MVP Health Care Medical Policy

Abatacept

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

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

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

Drugs Requiring Prior Authorization under the pharmacy benefit

Orencia SQ is non-preferred under the pharmacy benefit

Drugs Requiring Prior Authorization under the medical benefit

J0129 abatacept, 10mg (Orencia IV)

Overview

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

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

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

C. **Rheumatoid Arthritis**

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

- Member has a diagnosis of moderate to severe active adult RA as defined by persistent or recurrent symptoms with documented synovitis and morning stiffness of significant duration to inhibit activities of daily living.
- Chart notes are provided documenting a failure to respond to a three-month trial of methotrexate at a maximally tolerated dose.
    - Failure is demonstrated by documentation of provider assessment without improvement in joint counts and/or physical symptoms and inflammatory markers while on therapy.
    - If the member has a contraindication or significant intolerance to methotrexate

- Chart notes documenting a failure to respond to at least one other nonbiologic DMARDs at a maximally tolerated dose for at least 3 months **AND** documentation confirming why methotrexate cannot be used is required. If a trial of methotrexate is not appropriate due to alcohol use, chart notes must be provided indicating that the patient has been counseled on the need to abstain from alcohol use while taking methotrexate and is unwilling to abstain from alcohol use.

Initial approval for **6 months**.

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

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

D. **Juvenile Idiopathic Arthritis**

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

Initial approval for **6 months**.

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

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

E. **Psoriatic Arthritis**

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

- Member has a diagnosis of moderate to severe PsA as defined by three or more tender joints AND three or more swollen joints on two separate occasions at least one month apart
- Chart notes are provided documenting failure of at least one NSAID at maximum tolerated dose unless the member has contraindications to NSAID therapy such as cardiovascular disease, peptic ulcer disease or renal disease **AND**
- Chart notes are provided documenting failure to an adequate trial of at least one of the following nonbiologic disease modifying anti-rheumatic drugs (DMARDs): leflunomide, sulfasalazine, or methotrexate.

- **Members with pure axial manifestations** do not have to have a trial of nonbiologic disease modifying anti-rheumatic drugs (DMARDs)
- If a trial of methotrexate is not appropriate due to alcohol use, chart notes must be provided indicating that the patient has been counseled on the need to abstain from alcohol use while taking methotrexate and is unwilling to abstain from alcohol use.

Initial approval for **6 months**.

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

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

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

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

Initial approval for **6 months**.

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

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

Exclusions

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

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

References

1. Clinical Pharmacology. Abatacept. Revised 12/21/2021. Accessed 01/05/2023.
2. Orencia (abatacept) for injection. Prescribing information. Bristol-Myers Squibb Princeton, NJ. Revised 10/2023.
3. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis & Rheumatology Vol. 71, No. 1, January 2019, pp 5–32 DOI 10.1002/art.40726. 2018 American College of Rheumatology/ National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis

4. 2021 American College of Rheumatology Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Oligoarthritis, Temporomandibular Joint Arthritis, and Systemic Juvenile Idiopathic Arthritis. Arthritis and Rheumatology. Vol 74 No. 4 April 2022, pp553-569. Available at: https://www.rheumatology.org/Portals/0/Files/ACR-JIA%20Guideline-Oligo-TMJ-sJIA-EarlyView.pdf
5. Fraenkel et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care & Research Vol. 73, No. 7, July 2021, pp 924–939 DOI 10.1002/acr.24596. Available at: 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis (contentstack.io).

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

MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	
POS in Plan	Prior Auth
POS OOP	Prior Auth
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D
MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Select PPO	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Secure PPO	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D
MVP VT HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD
♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).	

***Medical Management Requirements**

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

MVP Health Care Medical Policy

Medicare Part B: Abatacept

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

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

Drugs Requiring Prior Authorization under the medical benefit

J0129 abatacept, 10mg (Orencia IV)

Overview/Summary of Evidence

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

Indications/Criteria

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

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

B. **Rheumatoid Arthritis**

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

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

Initial approval for **6 months**.

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

C. **Juvenile Idiopathic Arthritis**

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

Initial approval for **6 months**.

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

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

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

Initial approval for **6 months**.

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

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

Initial approval for **6 months**.

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

Exclusions

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

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

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References

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

MVP Health Care Medical Policy

ACL Inhibitors

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

Drugs Requiring Prior Authorization (covered under the pharmacy benefit)

Nexletol (Bempedoic acid)

Nexlizet (Bempedoic acid and ezetimibe)

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

Overview

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

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

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

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

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

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

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

UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
Healthy NY	Prior Authorization
MVP Premier	Prior Authorization
MVP Premier Plus	Prior Authorization
MVP Premier Plus HDHP	Prior Authorization
MVP Secure	Prior Authorization
MVP EPO	Prior Authorization
MVP EPO HDHP	Prior Authorization
MVP PPO	Prior Authorization
MVP PPO HDHP	Prior Authorization
Student Health Plans	Prior Authorization
ASO	See SPD
Vermont Products	
POS in Plan	Prior Authorization
POS OOP	Prior Authorization
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D
MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Select PPO	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Secure PPO	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D
MVP VT HMO	Prior Authorization
MVP VT Plus HMO	Prior Authorization
MVP VT HDHP HMO	Prior Authorization
MVP VT Plus HDHP HMO	Prior Authorization
MVP Secure	Prior Authorization
ASO	See SPD
♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).	

***Medical Management Requirements**

Prior Auth	Prior Authorization Required
Potential for Retrospective Review	No Prior Authorization Required. May be subject to Retrospective Review.
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:	**02/01/2023**
Approval Date:	**02/01/2024**
Effective Date:	**04/01/2024**

Related Policies:

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

Drugs Requiring Prior Authorization

J0800 (Injection, corticotropin, up to 40 units)

Overview

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

Indications/Criteria

Multiple Sclerosis

Acthar may be considered for coverage in the treatment of acute exacerbations of relapsing-remitting multiple sclerosis for patients greater than 18 years of age when prescribed by a neurologist and the following criteria are met:

1. The symptoms are severe and impair vision and/or mobility.
2. There is a documented severe allergic or hypersensitivity reaction, anaphylaxis, or angioedema to high-dose oral corticosteroids and/or IV methylprednisolone or dexamethasone.
3. Prescriber must rule out pseudo-exacerbation from other precipitating factors (i.e. infection, pain, stress, premenstrual syndrome)
4. Patient 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.

Coverage beyond one month will require clinical documentation indicating response to initial treatment and plan for continued therapy

Nephrotic Syndrome

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

- Prescribed by a nephrologist.
- Proteinuria of at least 3.5 g/24 hours.
- The patient has been compliant with a low-protein diet and lipid management
- Patient has a documented severe allergic or hypersensitivity reaction, anaphylaxis or angioedema to high-dose oral corticosteroids and/or IV methylprednisolone or dexamethasone
- Patient 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 not 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

Infantile Spasms

The following criteria must be met for the use of corticotropin gel for infantile spasms:

- Documentation supporting diagnosis of infantile spasms (with hypsarrythmia) including onset of age, description of symptoms
- Treatment plan and goals must be submitted with request.
- 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 a neurologist.

For continuation of therapy of infantile spasms, improvement in spasms must be documented within four weeks of initiation of therapy.

Other FDA approved indications:

For other FDA approved indications: Rheumatic Diseases, Collagen Diseases, Dermatologic Diseases, Respiratory Diseases, Ophthalmic Diseases or Allergic Conditions must be managed with high dose steroids, the member must be 2 years of age and the clinician must submit a treatment plan showing failure on standard therapies for the disease.

One-time approval for up to four weeks since corticotropin is generally used for acute conditions and acute exacerbations.

