed diagnosis of 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, beta blocker (i.e. propranolol, timolol, atenolol, nadolol), candesartan , amitriptyline, nortriptyline, verapamil, venlafaxine, duloxetine, rimegepant (Nurtec), atogepant (Qulipta), Erenumab (Aimovig), Fremanezumab (Ajovy), Galcanezumab (Emgality)) at maximally tolerated doses.

For episodic migraine:

- Confirmed diagnosis of episodic migraines
- 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, beta blockers (i.e. propranolol, timolol, atenolol, nadolol), candesartan, amitriptyline, nortriptyline, verapamil, venlafaxine, duloxetine, rimegepant (Nurtec), atogepant (Qulipta), Erenumab (Aimovig), Fremanezumab (Ajovy), Galcanezumab (Emgality) at maximally tolerated doses.

    - Documentation identifying medical necessity why the member is unable to use a self-administered CGRP product indicated for migraine prevention (such as 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 CGRP product indicated for migraine prevention.
        - 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.**

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

Exclusions

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- 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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1. Aimovig (erenumab-aooe) [Package Insert]. Thousand Oaks, CA: Amgen Inc.; 20182.
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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.

Classified as Confidential

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

Weight Loss Medications

Type of Policy: **Drug/Medical Therapy**
Prior Approval Date: **06/01/2026**
Approval Date: **06/09/2026**
Effective Date: **06/01/2026**
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

Saxenda injection (liraglutide)

Wegovy injection (semaglutide)

Wegovy HD injection (semaglutide)

Wegovy tablet (semaglutide)

Zepbound prefilled pens/auto injector (tirzepatide)*Zepbound kwikpens are excluded from coverage and only available through Eli Lilly's Direct-To-Consumer program.

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 in combination with a reduced calorie diet and increased physical activity to reduce excess body weight and maintain weight reduction long term in:

- Adults and pediatric patients aged 12 years and older with body weight greater than 60 kg and obesity.

    Adults with overweight in the presence of at least one weight-related comorbid condition

Wegovy injection 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.
    - Wegovy HD 7.2mg is the recommended maintenance dosing for adults patients who tolerate the 2.4mg dosage for at least 4 weeks and additional weight reduction is clinically indicated. Wegovy HD is not recommended per lackage labeling for pediatric patients.
    - Wegovy HD 7.2mg is indicated for weight reduction in adults only. It is not indicated for cardiovascular risk reduction in adults.
- For the treatment of noncirrhotic metabolic dysfunction associated steatohepatitis (MASH), formerly known as nonalcoholic steatohepatitis (NASH), with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis) in adults. The indication for MASH is approved under accelerated approval based on improvement of MASH and fibrosis. Continued approval for this indication may be contingent upon the verification and description of clinical benefit in a confirmatory trial.

Wegovy tablets are indicated in combination with a reduced calorie diet and increased physical activity:

- To reduce the risk of major adverse CV events (CV death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established CV disease and either obesity or overweight.
- To reduce excess body weight and maintain weight reduction long term in adults with obesity, or in adults with overweight in the presence of at least one weight-related comorbid condition.

- The Wegovy tablet is not indicated for pediatric patients

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), Vermont and Child Health Plus members, see Variation details.

Vermont Commercial and Exchange Variation

Medications used for weight loss management (both oral or injectable) are not covered for Vermont Commercial and Exchange 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.

Medicare Variation

Weight loss products are not covered for Medicare members.
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 (both oral or injectable) 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

A. Quantity Limits

For all indications, the following quantity limits apply:

- Wegovy injection and Wegovy HD injection
  - 4 (four) pens per 28 days
- Wegovy Tablets:
  - 30 tablets per 30 days
- Saxenda
  - 5 (five) pens per 28 days
- Zepbound
  - 4 (four) pens per 28 days

B. Weight loss for adult members

Saxenda, Zepbound, Wegovy tablets, Wegovy injection and Wegovy HD may be considered for coverage for weight loss **for adults** when all the following criteria are met:

- Chart notes documenting all of the following:
  - Member's current body mass index (BMI) of 40 or greater (Obesity, Class 3)
  - Member's current body weight and height
  - A failure of lifestyle interventions for at least 6 months following a plan approved weight loss program.
  - Documentation that a plan approved weight loss program would continue concurrently with Wegovy, Saxenda or Zepbound use.
  - Chart notes documenting proof of consultation 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 for up to 6 months when current chart notes document ALL of the following:

- Member continues to meet CDC defined BMI parameters for obesity or overweight (BMI ≥25)
- A decrease in baseline body weight (at least 5 percent from baseline)
- Member's prescription history must show compliance with medication.
- The member must be utilizing the maintenance dose for the requested medication:
    - For **Wegovy tablet:** the member must be utilizing 25mg as maintenance therapy after titration according to package labeling. The 1.5mg, 4mg and 9mg once daily are approved for initiation and escalation. They are not approved for maintenance dosing.