Exclusions

The use of corticotropin 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.
- Patients with 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

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

MVP Premier Plus HDHP	Prior Authorization
MVP Secure	Prior Authorization
MVP EPO	Prior Authorization
MVP EPO HDHP	Prior Authorization
MVP PPO	Prior Authorization
MVP PPO HDHP	Prior Authorization
Student Health Plans	Prior Authorization
ASO	Prior Authorization
Vermont Products	
POS in Plan	Prior Authorization
POS OOP	Prior Authorization
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Select PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Secure PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP VT HMO	Prior Authorization
MVP VT Plus HMO	Prior Authorization
MVP VT HDHP HMO	Prior Authorization
MVP VT Plus HDHP HMO	Prior Authorization
MVP Secure	Prior Authorization
ASO	Prior Authorization
♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).	
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***Medical Management Requirements**

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

MVP Health Care Medical Policy

Adakveo

Type of Policy:	Drug Therapy
Prior Approval Date:	10/01/2023
Approval Date:	10/01/2023
Effective Date:	12/01/2023
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 patients 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:

1. Chart notes confirming the diagnosis of sickle cell disease
2. Member is at least 16 years of age or older.
3. Baseline vaso-occlusive crises (number of crises within the past one year)
4. Member has had a 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 patient 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. Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling

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Member Product	Medical Management Requirements*
New York Products	
HMO	Prior Auth
PPO in Plan	Prior Auth
PPO OOP	Prior Auth
POS in Plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Prior Auth
MVP Child Health Plus	Prior Auth
MVP Harmonious Health Care Plan	Prior Auth
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure HMO POS	Prior Auth
MVP Medicare WellSelect PPO	Prior Auth
MVP Medicare WellSelect Plus PPO	Prior Auth
MVP Medicare Patriot Plan (PPO)	Prior Auth
MVP SmartFund MSA	Potential for Retrospective Review
MVP DualAccess D-SNP HMO (eff. 7/1/22)	Prior Auth
MVP DualAccess Complete D-SNP HMO (eff. 7/1/22)	Prior Auth
MVP DualAccess Plus D-SNP HMO (eff. 7/1/22)	Prior Auth
UVM Health Advantage Select PPO	Prior Auth
UVM Health Advantage Secure PPO	Prior Auth
UVM Health Advantage Preferred PPO	Prior Auth
Gold Anywhere PPO	Prior Auth
USACare PPO	Prior Auth
Healthy NY	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	
POS in Plan	Prior Auth
POS OOP	Prior Auth
MVP Medicare Preferred Gold HMO POS POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP Medicare WellSelectPPO	Prior Auth
MVP SmartFund MSA	Potential for Retrospective Review
UVM Health Advantage Select PPO	Prior Auth
UVM Health Advantage Secure PPO	Prior Auth
UVM Health Advantage Preferred PPO	Prior Auth
Gold AnyWhere PPO	Prior Auth
MVP VT HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD

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

***Medical Management Requirements**

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

MVP Health Care Medical Policy

Adalimumab

Type of Policy:	Drug Therapy
Prior Approval Date:	04/01/2023
Approval Date:	12/01/2023
Effective Date:	01/01/2024
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, uvitis, 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, colorectal surgeon, or ophthalmologist
- Must be prescribed for an FDA approved indication
- Humira, adalimumab-adaz and Hyrimoz are the preferred agents. Requests for other adalimumab biosimilars will only be considered for coverage when:
    - Documented failure, contraindication or ineffective response to all preferred/formulary therapies for the specific indication.

B. Rheumatoid arthritis (RA)

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

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

has been counseled on the need to abstain from alcohol use while taking methotrexate and is unwilling to abstain from alcohol use.

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

Initial approval will be for 6 months.

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

Extension requests where adalimumab did not have the full desired effect or considered a clinical failure will

require clinical rationale for continuing.

C. Psoriatic arthritis (PsA)

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

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

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

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

Initial approval will be for 6 months.

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

E. Ankylosing Spondylitis (AS)

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

- Member has a diagnosis of moderate to severe AS
- Chart notes documenting failure of at least one NSAID at maximum tolerated dose 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 persistent peripheral arthritis** failure of sulfasalazine or methotrexate at maximum tolerated dose in patients
- **For 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 adalimumab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

F. Crohn's Disease

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

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

  Has lost response to or is intolerant to infliximab.

Initial approval will be for 6 months.

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

G. Hidradenitis Suppurativa

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

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

Initial approval will be for 6 months.

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

H. Uveitis

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

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

Initial approval will be for 6 months.

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

I. Polyarticular juvenile idiopathic arthritis

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

Initial approval will be for 6 months.

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

J. Ulcerative Colitis

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

- Diagnosis of moderate to severe ulcerative colitis
- Documentation identifying 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).
    a. 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[12]

Exclusions

Adalimumab will not be covered for the following situations:

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

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31. Ritchlin CT, Kavanaugh A, Gladman DD, et al: (2008) Treatment recommendations for psoriatic arthritis. Ann Rheum Dis 2009 Sep;68(9):1387-94.

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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
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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).	

***Medical Management Requirements**

Prior Auth	Prior Authorization Required
Potential for Retrospective Review	No Prior Authorization Required. May be subject to Retrospective Review.
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: 03/01/2023
Approval Date: 11/01/2023
Effective Date: 01/01/2024
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 diagnosed with 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
- Presence of personal distress and/or interpersonal difficulties due to low sexual desire
- Secondary causes of HSDD such as chronic illness, emotional issues, gynecologic issues, hormone changes, major life events have been evaluated
- Vyleesi: member has been assessed for cardiovascular risk and their blood pressure is under control

Initial approval will be for 3 months

For continuation of therapy for 6 months, **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.

Exclusions

- Not indicated for treatment of HSDD in postmenopausal women
- Low sexual desire due to a medical or psychiatric condition
- Exclusions associated with REMS criteria
- Use to enhance sexual performance
- Addyi:
    - greater than one tablet per day

Contraindicated in patients with hepatic impairment, strong or moderate CYP3A4 inhibitors, and concurrent use with alcohol

- Vyleesi:
    - more than 8 doses per month

    Contraindicated in patients with uncontrolled hypertension or known cardiac disease

References

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

Member Product	Medical Management Requirements*
New York Products	
HMO	Prior Auth
PPO in Plan	Prior Auth
PPO OOP	Prior Auth
POS in Plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Child Health Plus	
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	Not Covered
MVP Medicare Secure Plus HMO POS	Not Covered
MVP Medicare WellSelect PPO	Not Covered
MVP Medicare WellSelect Plus PPO	Not Covered
MVP Medicare Patriot Plan PPO	Not Covered
MVP DualAccess D-SNP HMO	Not Covered
MVP DualAccess Complete D-SNP HMO	Not Covered
MVP DualAccess Plus D-SNP HMO	Not Covered
UVM Health Advantage Select PPO	Not Covered
UVM Health Advantage Secure PPO	Not Covered
UVM Health Advantage Preferred PPO	Not Covered
Healthy NY	Prior Auth

MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Not Covered
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	
POS in Plan	Prior Auth
POS OOP	Prior Auth
MVP Medicare Preferred Gold HMO POS	Not Covered
MVP Medicare Secure Plus HMO POS	Not Covered
UVM Health Advantage Select PPO	Not Covered
UVM Health Advantage Secure PPO	Not Covered
UVM Health Advantage Preferred PPO	Not Covered
MVP VT HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Not Covered
ASO	See SPD
♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).	

***Medical Management Requirements**

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

MVP Health Care Medical Policy

Apremilast

Type of Policy: Drug Therapy
Prior Approval Date: 02/01/2023
Approval Date: 10/01/2023
Effective Date: 12/01/2023
Related Policies: Adalimumab
Etanercept
Infliximab
Risankizumab
Secukinumab
Tofacitinib
Upadacitinib
Ustekinumab
Ozanimod

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

Drugs Requiring Prior Authorization under the pharmacy benefit

Otezla (apremilast)

Overview

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

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

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 a 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 4 months.

Extension requests will be approved for 12 months 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. 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 12 months 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 6 months.

Extension requests will be approved for 12 months 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; 2021 Dec.
2. H Weisman and M E Weinblatt Emery, et al. Updated consensus statement on biological agents for the treatment of rheumatic diseases, 2007. Ann Rheum Dis 2007;66;2-22.
3. Ritchlin CT, Kavanaugh A, Gladman DD, et al: (2008) Treatment recommendations for psoriatic arthritis. Ann Rheum Dis 2009 Sep;68(9):1387-94.
4. Callen, Jeffrey P., Krueger, Gerald G., Lebwohl, Mark, et al., American Academy of Dermatology Consensus Statement of Psoriasis Therapies. Journal of American Academy of Dermatology. (2003).
5. Pardasani, Asha MD., Feldman, Steven MD., PhD, and et al, (2000). Treatment of Psoriasis: An algorithm-based approach for primary care physicians. American Family Physician, Vol. 61, pp. 725-33,736. (On-line) Available: www. aafp.org/afp.
6. Khachmoune, Amor, Phillips, Tania, (2000). Current treatment options in psoriasis.
7. American Academy of Dermatology, (2012). Public resources: Psoriasis. (On-line). Available: http://www.aad.org/skin-conditions/dermatology-a-to-z/psoriasis
8. Richards HL, Fortune DG, O'Sullivan TM, et al, (1999) Patients with psoriasis and their compliance with medications. American Academy of Dematology, Oct; 41(4):581-3. (abstract).

9. Finlay AY, Khan GK, et al., (1990). Validation of sickness impact profile and psoriasis disability index in psoriasis. British Journal of Dermtology Dec. 123 (6) 751-6. (abstract).

10. Fortune DG, Main CJ, O'Sullivan TM, Griffiths CE, (1997) Quality of life in patients with psoriasis: the contribution of clinical variables and psoriasis-specific stress. British Journal of Dermatology Nov; 137(5): 755-60. (abstract).

11. Menter A, Gottlieb A, Feldman SR et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 1. Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. J Am Acad Dermatol 2008; 58:826-50.

12. 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

13. Coates LC, Kavanaugh A, Mease PJ, et al. Group for Research and Assessment of Psoriasis and Psoriatic Artritis (GRAPPA) 2015 Treatment Recommendations for Psoriatic Arthritis. Arthritis Rheumatol. 2016;68:1060-1071. Epub 2016 Mar23.

14. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis & Rheumatology. 2019;71:5-32. 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 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	
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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).	

***Medical Management Requirements**

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

MVP Health Care Medical Policy

Amtagvi (Lifileucel)

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

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

Drugs Requiring Prior Authorization under the medical benefit

J999 Amtagvi (Lifileucel)

Overview

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

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

Indications/Criteria

Unresectable or metastatic melanoma

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

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

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

Exclusions

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

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

References

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

Member Product	Medical Management Requirements*
New York Products	
HMO	Prior Auth
PPO in Plan	Prior Auth
PPO OOP	Prior Auth
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POS OOP	Prior Auth
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MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	
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MVP VT Plus HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
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MVP Secure	Prior Auth
ASO	See SPD
♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).	

***Medical Management Requirements**

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

MVP Health Care Medical Policy

Medicare Part B: Amtagvi (Lifileucel)

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

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

Drugs Requiring Prior Authorization under the medical benefit

J999 Amtagvi (Lifileucel)

Overview

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

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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

Antibiotic/Antiviral (oral) Prophylaxis

Type of Policy: **Drug Therapy**
Prior Approval Date: **12/01/2022**
Approval Date: **12/01/2024**
Effective Date: **02/01/2024**
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 patients 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: Judicious Use of Antibiotics. Available: http://www.nyhealth.gov/nysdoh/antibiotic/antibiotic.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	Prior Auth
MVP Child Health Plus	Prior Auth
MVP Harmonious Health Care Plan	Prior Auth
MVP Medicare Gold Giveback	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Secure HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare WellSelect PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare WellSelect Plus PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Patriot Plan PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess Complete D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess Plus D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Select PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Secure PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	
POS in Plan	Prior Auth
POS OOP	Prior Auth
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Select PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Secure PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP VT HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD
♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).	
© 2024 MVP Health Plan, Inc. All rights reserved. Descriptions contained within MVP's Medical Policies are not a guarantee of coverage. Each MVP Group or Subscriber Contract contains specific limitations, exclusions and requirements that may affect a Policy. If there is any discrepancy between your Group or Subscriber Contract and a Policy, your Group or Subscriber Contract shall in all cases govern.	

***Medical Management Requirements**

Prior Auth — Prior Authorization Required

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

MVP Health Care Medical Policy

Baricitinib

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

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

Drugs Requiring Prior Authorization under the pharmacy benefit

Baricitinib (Olumiant)

Overview

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

Indications/Criteria

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

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

A. Rheumatoid Arthritis (RA)

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

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

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

B. Alopecia areata

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

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

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

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 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.
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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.
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.
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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.
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).	

***Medical Management Requirements**

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

MVP Health Care Medical Policy

Biosimilars, Select Medical

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

Prior Approval Date: **02/01/2020**

Approval Date: **10/01/2023**

Effective Date: **12/01/2023**

Related Policies:

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.
Infliximab

Codes Subject to Retrospective Review under the medical benefit

J9035 Avastin Injection, bevacizumab, 10 mg

Q5107 Mvasi Injection, bevacizumab-awwb, biosimilar,10 mg

Q5118 Zirabev Injection, bevacizumab-bvzr, biosimilar,10 mg

J9312 Rituxan Injection, rituximab, 10 mg

Q5115 Truxima Injection, rituximab-abbs, biosimilar,10 mg

Q5119 Ruxience rituximab-pvvr, biosimilar, 10mg

J9999 Riabni Injection, rituximab-arrx, 10mg

J9355 Herceptin Injection, trastuzumab, excludes biosimilar, 10 mg

J9356 Herceptin Hylecta Injection, trastuzumab, 10 mg and Hyaluronidase-oysk

Q5117 Kanjinti Injection, trastuzumab-anns, biosimilar,10 mg

Q5114 Ogivri Injection, Trastuzumab-dkst, biosimilar,10 mg

Q5116 Trazimera Injection, trastuzumab-qyyp, biosimilar,10 mg

Q5112 Ontruzant Injection, trastuzumab-dttb, biosimilar, 10 mg

Q5113 Herzuma Injection, trastuzumab-pkrb, biosimilar,10 mg

Q5129 Vegzelma injection, bevacizumab-adcd, biosimilar, 10mg

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

Biosimilars are approved by the FDA as highly similar to an already approved biologic medication (also known as a "reference product") and has no clinically meaningful difference from the reference product. MVP Health Care will cover all codes listed above when used for an FDA approved indication. On label use of medical drugs are covered under the member's medical benefit and is 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.

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1. **Bevacizumab**

Indication	**FDA Indicated Bevacizumab Therapies**
Metastatic colorectal cancer, in combination with intravenous fluorouracil-based chemotherapy for first- or second-line treatment	Avastin, Mvasi, Zirabev, Vegzelma
Metastatic colorectal cancer, in combination with fluoropyrimidine-irinotecan- or fluoropyrimidine-oxaliplatin-based chemotherapy for second-line treatment in patients who have progressed on a first-line bevacizumab product-containing regimen.	Avastin, Mvasi, Zirabev, Vegzelma
Unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer, in combination with carboplatin and paclitaxel for first-line treatment	Avastin, Mvasi, Zirabev, Vegzelma
Recurrent Glioblastoma in adults	Avastin, Mvasi, Zirabev, Vegzelma
Metastatic renal cell carcinoma in combination with interferon-alfa	Avastin, Mvasi, Zirabev, Vegzelma
Persistent, recurrent, or metastatic cervical cancer, in combination with paclitaxel and cisplatin, or paclitaxel and topotecan	Avastin, Mvasi, Zirabev, Vegzelma
Epithelial ovarian, fallopian tube, or primary peritoneal cancer: • in combination with carboplatin and paclitaxel, followed by Avastin as a single agent, for stage III or IV disease following initial surgical resection • in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan for platinum-resistant recurrent disease who received no more than 2 prior chemotherapy regimens • in combination with carboplatin and paclitaxel or	Avastin, Mvasi, Zirabev , Vegzelma

carboplatin and gemcitabine, followed by Avastin as a single agent, for platinum-sensitive recurrent disease	