    - For **Wegovy injection**: the member must be utilizing the 2.4mg OR the 1.7mg dose as maintenance therapy. The 0.25mg, 0.5mg and 1mg once weekly dosages are approved for initiation and escalation. They are not approved for maintenance dosing.

        - Note: Wegovy HD 7.2mg is only indicated for adult members who have tolerated 2.4mg for at least 4 weeks.

    - For **Saxenda**: the member must be utilizing the 3mg once daily dose for maintenance therapy.

    - For **Zepbound**: the member must be utilizing the dosages ≥5mg once weekly as maintenance therapy. The 2.5mg once weekly dosage is not approved as maintenance dosing.

- Current chart notes documenting the member continues and is compliant with a plan approved weight loss program. See Appendix A for Plan Approved Weight Loss Programs.
- Continuation requests where the medication did not demonstrate effectiveness and/or the member did not meet the continuation criteria above will exclude future coverage of the same drug.

C. Cardiovascular disease risk reduction

Wegovy injection and Wegovy tablets may be considered for coverage to reduce the risk of heart attack and stroke in adults with obesity or overweight with cardiovascular disease when the following criteria are met:

- Note: **Wegovy HD** is indicated for weight reduction in adults only. It is not indicated for cardiovascular risk reduction in adults.
- Member's current body mass index (BMI) is ≥40kg/m2
- Wegovy is prescribed by or in consultation with a cardiologist
- Current chart notes documenting a failure of lifestyle interventions for at least 6 months.
- Current chart notes documenting that the member is following a heart healthy diet and exercise for at least 6 months.
- Current chart notes documenting the member continues and is compliant with a plan approved weight loss program. See Appendix A for Plan Approved Weight Loss Programs.
- Chart notes documenting proof of consultation 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 1 or type 2 diabetes
- Current chart notes documenting 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 one of the following cardiovascular disease diagnoses: prior myocardial infarction, prior stroke, or peripheral arterial disease)

- Chart notes documenting that the member is concurrently taking guidelines-directed management and therapy for cardiovascular disease (i.e. lipid lowering agents, antiplatelets, angiotensin converting enzyme inhibitors, angiotensin II receptor blockers, beta-blockers, etc.). Claims history will be reviewed to ensure compliance.

  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:
  - Member continues to meet CDC defined BMI parameters for obesity or overweight (BMI ≥25)
  - Member has a clinical benefit to the medication:
    - A decrease in baseline body weight (at least 5 percent from baseline)
  - Member's prescription history must show compliance with both Wegovy and current medications for cardiovascular disease (i.e. lipid lowering agents, antiplatelets, angiotensin converting enzyme inhibitors, angiotensin II receptor blockers, beta-blockers, etc.). Claims history will be reviewed to ensure compliance.
  - Current chart notes documenting the member continues and is compliant with heart healthy diet and exercise.
  - The member must be utilizing the maintenance dose for the requested medication:
    - For **Wegovy tablet:** the member must be utilizing 25mg as maintenance therapy after titration according to package labeling. The 1.5mg, 4mg and 9mg once daily are approved for initiation and escalation. They are not approved for maintenance dosing.

    - For **Wegovy injection**: the member must be utilizing the 2.4mg OR the 1.7mg dose as maintenance therapy. The 0.25mg, 0.5mg and 1mg once weekly dosages are approved for initiation and escalation. They are not approved for maintenance dosing.

- Note: **Wegovy HD** is indicated for weight reduction in adults only. It is not indicated for cardiovascular risk reduction in adults.