2. **Rituximab**

Indication	**FDA Indicated Rituximab Therapies**
Non-Hodgkin's Lymphoma (NHL): • Relapsed or refractory, low grade or follicular, CD20-positive Bcell NHL as a single agent. • Previously untreated follicular, CD20-positive, B-cell NHL in combination with first line chemotherapy and, in patients achieving a complete or partial response to a rituximab product in combination with chemotherapy, as single-agent maintenance therapy. • Non-progressing (including stable disease), low-grade, CD20- positive, B-cell NHL as a single agent after first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy. • Previously untreated diffuse large B-cell, CD20-positive NHL in combination with (cyclophosphamide, doxorubicin, vincristine, and prednisone) (CHOP) or other anthracycline-based chemotherapy regimens.	Rituxan,Truxima, Ruxience, Riabni
Chronic Lymphocytic Leukemia (CLL): Previously untreated and previously treated CD20-positive CLL in combination with fludarabine and cyclophosphamide (FC)	Rituxan,Truxima, Ruxience, Riabni
Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA) in adult and pediatric patients 2 years of age and older in combination with glucocorticoids	Rituxan, Ruxience, Riabni (adults only)
Moderate to severe Pemphigus Vulgaris (PV) in adult patients	Rituxan

3. **Trastuzumab**

Indication	**FDA Indicated Trastuzumab Therapies**
The treatment of HER2-overexpressing breast cancer	Herceptin, Herceptin Hylecta, Kanjinti, Ogivri, Trazimera, Ontruzant, Herzuma
The treatment of HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma	Herceptin, Kanjinti, Ogivri, Trazimera, Ontruzant, Herzuma

References

1. FDA Prescribing Information, Avastin. Accessed November 2019.
2. FDA Prescribing Information, Mvasi. Accessed November 2019.
3. FDA Prescribing Information, Zirabev. Accessed November 2019.
4. FDA Prescribing Information, Herceptin. Accessed November 2019.
5. FDA Prescribing Information, Kanjinti. Accessed November 2019.
6. FDA Prescribing Information, Ogivri. Accessed November 2019.
7. FDA Prescribing Information, Trazimera. Accessed November 2019.
8. FDA Prescribing Information, Ontruzant, Accessed November 2019.
9. FDA Prescribing Information, Herzuma. Accessed November 2019.
10. FDA Prescribing Information, Rituxan. Accessed November 2019.
11. FDA Prescribing Information, Truxima. Accessed November 2019.
12. FDA Prescribing Information, Ruxience. Accessed November 2019
13. Biosimilar and Interchangeable Products. U.S Food & Drug Administration. Accessed November 2019: https://www.fda.gov/drugs/biosimilars/biosimilar-and-interchangeable-products#biosimilar
14. FDA Prescribing Information, Riabni. Accessed January 2021

Member Product	Medical Management Requirements*
New York Products	
HMO	Retro Review
PPO in Plan	Retro Review
PPO OOP	Retro Review
POS in Plan	Retro Review
POS OOP	Retro Review
Essential Plan	Retro Review
MVP Medicaid Managed Care	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Potential for Retro Review
MVP Child Health Plus	Retro Review
MVP Harmonious Health Care Plan	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Potential for Retro Review
MVP Medicare Preferred Gold HMO POS	Potential for Retro Review
MVP Medicare Secure HMO POS	Potential for Retro Review
MVP Medicare Secure Plus HMO POS	Potential for Retro Review
MVP Medicare WellSelect PPO	Potential for Retro Review
MVP Medicare WellSelect Plus PPO	Potential for Retro Review
MVP Medicare Patriot Plan PPO	Potential for Retro Review
MVP DualAccess D-SNP HMO	Potential for Retro Review
MVP DualAccess Complete D-SNP HMO	Potential for Retro Review
MVP DualAccess Plus D-SNP HMO	Potential for Retro Review
UVM Health Advantage Select PPO	Potential for Retro Review
UVM Health Advantage Secure PPO	Potential for Retro Review
UVM Health Advantage Preferred PPO	Potential for Retro Review
Healthy NY	Retro Review
MVP Premier	Retro Review
MVP Premier Plus	Retro Review
MVP Premier Plus HDHP	Retro Review
MVP Secure	Potential for Retro Review
MVP EPO	Retro Review
MVP EPO HDHP	Retro Review
MVP PPO	Retro Review
MVP PPO HDHP	Retro Review
Student Health Plans	Retro Review

ASO	See SPD
Vermont Products	
POS in Plan	Retro Review
POS OOP	Retro Review
MVP Medicare Preferred Gold HMO POS	Potential for Retro Review
MVP Medicare Secure Plus HMO POS	Potential for Retro Review
UVM Health Advantage Select PPO	Potential for Retro Review
UVM Health Advantage Secure PPO	Potential for Retro Review
UVM Health Advantage Preferred PPO	Potential for Retro Review
MVP VT HMO	Retro Review
MVP VT Plus HMO	Retro Review
MVP VT HDHP HMO	Retro Review
MVP VT Plus HDHP HMO	Retro Review
MVP Secure	Potential for Retro Review
ASO	See SPD
♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).	

***Medical Management Requirements**

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

MVP Health Care Medical Policy

C. Difficile Drug Therapy

Type of Policy:	Drug Therapy
Prior Approval Date:	NA
Approval Date:	07/01/2023
Effective Date:	08/01/2023
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. 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:

MVP Health Care Medical Policy

CAR-T Cell Therapy

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

Related Policies:

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

Amtagvi

Codes Requiring Prior Authorization (covered under the medical benefit)

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

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

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

Overview

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

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

1. Kymriah

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

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

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

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

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

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

2. Yescarta

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

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

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

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

3. Tecartus

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

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

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

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

4. Breyanzi

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

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

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

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

5. Abecma

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

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

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

6. Carvykti

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

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

Exclusions

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

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

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

Members with a history of CNS lymphoma or CNS disorders

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2. Yescarta (axicabtagene ciloleucel) suspension for intravenous infusion. Prescribing Information. Santa Monica, CA. Kite Pharma, Inc. October 2017.
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18. Member Product	Medical Management Requirements*
New York Products	
HMO	Prior Auth
PPO in Plan	Prior Auth
PPO OOP	Prior Auth
POS in Plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Child Health Plus	Prior Auth
MVP Harmonious Health Care Plan	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Medicare Gold Giveback	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Secure HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare WellSelect PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare WellSelect Plus PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Patriot Plan PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess Complete D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess Plus D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Select PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Secure PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth

MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	
POS in Plan	Prior Auth
POS OOP	Prior Auth
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D
MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Select PPO	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Secure PPO	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D
MVP VT HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD
♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).	
© 2024 MVP Health Plan, Inc. All rights reserved. Descriptions contained within MVP's Medical Policies are not a guarantee of coverage. Each MVP Group or Subscriber Contract contains specific limitations, exclusions and requirements that may affect a Policy. If there is any discrepancy between your Group or Subscriber Contract and a Policy, your Group or Subscriber Contract shall in all cases govern.	

***Medical Management Requirements**

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

MVP Health Care Medical Policy

Casgevy (Exagamglogene Autotemcel)

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

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

Drugs Requiring Prior Authorization under the medical benefit

J3590 Casgevy (Exagamglogene Autotemcel)

Overview

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

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

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

Indications/Criteria

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

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

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

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

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

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

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

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

C. Transfusion Dependent β-Thalassemia (TDT)

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

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

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

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

Exclusions

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

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

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

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

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

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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: Casgevy (Exagamglogene Autotemcel)

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

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

Drugs Requiring Prior Authorization under the medical benefit

J3590 Casgevy (Exagamglogene Autotemcel)

Overview

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

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

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

Indications/Criteria

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

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

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

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

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

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

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

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

C. Transfusion Dependent β-Thalassemia (TDT)

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

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

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

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

Exclusions

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

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

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

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

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

References

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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

Certolizumab

Type of Policy:	**Medical Therapy**
Prior Approval Date:	**12/01/2023**
Approval Date:	**02/01/2024**
Effective Date:	**04/01/2024**
Related Policies:	**Apremilast, Adalimumab , Infliximab, Risankizumab, Secukinumab, Tofacitinib, Upadacitinib, Ustekinumab, Ozanimod, Abatacept, Golimumab, Tocilizumab**

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

Drugs Requiring Prior Authorization under the pharmacy benefit

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

Drug Requiring Prior Authorization under the medical benefit

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

Overview

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

Medicaid Variation: Medications that are a pharmacy benefit are covered and billed to New York State Fee-For-Service (FFS) program. They are defined as medications that go

through a retail or specialty pharmacy, including self-administered injectable products. Pharmacy medications are subject to FFS's clinical criteria including (but not limited to) coverage, quantity limit, step therapy, and prior authorization. Pharmacy benefit information can be found here: https://www.emedny.org/info/fullform.pdf

Indications/Criteria

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

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

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

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

stomatitis, absess, fever >37.5 in the last week), taking opiates or diphenoxylate/atropine for diarrhea, anemia, and weight loss >10%.

Initial approval for **6 months**.

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

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

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

Initial approval for **6 months**.

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

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

D. **Psoriasis**

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

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

Initial approval for **6 months**.

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

E. **Psoriatic arthritis**

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

- Member has a diagnosis of moderate to severe PsA as defined by three or more tender joints AND three or more swollen joints on two separate occasions at least one month apart
- Chart notes documenting failure of at least one NSAID at maximum tolerated dose unless the member has contraindications to NSAID therapy such as cardiovascular disease, peptic ulcer disease or renal disease **AND**

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

Initial approval for **6 months**.

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

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

Initial approval for **6 months**.

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

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

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

Initial approval for **6 months**.

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

Exclusions

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

- Diagnosis of multiple sclerosis
- 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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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).	

***Medical Management Requirements**

Prior Auth	Prior Authorization Required
Potential for Retrospective Review	No Prior Authorization Required. May be subject to Retrospective Review.
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:	**11/01/2023**
Approval Date:	**02/01/2024**
Effective Date:	**04/01/2024**
Related Policies:	**Abatacept, Golimumab, Infliximab, Risankizumab, Tocilizumab, Ustekinumab**

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

Drug Requiring Prior Authorization under the medical benefit

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

Overview/Summary of Evidence

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

Indications/Criteria

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

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

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

B. **Crohn's disease**

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

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

Initial approval for **6 months**.

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

C. **Rheumatoid arthritis**

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

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

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

Initial approval for **6 months**.

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

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

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

Initial approval for **6 months**.

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

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

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

Initial approval for **6 months**.

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

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

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

Initial approval for **6 months**.

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

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

Initial approval for **6 months**.

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

Exclusions

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

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

MVP Health Care Medical Policy

Calcitonin Gene-Related Peptide (CGRP) Antagonists

Type of Policy:	Drug Therapy
Prior Approval Date:	08/01/2023
Approval Date:	08/01/2024
Effective Date:	10/01/2024
Related Policies:	Migraine Agents

Codes Requiring Prior Authorization (covered under the pharmacy benefit)

Aimovig (erenumab-aooe) auto-injector

Ajovy (fremanezumab-vfrm) prefilled syringe

Emgality (galcanezumab-gnlm) prefilled pen/syringe

Ubrelvy (ubrogepant) – when quantity limit is exceeded

Nurtec ODT (rimegepant) – when quantity limit is exceeded

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.

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

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

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

Indications/Criteria

A. Aimovig, Ajovy, Emaglity may be considered for coverage for migraine prophylaxis when all the following are met:

-
- Confirmed diagnosis of chronic or episodic migraine
- For episodic cluster headaches:
    - Emgality is the only CGRP Antagonist indicated for episodic cluster headaches
- Confirmed diagnosis of episodic cluster headachesFor chronic migraine:
    - Inadequate response (defined as less than a 2 day decrease per month in headache frequency) to at least a 1 (one) trial to at least **1** (one) prophylactic medication (i.e., topiramate, divalproex, propranolol, metoprolol, timolol, amitriptyline, verapamil, venlafaxine) at maximally tolerated doses.

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

- For episodic cluster headaches:
    - Inadequate response to a trial of prophylactic medications at the maximally tolerated doses (i.e. verapamil and lithium) **OR**Member has a contraindication to all prophylactic medications

- For Vyepti:

- All applicable criteria listed above **AND**
- Documentation identifying medical necessity why the member is unable to use a self-administered product (such as a failure, intolerance, or contraindication to self-administered products).
    - If applicable, documentation should also include why the member or caregiver is unable to administer a self-administered product.

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.

B. Quantity Limits for Nurtec and Ubrelvy

- Ubrelvy quantity is limited to 16 tablets per 30 days and Nurtec quantity is limited to 16 tablets per 30 days. Requests exceeding these quantities will be considered for coverage when the following criteria is met:
    - Headache diary identifies more than 4 headaches per month
    - Chart notes identifying consult with a neurologist
    - Preventative treatment has been initiated or rationale provided why **all non-CGRP Antagonist preventative therapies** are contraindicated (e.g., antiepileptics, antidepressants, beta-blockers).
    - The quantity limit amount has been tried and does not provide adequate coverage for the number of headaches identified in the headache diary
    - If the preventative therapy has not decreased the number of headaches per week, a 2-month trial of a different preventative drug will be expected until **all non-CGRP Antagonist preventative drug classes** have been exhausted

Initial approval will be for 3 months

Extension requests will be up to 12 months based upon clinical response and must include current chart notes identifying continued 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

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Exclusions

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

References

1. Aimovig (erenumab-aooe) [Package Insert]. Thousand Oaks, CA: Amgen Inc.; 20182.
2. Olesen J, Bes A, Kunkel R, et al. The international classification of headache disorders, 3rd edition. Cephalagia. 2018; 38(1):1-211.
3. https://americanmigrationfoundation.org/understanding-migraine/medication-overuse-headache-2/
4. Ajovy (fremanezumab-vfrm) [Package Insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc. September 2018.
5. Emgality (galcanezumab-gnlm) [Package Insert]. Indianapolis, IN: Eli Lilly and Company. June 2019.
6. https://clinicaltrials.gov/ct2/show/study/NCT02397473?term=NCT02397473&rank=1
7. Olesen J, Bes A, Kunkel R, et al. The International Classification of Headache Disorders. 3rd edition. *Cephalalgia.* 2018; 38(1): 41-42.
8. Robbins M.S, Starling A.J, et al (2016). Treatment of Cluster Headache: The American Headache Society Evidence-Based Guidelines. *Headache: The Journal of Head and Face Pain.* 56 (7): 1093-1106. DOI: 10.1111/head.12866
9. Local Coverage Determination L33646; Botulinum Toxins; effective 10/31/2019
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11. Ailani J, Burch RC, Robbins MS; Board of Directors of the American Headache Society. The American Headache Society Consensus Statement: Update on integrating new migraine treatments into clinical practice. Headache. 2021;61(7):1021-1039. doi:10.1111/head.14153.

12. Aimovig. Study Details | Study to Evaluate the Efficacy and Safety of Erenumab (AMG 334) in Migraine Prevention | ClinicalTrials.gov. A Controlled Trial of Erenumab for Episodic Migraine | New England Journal of Medicine (nejm.org)

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

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

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).	