D. Weight loss for pediatric members

Saxenda and Wegovy may be considered for coverage for weight loss **for pediatric members** when all the following criteria are met:

- Note: Wegovy tablets and Wegovy HD are not approved pediatric members.
- Member is 12 years of age of older
- For Wegovy requests
  - Member has an initial BMI at the 95th 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

E. 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 are met:

- Chart notes documenting the member has a current body mass index (BMI) of 30 kg/m^2 or greater (obesity)
- Member does not have Type 1 or Type 2 diabetes
- Member does not have a diagnosis of Central or Mixed Sleep Apnea with % of mixed or central apneas/hypopneas ≥50%, or diagnosis of Cheyne Stokes Respiration
- Member does not have Obesity Hypoventilation Syndrome or daytime hypercapnia
- Zepbound is being prescribed by or in consultation with a sleep specialist
- Chart notes documenting the member's current body weight and height
- Chart notes documenting baseline Epworth Sleepiness Scale (ESS)
- Chart notes documenting a **current** diagnosis of moderate to severe obstructive sleep apnea including documentation of a sleep study
    - Sleep study results indicate a diagnosis of moderate to severe sleep apnea AND the member has an apnea-hypopnea index [AHI] ≥15)
- Chart notes confirming persistent obstructive sleep apnea symptoms despite adherence to positive airway pressure (PAP) therapy.
    - Adherence to PAP therapy is defined as ≥ 4 hours of use per night for ≥ 70 percent of nights.
    - If PAP therapy is not appropriate for the member, chart notes documenting the reason PAP or other therapies are medically inappropriate must be provided.
- Current chart notes documenting the following:
    - A failure of lifestyle interventions for at least 6 months following a plan approved weight loss program
    - Documentation that a plan approved weight loss program would continue concurrently with Zepbound use.

- Chart notes documenting proof of consultation 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 document ALL of the following:

- Member continues to meet CDC defined BMI parameters for obesity or overweight (BMI ≥25) **AND**
- For **initial extension requests**, the member has a documented decrease in baseline body weight (at least 5 percent from baseline)
- For **subsequent extension requests**, member has a documented clinical benefit to the medication and meets the criteria below:
    - Current documentation that the member has a decrease in baseline body weight (at least 5 percent from baseline) **AND**
    - For members on current PAP therapy, documentation is provided confirming a decrease from baseline in one of the following:
        - Apnea Hypopnea Index (AHI)
        - Respiratory Disturbance Index (RDI)
        - Respiratory Event Index
    - For members who are not using PAP therapy, provider attestation must be provided indicating the member is not a candidate for PAP therapy.
    - Chart notes documenting a decrease in baseline for Epworth Sleepiness Scale
    - Chart notes documenting an improvement in OSA symptoms such as:
        - Reduced snoring and gasping episodes
        - Better daytime focus
        - Reduction in morning headaches
        - Reduction in dry mouth
        - Decrease in blood pressure

- Member's prescription history must show compliance with medication. The member must be utilizing the dosages ≥5mg once weekly as maintenance therapy. The 2.5mg once weekly dosage is not approved as maintenance dosing.
- Current chart notes documenting the member continues and is compliant with a plan approved weight loss program. See Appendix A for Plan Approved Weight Loss Programs.
- Continuation requests where the medication did not demonstrate effectiveness and/or the member did not meet the continuation criteria above will exclude future coverage of the same drug.

Appendix A: Plan Approved Weight Loss Programs

Programs that qualify

- A program that includes a holistic approach to achieving weight loss that is healthy and sustained. The program must include ALL of the following components: nutrition management, physical activity, behavior modifications and ongoing support (i.e. individual or group counseling sessions).
    - The following must be provided:
        - Documentation must include the details of the specific Weight Loss Program. The documentation must outline how the program fulfills all the required components of a plan approved weight loss program. The required components that must be addressed are: nutrition management, physical activity, behavior modification and counseling.
        - The documentation must detail the member's specific weight loss plan and include how the member is engaging in the weight loss program to meet all the required components of program (nutrition management, physical activity, behavior modification and counseling).
            - Documentation must provide how often the member is engaging in the Weight Loss Program.

- Provide clinical documentation showing at least four (4) visits per six (6) months on a consistent cadence.
- Proof of attendance, enrollment and participation is required and must be verifiable. Additional documentation may be requested.
  - **Participation** is defined as documented, ongoing engagement that requires direct interaction with a qualified professional (e.g., dietitian, coach, or clinician) and active engagement of implementing recommended changes such as nutrition tracking, goal setting, behavioral exercises, or physical activity plans. Participation must be demonstrated through verifiable evidence of two-way interaction, progress review, or activity completion
  - Passive attendance (e.g., viewing webinars without interaction) does not meet this requirement.