***Medical Management Requirements**

Prior Auth	Prior Authorization Required
Potential for Retrospective Review	No Prior Authorization Required. May be subject to Retrospective Review.
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: Calcitonin Gene-Related Peptide (CGRP) Antagonists

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

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

Codes Requiring Prior Authorization (covered under the medical benefit)

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

Overview/Summary of Evidence

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

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

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

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

Indications/Criteria for prophylaxis for Vyepti

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

- Confirmed diagnosis of chronic or episodic migraine

For chronic migraine:

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

For episodic migraine:

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

For Vyepti:

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

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

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

Exclusions

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

References

1. Aimovig (erenumab-aooe) [Package Insert]. Thousand Oaks, CA: Amgen Inc.; 20182.
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14. Emgality. Evaluation of Galcanezumab in the Prevention of Episodic Migraine- the EVOLVE-1 Study - Full Text View - ClinicalTrials.gov

MVP Health Care Medical Policy

Cialis for BPH

Type of Policy:	Drug Therapy
Prior Approval Date:	08/01/2023
Approval Date:	08/01/2024
Effective Date:	10/01/2024
Related Policies:	Quantity Limit for Prescription Drugs 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. PDE-5 inhibitors were not included in the 2010 AUA Guidelines as of the date of this policy.

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

Indications/Criteria

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

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

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

For continued therapy:

- Documentation of a reduction in BPH symptoms

Exclusions

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

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

References

1. Cialis® (tadalafil). Prescribing Information. Indianapolis, IN: Eli Lilly and Company; April 2023.
2. Prostate Enlargement: Benign Prostatic Hyperplasia [Internet]. March 2012 [cited 2014 July 7]. Available from: http://kidney.niddk.nih.gov/kudiseases/pubs/prostateenlargement/.
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4. American Urological Association (AUA) Education and Research, Inc. AUA Clinical Practice Guidelines for the Management of BPH [Internet]. September 2010. Available: http://www.auanet.org/common/pdf/education/clinical-guidance/Benign-Prostatic-Hyperplasia.pdf.
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7. 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 Medicare Gold Giveback	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Secure HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare WellSelect PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare WellSelect Plus PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Patriot Plan PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess Complete D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess Plus D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Select PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Secure PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth

MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	
POS in Plan	Prior Auth
POS OOP	Prior Auth
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D
MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Select PPO	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Secure PPO	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D
MVP VT HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD
♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).	

***Medical Management Requirements**

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

MVP Health Care Medical Policy

Colony Stimulating Factors (CSF)

Type of Policy:	**Drug Therapy**
Prior Approval Date:	**12/01/2022**
Approval Date:	**10/01/2023**
Effective Date:	**12/01/2023**
Related Policies:	

Codes Subject to Retrospective Review

J2506 – Injection, pegfilgrastim, 6 mg (Neulasta)
Q5130Injection, 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-filgraUDEstim, 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)

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.

I. 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

II. Initial Approval Criteria

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

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

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 patients with non-myeloid malignancy

- Patient is undergoing myelosuppressive chemotherapy with an expected incidence of febrile neutropenia of 20% or greater; **OR**
- Patient 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 patients (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
  - Patient 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

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

- Used for the treatment of chemotherapy induced febrile neutropenia; **AND**
  - Patient has been on prophylactic therapy with filgrastim; **OR**
  - Patient has not received prophylactic therapy with a granulocyte colony stimulating factor; **AND**
    - Patient 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

Patient who experienced a neutropenic complication from a prior cycle of the same chemotherapy

Acute Myeloid Leukemia (AML) patient following induction or consolidation chemotherapy

Bone Marrow Transplantation (BMT) failure or Engraftment Delay

Severe chronic neutropenia

- Patient must have an absolute neutrophil count (ANC) < 500/mm^3; **AND**
- Patient must have a diagnosis of one of the following:
  - Congenital neutropenia; **OR**
  - Cyclic neutropenia; **OR**
  - Idiopathic neutropenia

Myelodysplastic Syndrome

- Endogenous serum erythropoietin level of ≤500 mUnits/mL; **AND**
- Patient is receiving concurrent therapy with Erythropoiesis Stimulating Agents (ESAs)

Patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Subsyndrome of Acute Radiation Syndrome

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

Prophylactic use in patients with non-myeloid malignancy

- Patient is undergoing myelosuppressive chemotherapy with an expected incidence of febrile neutropenia of 20% or greater; **OR**

- Patient 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 patients (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
  - Patient 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

Patient who experienced a neutropenic complication from a prior cycle of the same chemotherapy

Patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Subsyndrome of Acute Radiation Syndrome)

Bone marrow transplantation (BMT) failure or engraftment delay

Peripheral blood progenitor cell (PBPC) mobilization and transplant

III. Renewal Criteria

Coverage can be renewed if patient continues to meet above criteria

IV. 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 patients with acute radiation exposure

References

1. Nivestym [package insert]. Lake Forest, IL; Hospira Inc; July 2018. Accessed July 2018.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) filgrastim-aafi. National Comprehensive Cancer Network, 2018. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc." To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed July 2018.
3. Smith TJ, Bohlke K, Lyman GH, Carson KR, Crawford J, Cross SJ, Goldberg JM, Khatcheressian JL, Leighl NB, Perkins CL, Somlo G, Wade JL, Wozniak AJ, Armitage JO. Recommendations for the use of WBC growth factors: American Society of Clinical Oncology Clinical Practice Guideline Update. J Clin Oncol. 2015 Jul 13. pii: JCO.2015.62.3488. [Epub ahead of print]

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7. Isidori A, Tani M, Bonifazi F, et al. Phase II study of a single pegfilgrastim injection as an adjunct to chemotherapy to mobilize stem cells into the peripheral blood of pretreated lymphoma patients. Haematologica January 200590:225-231
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10. Staber, P. B., et al. "Fixed-dose single administration of Pegfilgrastim vs daily Filgrastim in patients with haematological malignancies undergoing autologous peripheral blood stem cell transplantation." Bone marrow transplantation 35.9 (2005): 889-893.
11. Vanstraelen, Gaëtan, et al. "Pegfilgrastim compared with Filgrastim after autologous hematopoietic peripheral blood stem cell transplantation." Experimental hematology 34.3 (2006): 382-388.
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15. Zarxio [package insert]. Princeton, NJ; Sandoz Inc; March 2015. Accessed March 2019.

16. Granix [package insert]. North Wales, PA; Teva Pharmaceuticals; July 2018. Accessed March 2019.
17. Wisconsin Physicians Service Insurance Corporation. Local Coverage Determination (LCD): Human Granulocyte/Macrophage Colony Stimulating Factors (L34699). Centers for Medicare & Medicaid Services, Inc. Updated on 1/23/2018 with effective date 02/1/2018. Accessed March 2018.
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20. Nyvepria [package insert]. Lake Forest, Il; Hospira. April 2021.

Member Product	Medical Management Requirements*
New York Products	
HMO	Potential for Retrospective Review
PPO in Plan	Potential for Retrospective Review
PPO OOP	Potential for Retrospective Review
POS in Plan	Potential for Retrospective Review
POS OOP	Potential for Retrospective Review
Essential Plan	Potential for Retrospective Review
MVP Medicaid Managed Care	Potential for Retrospective Review
MVP Child Health Plus	Potential for Retrospective Review
MVP Harmonious Health Care Plan	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
UVM Health Advantage Secure PPO	Potential for Retrospective Review
UVM Health Advantage Preferred 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
UVM Health Advantage Select PPO	Potential for Retrospective Review
UVM Health Advantage Secure PPO	Potential for Retrospective Review
UVM Health Advantage Preferred PPO	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).	

***Medical Management Requirements**

Prior Auth	Prior Authorization Required
Potential for Retrospective Review	No Prior Authorization Required. May be subject to Retrospective Review.
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: **03/01/2023**
Approval Date: **12/01/2023**
Effective Date: **02/01/2024**
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 patient. Traditional compounding typically is used to prepare medications that are not available commercially, such as a drug for a patient who is allergic to an ingredient in a mass-produced drug, or diluted dosages for children.[1]

Indications/Criteria

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

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

- For topical compounds, the compound ingredients are FDA or compendia supported for topical use
- Documentation supporting clinical necessity of a compounded medication that has the same active ingredient as a commercially available product except for the dose, inactive ingredients, and/or dosage form (e.g., weight or age of patient 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 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"
- 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)

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
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

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References

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

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

***Medical Management Requirements**

Prior Auth	Prior Authorization Required
Potential for Retrospective Review	No Prior Authorization Required. May be subject to Retrospective Review.
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:	
Approval Date:	06/01/2024
Effective Date:	08/01/2024
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.
- 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).
- Except for contraceptives covered under Women's Preventive Services of the Affordable Care Act,
  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.
- Except for contraceptives covered under Women's Preventive Services of the Affordable Care Act,
  no co-payment reduction will be considered when member preference or increases in member adherence are the reason for the request.
- 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 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	Not covered
MVP Child Health Plus	Prior Authorization
MVP Harmonious Health Care Plan	Not covered
MVP Medicare Gold Giveback	N/A
MVP Medicare Preferred Gold HMO POS	N/A
MVP Medicare Secure HMO POS	N/A
MVP Medicare Secure Plus HMO POS	N/A
MVP Medicare WellSelect PPO	N/A
MVP Medicare WellSelect Plus PPO	N/A
MVP Medicare Patriot Plan PPO	N/A
MVP DualAccess D-SNP HMO	N/A
MVP DualAccess Complete D-SNP HMO	N/A
MVP DualAccess Plus D-SNP HMO	N/A
UVM Health Advantage Select PPO	N/A
UVM Health Advantage Secure PPO	N/A
UVM Health Advantage Preferred PPO	N/A
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	N/A
MVP Medicare Secure Plus HMO POS	N/A
UVM Health Advantage Select PPO	N/A
UVM Health Advantage Secure PPO	N/A
UVM Health Advantage Preferred PPO	N/A
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).	

***Medical Management Requirements**

Prior Auth	Prior Authorization Required
Potential for Retrospective Review	No Prior Authorization Required. May be subject to Retrospective Review.
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:	04/01/2023
Approval Date:	04/01/2024
Effective Date:	06/01/2024
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
deoxycholic acid	Kybella
dihydroxyacetone	Chromelin, Vitadye, Dy-o-derm solution
eflornithine	Vaniqa
Finasteride 1mg	Propecia
hyaluronic acid, sodium hyaluronate	Perlane, Restylane, Volbella XC, Prevelle Silk, Juvederm
hydroquinone	Melquin, Esoterica, Aclaro, Epiquin Micro, Kaxm, Keido, Kuxm, Kutea, Remergent, Blanche cream, Esoterica, Ambi-fade, Skin Success cream, Keya

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

Overview

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

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

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

Indications/Criteria

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

Exclusions

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

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

Member Product	Medical Management Requirements*
New York Products	
HMO	Prior Auth
PPO in Plan	Prior Auth
PPO OOP	Prior Auth
POS in Plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Child Health Plus	Prior Auth
MVP Harmonious Health Care Plan	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Medicare Gold Giveback	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Secure HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare WellSelect PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare WellSelect Plus PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Patriot Plan PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess Complete D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess Plus D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Select PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Secure PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	
POS in Plan	Prior Auth
POS OOP	Prior Auth

MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D
MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Select PPO	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Secure PPO	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D
MVP VT HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD
♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).	
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***Medical Management Requirements**

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

MVP Health Care Medical Policy

Cystic Fibrosis (select agents for inhalation)

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

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

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

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

Overview

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

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

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

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

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.

References

1. Pulmozyme® (dornase alfa for inhalation). Prescribing Information. South San Francisco, CA: Genentech, Inc.; December 2014.
2. TOBI® (tobramycin inhalation solution). Prescribing Information. East Hanover, NJ: Novartis Pharmaceutical Corporation; October 2018.
3. NHIC, Inc. Local Coverage Determination (LCD) for Nebulizers (L33370). Original Determination Effective Date 10/1/2015. Revised 04/14/2022. Available from: https://www.cms.gov/medicare-coverage-database/search/search-results.aspx?
4. NHIC, Inc. Article for Nebulizers (A52466). Original Article Effective Date 10/1/2015. Revised 04/14/2022. Available from: https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=52466
5. Cayston (aztreonam for inhalation). Prescribing Information. Foster City, CA: Gilead Sciences, Inc.; Revised November 2019.
6. TOBI Podhaler® (tobramycin inhalation powder). Prescribing Information. East Hanover, NJ: Novartis Pharmaceutical Corporation; Revised October 2020.
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8. Flume PA et al. Cystic Fibrosis Pulmonary Guidelines: Chronic Medications for Maintenance of Lung Health. Am J Respir Crit Care Med. 29 Aug 2007; 176: 957-969.
9. 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.
10. TOBI Podhaler® (tobramycin inhalation solution). Prescribing Information. East Hanover, NJ: Novartis Pharmaceutical Corporation; Revised 02/2023.

11. KITABIS PAK (tobramycin inhalation solution, USP). Prescribing Information. Midlothian, VA: PARI Respiratory, Inc. Revised 08/2021.
12. KITABIS PAK (tobramycin inhalation solution, USP). Prescribing Information. Midlothian, VA: PARI Respiratory, Inc. Revised 08/2023.
13. Pulmozyme® (dornase alfa for inhalation). Prescribing Information. South San Francisco, CA: Genentech, Inc.; February 2024
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
MVP Child Health Plus	Prior Auth
MVP Harmonious Health Care Plan	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Medicare Gold Giveback	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Secure HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare WellSelect PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare WellSelect Plus PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Patriot Plan PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess Complete D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess Plus D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Select PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Secure PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth

MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	
POS in Plan	Prior Auth
POS OOP	Prior Auth
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D
MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Select PPO	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Secure PPO	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D
MVP VT HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD
♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).	

***Medical Management Requirements**

Prior Auth	Prior Authorization Required
Potential for Retrospective Review	No Prior Authorization Required. May be subject to Retrospective Review.
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:	**NA**
Approval Date:	**11/01/2023**
Effective Date:	**01/01/2024**
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:

- Confirmed 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.
        - Typical RTT requires the following clinical criteria: all main criteria and all exclusion criteria listed below.
        - Atypical RTT requires the following clinical criteria: at least 2 of 4 main criteria and 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 3 months.

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

Exclusions

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

- Dosing, age, and/or frequency outside of the FDA approved package labeling

References

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

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

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

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9. *Acadia Pharmaceuticals*. (2023, July). Daybue (trofinetide). https://daybuehcp.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 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
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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

Cystic Fibrosis (select oral agents)

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

Drugs Requiring Prior Authorization (covered under the pharmacy benefit)

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

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

Overview

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

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

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

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

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

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

Indications/Criteria

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

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

- Member has a confirmed diagnosis of cystic fibrosis

B. Kalydeco

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

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

B. Orkambi

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

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

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

C. Symdeko

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

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

D. Trikafta

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

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

For Kalydeco, Orkambi, Symdeko and Trikafta:

Initial approval will be for 6 months

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

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

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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

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References

1. 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.
2. Brooks M (Medscape Contributor). FDA expands use of Ivacftor (Kalydeco) for cystic fibrosis [Internet]. 2014 [cited 2015 Apr 15]. Available from: http://www.medscape.com/viewarticle/837406.
3. 10. Flume PA et al. Cystic Fibrosis Pulmonary Guidelines: Chronic Medications for Maintenance of Lung Health. Am J Respir Crit Care Med. 29 Aug 2007; 176: 957-969.
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.
5. .
6. Trikafta (elexacaftor, tezacaftor and ivacaftor tablets; ivacaftor tablets), co-packaged for oral use. Prescribing information. Boston, MA: Vertex Pharmaceuticals Incorporated; Revised 04/2023.
7. Kalydeco (ivacftor tablets for oral use). Prescribing information. Boston, MA: Vertex Pharmaceuticals Incorporated; Revised 08/2023. uspi_ivacaftor.pdf (vrtx.com)
8. Orkambi (lumacaftor/ivacaftor tablets for oral use). Prescribing information. Boston, MA: Vertex Pharmaceuticals Incorporated; Revised 08/2023.
9. Symdeko (tezacaftor/ivacaftor) tablets; ivacaftor tablets, for oral use. Prescribing information. Boston, MA: Vertex Pharmaceuticals Incorporated; Revised 08/2023.
10. Lahiri T, Hempstead SE, Brady C, et al. Clinical Practice Guidelines From the Cystic Fibrosis Foundation for Preschoolers With Cystic Fibrosis. Pediatrics. 2016;137(4):e20151784

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.
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MVP Medicare Patriot Plan PPO	Refer to the MVP website for the Medicare Part B and Part D policies.