- Documentation must include details of increasing physical activity including type, intensity, length and frequency. Increasing physical activity may occur outside of scheduled appointments or time with the Weight Loss Program but must be documented in one of the following ways:
  - Minimum requirement for increasing physical activity is:
    - At least 150 minutes of exercise per week (as recommended by the CDC Physical Activity Guidelines for Americans) **OR**
    - Individualized provider-directed exercise
  - Clinical documentation must be provided indicating that the Weight Loss Program has a physical activity component and the member is meeting the requirement on a consistent basis.
  - Clinical chart notes must be provided documenting that the member is adhering to the Weight Loss Program by exercising or increasing physical activity on a consistent basis.

- Examples may include the following below. Please note that "ongoing/consistent appointments or counseling" is defined as at least four (4) visits per six (6) months.:
    - Ongoing/consistent appointments with a qualified dietician
    - Ongoing/consistent appointments with a qualified lifestyle coach or counselor
    - Ongoing/consistent one-on-one or group counseling
    - Any of the above paired with increasing physical activity (see above for physical activity requirements).
- Online or telehealth programs may be considered, however they must meet all of the criteria above for a Plan Approved Weight Loss Program.

Programs that do not qualify

- Stand alone calorie counting or step tracking apps.
- Exercise only program
- Programs that do not address all of the following: nutrition management, physical activity, behavior modifications, and continued support
- Programs where attendance, enrollment and participation cannot be verified

Documentation will be reviewed for meeting the criteria of a Plan approved weight management program and documentation may be requested for further review for additional information.

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.
- Obesity induced by other endocrinologic disorders or monogenetic or syndromic forms of obesity
- Wegovy to treat adults with noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH) with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis) **alone**, is excluded from coverage as the clinical benefit has not been confirmed. A member with MASH who meets any of the coverage criteria above, may be considered for coverage.

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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 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).	

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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.

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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References

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2. Rosenwasser, L.J. & Nash, D.B. (2003). Incorporating omalizumab into asthma treatment guidelines: consensus panel recommendations. P&T 28(6) 400-10.
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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

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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1. Xolair® (omalizumab). Prescribing Information. South San Francisco, CA: Genentech Inc.; February 2024.
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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.
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6. Acute and Chronic Urticaria: Evaluation and Treatment - American Family Physician (aafp.org)

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MVP Health Care Medical Policy

Yorvipath

Type of Policy:	Drug therapy (administered by the pharmacy department)
Prior Approval Date:	07/01/2025
Approval Date:	02/01/2026
Effective Date:	04/01/2026
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

YORVIPATH® (palopegteriparatide) injection, for subcutaneous use

Overview

Yorvipath® (palopegteriparatide) is a parathyroid hormone analog (PTH 1-34) approved by the U.S. FDA in 2024 for the treatment of chronic hypoparathyroidism in adults. Yorvipath is administered as a once-daily subcutaneous injection and is designed to restore physiological PTH levels, thereby improving calcium homeostasis and reducing the need for high doses of oral calcium and active vitamin D. Yorvipath is not indicated for acute post-surgical hypoparathyroidism. The titration scheme was only evaluated in adults who first achieved an albumin-corrected serum calcium of at least 7.8 mg/dL using calcium and active vitamin D treatment.

Indications/Criteria

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

- Prescribed by or in consultation with an Endocrinologist or a Nephrologist

B. Chronic Hypoparathyroidism

In addition to section A, Yorvipath will be considered for coverage when **all** of the following are met:

- Member has a documented diagnosis of chronic (≥6 months) hypoparathyroidism confirmed by **both** of the following:
  - Pretreatment low albumin-corrected serum calcium ≤ 8.5 mg/dL, confirmed on at least two occasions, ≥2 weeks apart **AND**
  - Pretreatment low intact parathyroid (PTH) < 20 pg/mL, confirmed on at least two occasions using a second- or third-generation immunoassay
- Member is **currently on** adequate calcium and active vitamin D supplementation as confirmed by the following:
  - Albumin-corrected serum calcium between 7.8–10.6 mg/dL **AND**
  - Serum 25(OH) vitamin D level between 20–80 ng/mL
    - **OR**
  - Member has a contraindication to active vitamin D and calcium supplementation
- Member had an inadequate response to maximally tolerated calcium and active vitamin D supplementation
- Provider attestation indicating the following:
  - Calcium and active vitamin D supplementation will be continued during titration of Yorvipath to appropriate dose
  - The dose will be individualized based on albumin-corrected serum calcium levels
  - Serum calcium levels will be measured 7 to 10 days after initial dose, after any dose changes, and at least every 4 to 6 weeks after maintenance dosing is achieved

Initial approval will be for **12 months**

Extension requests will be approved for up to **12 months** if the member meets **all** of the following:

- The member has a continued benefit to therapy with a **positive clinical response** (e.g. normal albumin-corrected serum calcium (8.3–10.6 mg/dL), reduced or eliminated need for active vitamin D and calcium supplements (e.g. ≤600 mg/day of calcium), etc.)
- Yorvipath is prescribed or in consultation with an Endocrinologist or a Nephrologist

Exclusions

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

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling
- Use of 2 injections the achieve the recommended dose
- **Acute** post-surgical hypoparathyroidism
- Members who did NOT initially achieve an albumin-corrected serum calcium of at least 7.8 mg/dL using calcium and active vitamin D treatment

References

1. Yorvipath [package insert]. Princeton, NJ: Ascendis Pharma, Inc.; Initial U.S. Approval/Publication Year: 2024. Revised: 08/2024.
2. Khan AA, Rubin MR, et al. Efficacy and Safety of Parathyroid Hormone Replacement With TransCon PTH in Hypoparathyroidism: 26-Week Results From the Phase 3 PaTHway Trial. J Bone Miner Res. 2023 Jan;38(1):14-25. doi: 10.1002/jbmr.4726. Epub 2022 Nov 12. PMID: 36271471; PMCID: PMC10099823.
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4. Palopegteriparatide: YORVIPATH. In: Clinical Pharmacology [database on the Internet]. Tampa (FL): Elsevier. 2025 [12/30/2025]. Available from: www.clinicalpharmacology.com. Subscription required to view.
5. Palopegteriparatide. In: Merative Micromedex [database on the Internet]. Greenwood Village (CO): IBM Corporation; 2025 [12/30/2025]. Available from: www.micromedexsolutions.com. Subscription required to view.

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).	
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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

Zinplava (bezlotoxumab)

Type of Policy:	**Drug Therapy**
Prior Approval Date:	**12/01/2024**
Approval Date:	**12/01/2025**
Effective Date:	**02/01/2026**
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
    - 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), or 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

Exclusions

- Any repeat dose is considered experimental or investigational
- 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

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

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	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 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
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 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:	**01/01/2025**
Approval Date:	**12/01/2025**
Effective Date:	**02/01/2026**
Related Policies:	**C. Difficile Drug Therapy**

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.

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.

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), or 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

Exclusions

- Any repeat dose is considered experimental or investigational

- 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

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

Classified as Confidential

MVP Health Care Medical Policy

Zopapogene Imadenovex (Papzimeos)

Type of Policy: Medical Drug therapy (administered by the pharmacy department)
Prior Approval Date: N/A
Approval Date: 06/01/2026
Effective Date: 06/01/2026
Related Policies: CAR-T Cell Therapy, Amtagvi

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

Drugs Requiring Prior Authorization under the medical benefit

J3404 Papzimeos (injection, zopapogene imadenovec-drba suspension, per therapeutic dose)

Overview

Recurrent respiratory papillomatosis (RRP) is a rare, benign neoplastic disease caused by chronic infection with human papillomavirus (HPV) types 6 or 11. It is characterized by recurrent growth of papillomas throughout the aerodigestive tract, predominantly in the larynx, trachea, and occasionally the lungs.

Zopapogene imadenovec (Papzimeos) is a nonreplicating adenoviral vector-based immunotherapy indicated for the treatment of individuals with recurrent respiratory papillomatosis (RRP). It is the first FDA-approved immunotherapy for adult RRP and is a novel therapeutic approach targeting the underlying HPV infection rather than just removing papillomas surgically. It works by expressing a fusion antigen derived from selected regions of human papillomavirus (HPV) types 6 and 11 proteins, thereby generating an immune response targeted against HPV 6 and 11 infected cells.

Indications/Criteria

A. Recurrent Respiratory Papillomatosis (RRP)

Papzimeos may be considered for coverage when all the following is provided:

- Chart notes are provided confirming a diagnosis of recurrent respiratory papillomatosis (RRP)
- Papzimeos is prescribed by or in consultation with an appropriate specialist (e.g. otolaryngologist, laryngologist, oncologist, pulmonologist).
- Confirmation that the member has not received a previous treatment course of Papzimeos
- Provider attestation that surgical debulking of visible papilloma is performed prior to the initial, third and fourth dose of Papzimeos.

Papzimeos will be for one (1) treatment course within a 6-month period. One treatment course is 4 doses over a 12-week interval.
Requests for extensions beyond one (1) completed treatment course are excluded from coverage.

Exclusions

The use of Papzimeos will not be covered in the following situations:

- More than one (1) treatment course (4 doses within a 12-week interval) per lifetime.
- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling

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References

1. Zopapogene Imadenovec (Papzimeos). Clinical Pharmacology [database on the Internet]. Tampa (FL): Elsevier; 2017 [cited 2026 Mar 27]. Available from: www.clinicalpharmacology.com. Subscription required to view.

2. Papzimeos [package insert]. Germantown, MD: Precigen, Inc. Aug 2025. PAPZIMEOS United States Prescribing Information V1.0 Approved

3. Norberg SM, Valdez J, Napier S, Kenyon M, Ferraro E, Wheatley M, Parsons-Wandell L, Doran SL, Lankford A, Sabzevari H, Brough DE, Schlom J, Gulley JL, Allen CT. PRGN-2012 gene therapy in adults with recurrent respiratory papillomatosis: a pivotal phase 1/2 clinical trial. Lancet Respir Med. 2025 Apr;13(4):318-326. doi: 10.1016/S2213-2600(24)00368-0. Epub 2025 Jan 21. Erratum in: Lancet Respir Med. 2025 Apr;13(4):e22. PRGN-2012 gene therapy in adults with recurrent respiratory papillomatosis: a pivotal phase 1/2 clinical trial - PubMed

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).	

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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: Zopapogene Imadenovex (Papzimeos)

Type of Policy: Medical Drug therapy (administered by the pharmacy department)
Prior Approval Date: N/A
Approval Date: 06/01/2026
Effective Date: 06/01/2026
Related Policies: CAR-T Cell Therapy, Amtagvi

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

Drugs Requiring Prior Authorization under the medical benefit

J3404 Papzimeos (injection, zopapogene imadenovec-drba suspension, per therapeutic dose)

Overview

Recurrent respiratory papillomatosis (RRP) is a rare, benign neoplastic disease caused by chronic infection with human papillomavirus (HPV) types 6 or 11. It is characterized by recurrent growth of papillomas throughout the aerodigestive tract, predominantly in the larynx, trachea, and occasionally the lungs.

Zopapogene imadenovec (Papzimeos) is a nonreplicating adenoviral vector-based immunotherapy indicated for the treatment of individuals with recurrent respiratory papillomatosis (RRP). It is the first FDA-approved immunotherapy for adult RRP and is a novel therapeutic approach targeting the underlying HPV infection rather than just removing papillomas surgically. It works by expressing a fusion antigen derived from selected regions of human papillomavirus (HPV) types 6 and 11 proteins, thereby generating an immune response targeted against HPV 6 and 11 infected cells.

Indications/Criteria

A. Recurrent Respiratory Papillomatosis (RRP)

Papzimeos may be considered for coverage when all the following is provided:

- Chart notes are provided confirming a diagnosis of recurrent respiratory papillomatosis (RRP)
- Papzimeos is prescribed by or in consultation with an appropriate specialist (e.g. otolaryngologist, laryngologist, oncologist, pulmonologist).
- Confirmation that the member has not received a previous treatment course of Papzimeos
- Provider attestation that surgical debulking of visible papilloma is performed prior to the initial, third and fourth dose of Papzimeos.

Papzimeos will be for one (1) treatment course within a 6-month period. One treatment course is 4 doses over a 12-week interval.
Requests for extensions beyond one (1) completed treatment course are excluded from coverage.

Exclusions

The use of Papzimeos will not be covered in the following situations:

- More than one (1) treatment course (4 doses within a 12-week interval) per lifetime.
- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling

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References

1. Zopapogene Imadenovec (Papzimeos). Clinical Pharmacology [database on the Internet]. Tampa (FL): Elsevier; 2017 [cited 2026 Mar 27]. Available from: www.clinicalpharmacology.com. Subscription required to view.

2. Papzimeos [package insert]. Germantown, MD: Precigen, Inc. Aug 2025. PAPZIMEOS United States Prescribing Information V1.0 Approved

3. Norberg SM, Valdez J, Napier S, Kenyon M, Ferraro E, Wheatley M, Parsons-Wandell L, Doran SL, Lankford A, Sabzevari H, Brough DE, Schlom J, Gulley JL, Allen CT. PRGN-2012 gene therapy in adults with recurrent respiratory papillomatosis: a pivotal phase 1/2 clinical trial. Lancet Respir Med. 2025 Apr;13(4):318-326. doi: 10.1016/S2213-2600(24)00368-0. Epub 2025 Jan 21. Erratum in: Lancet Respir Med. 2025 Apr;13(4):e22. PRGN-2012 gene therapy in adults with recurrent respiratory papillomatosis: a pivotal phase 1/2 clinical trial - PubMed

MVP Health Care Medical Policy

Zoladex- Medicaid

Type of Policy: **Medical Therapy**
Prior Approval Date: **11/01/2024**
Approval Date: **08/01/2025**
Effective Date: **10/01/2025**
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)

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).	
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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

Zynteglo

Type of Policy: **Drug/Medical Therapy**
Prior Approval Date: **01/01/2025**
Approval Date: **12/01/2025**
Effective Date: **02/01/2026**
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 (5.0×10^6 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
- 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 5.0×10^6 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 5.0×10^6 CD34+ cells/kg of bodyweight, in one or more infusion bags

Indication	Dose
Beta Thalassemia	**Mobilization and Apheresis** – 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 × 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.)* – A back-up collection of CD34+ cells of ≥ 1.5 × 10^6 CD34+ cells/kg (if collected by apheresis) or > 1.0 × 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: o Compromise of hematopoietic stem cells or Zynteglo before infusion o Primary engraftment failure o Loss of engraftment after infusion with Zynteglo – Note: G-CSF and plerixafor were used for mobilization **Myeloablative Conditioning** – Full myeloablative conditioning must be administered before infusion of Zynteglo. Consult prescribing information for the myeloablative conditioning agent(s) prior to treatment. – Prophylaxis for hepatic veno-occlusive disease (VOD) is recommended and prophylaxis for seizures should be considered, as appropriate. – 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. – Note: busulfan was used for myeloablative conditioning **Administration** – Verify that the patient's identity matches the unique patient identification information on the Zynteglo infusion bag(s) prior to infusion. – Do not sample, alter, or irradiate Zynteglo. – Do not use an in-line blood filter or an infusion pump. – 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. – 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. – 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)

11. Department of Health Pharmacy Technical Workgroup Meeting #78. August 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 Medicare 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 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 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
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 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: Zynteglo

Type of Policy: **Drug/Medical Therapy**
Prior Approval Date: **01/01/2025**
Approval Date: **12/01/2025**
Effective Date: **02/01/2026**
Related Policies: **N/A**

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

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

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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 5.0×10^6 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 5.0×10^6 CD34+ cells/kg of bodyweight, in one or more infusion bags

Indication	Dose
Beta Thalassemia	**Mobilization and Apheresis** – 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 ≥ 12×10^6 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.)* – A back-up collection of CD34+ cells of ≥ 1.5×10^6 CD34+ cells/kg (if collected by apheresis) or > 1.0×10^8 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: o Compromise of hematopoietic stem cells or Zynteglo before infusion o Primary engraftment failure o Loss of engraftment after infusion with Zynteglo – Note: G-CSF and plerixafor were used for mobilization **Myeloablative Conditioning** – Full myeloablative conditioning must be administered before infusion of Zynteglo. Consult prescribing information for the myeloablative conditioning agent(s) prior to treatment. – Prophylaxis for hepatic veno-occlusive disease (VOD) is recommended and prophylaxis for seizures should be considered, as appropriate. – 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. – Note: busulfan was used for myeloablative conditioning **Administration** – Verify that the patient's identity matches the unique patient identification information on the Zynteglo infusion bag(s) prior to infusion. – Do not sample, alter, or irradiate Zynteglo. – Do not use an in-line blood filter or an infusion pump. – 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. – 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. – 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.	

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