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MVP DualAccess 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 Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
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MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	
POS in Plan	Prior Auth
POS OOP	Prior Auth
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D
MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part D
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UVM Health Advantage Secure PPO	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D
MVP VT HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD
♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).	

***Medical Management Requirements**

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

MVP Health Care Medical Policy

Diclofenac (topical) Products

Type of Policy:	Drug Therapy
Prior Approval Date:	04/01/2023
Approval Date:	04/01/2024
Effective Date:	06/01/2024
Related Policies:	N/A

Drugs Requiring Prior Authorization

Pennsaid (brand name, diclofenac sodium) 1.5%, 2% drops
Solaraze (diclofenac sodium) 3% gel
Diclofenac sodium 3% gel

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

Overview

Diclofenac is a nonsteroidal anti-inflammatory agent available in various formulations, including oral and topical. Topical administration of NSAIDs offers the advantage of local drug delivery and thus reducing the risk of systemic adverse effects.

The use of topical diclofenac products will be limited to FDA approved indications, or indications supported by the compendia.

Indications/Criteria

Solaraze 3% gel and diclofenac 3% gel may be considered for coverage when all the following criteria are met:

- Chart notes are provided documenting a diagnosis of actinic keratosis
- For brand name Solaraze 3% gel must have failure of generic diclofenac 3% gel
- Approval will be for 3 months

Pennsaid solution (brand) may be considered for coverage when all the following criteria are met:

- Chart notes are provided documenting a diagnosis of osteoarthritis of the knees
- Chart notes are provided documenting a failure of **TWO** oral NSAIDs (or documented contraindication, intolerance, or drug interaction)
- Member must have a failure of generic diclofenac drops
- Approval will be for 6 months

Exclusions

- Non-FDA approved indication, or use not supported by the compendia
- Dosing, age, and/or frequency exceeding the FDA approved package labeling.
- Peri-operative pain in the setting of coronary artery bypass graft (CABG) surgery

References

1. Pennsaid (diclofenac sodium) solution. Prescribing Information. Hazelwood, MO: Mallinckrodt Pharmaceuticals.
2. Solaraze (diclofenac sodium) gel. Prescribing Information. Melville, NY: PharmaDerm

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.
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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.
UVM Health Advantage Select PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Secure PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	
POS in Plan	Prior Auth
POS OOP	Prior Auth
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D
MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Select PPO	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Secure PPO	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D
MVP VT HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD
♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).	

***Medical Management Requirements**

Prior Auth	Prior Authorization Required
Potential for Retrospective Review	No Prior Authorization Required. May be subject to Retrospective Review.
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:	**10/01/2022**
Approval Date:	**10/01/2023**
Effective Date:	**12/01/2023**
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 for pediatric and adult patients with molecularly confirmed long-chain fatty acid oxidation disorders (LC-FAODs). LC-FAODs are a group of rare, inborn errors of metabolism in which the body is unable to convert long-chain fatty acids into energy.

Indications/Criteria

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

1. Confirmed diagnosis of severe LC-FAOD such as one of the following:
    - Very long-chain acyl-CoA dehydrogenase (VLCAD) deficiency
    - Carnitine palmitoyltransferease II (CPT II) deficiency
    - Carnitine palmitoyltransferase I (CPT I) deficiency
    - Carnitine-acylcarnitine translocase (CACT) deficiency
    - Trifunctional protein (TFP) deficiency **or**
    - Long-chain 3-hydroxyacyl-CoA dehydrogenase deficiency (LCHAD)

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. Evidence of one of the following:
    - Chronic elevated creatinine kinase (CK) with major clinical events
    - Episodic elevated CK with muscle dysfunction
    - Highly elevated CK but asymptomatic
    - Episodes of hypoglycemia, rhabdomyolysis, or exacerbation of cardiomyopathy requiring emergency room visits, acute care visits or hospitalizations
    - Severe susceptibility to hypoglycemia or recurrent symptomatic hypoglycemia requiring intervention
    - Evidence of functional cardiomyopathy documenting poor ejection fraction requiring ongoing medical management.

Initial authorization will be granted for 3 months.

Subsequent authorization up to 6 months will be granted with documentation of continued clinical benefit and continued compliance with dietary management.

Exclusions

- Dose, frequency outside of FDA approved labeling

References

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

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
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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

Donislecel

Type of Policy:	**Drug Therapy**
Prior Approval Date:	**N/A**
Approval Date:	**02/01/2024**
Effective Date:	**02/01/2024**

Related Policies: **Teplizumab**

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

Drugs Requiring Prior Authorization under the medical benefit

J3590 donislecel-JUJN, IV suspension (Lantidra)

Overview

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

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

Indications/Criteria

Type 1 Diabetes

Lantidra (donislecel) may be considered for coverage when:

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

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

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

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

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

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Exclusions

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

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

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References

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

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

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

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

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

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

***Medical Management Requirements**

Prior Auth	Prior Authorization Required
Potential for Retrospective Review	No Prior Authorization Required. May be subject to Retrospective Review.
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: **N/A**
Approval Date: **02/01/2024**
Effective Date: **02/01/2024**

Related Policies: **Teplizumab**

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

Drugs Requiring Prior Authorization under the medical benefit

J3590 donislecel-JUJN, IV suspension

Overview/Summary of Evidence

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

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

Indications/Criteria

Type 1 Diabetes

Lantidra (donislecel) may be considered for coverage when:

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

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

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

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

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

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Exclusions

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

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

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References

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

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

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

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

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

MVP Health Care Medical Policy

Drug Utilization Review and Monitoring Program

Type of Policy:	**N/A**
Prior Approval Date:	**07/01/2023**
Approval Date:	**12/01/2023**
Effective Date:	**01/01/2024**
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 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

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. 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.

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	Monthly	The prescribing physician or other appropriate member of the healthcare team will be contacted by mail; and the member	Re-assessed within 12 months

	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.		may receive a letter to discuss the issue with their provider.	
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

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
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	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

	following age groups: a. 0-5 years; b. 6-12 years; 13-17 years; and d. 18-20 years.			
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 the FDA approved max dose.	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 3 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	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

	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.			
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.	
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.

MVP Health Care Medical Policy

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

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

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

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

Overview

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

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

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

Criteria

Prescription Drugs

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

For the most up to date coverage information for the products below, refer to the NYRx List of Reimbursable Drugs.

Prescription Drugs covered for dual eligible beneficiaries:

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

Over-the-Counter (OTC) Drugs

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

Exclusions

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

References

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

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

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

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

Member Product	Medical Management Requirements*
New York Products	
HMO	N/A
PPO in Plan	N/A
PPO OOP	N/A
POS in Plan	N/A
POS OOP	N/A
Essential Plan	N/A
MVP Medicaid Managed Care	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Child Health Plus	N/A
MVP Harmonious Health Care Plan	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP 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	N/A
MVP Premier	N/A

MVP Premier Plus	N/A
MVP Premier Plus HDHP	N/A
MVP Secure	N/A
MVP EPO	N/A
MVP EPO HDHP	N/A
MVP PPO	N/A
MVP PPO HDHP	N/A
Student Health Plans	N/A
ASO	N/A
Vermont Products	
POS in Plan	N/A
POS OOP	N/A
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D 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	N/A
MVP VT Plus HMO	N/A
MVP VT HDHP HMO	N/A
MVP VT Plus HDHP HMO	N/A
MVP Secure	N/A
ASO	N/A
♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).	

***Medical Management Requirements**

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

MVP DualAccess Complete D-SNP HMO	Prior Auth
MVP DualAccess Plus D-SNP HMO	Prior Auth
UVM Health Advantage Select PPO	Prior Auth
UVM Health Advantage Secure PPO	Prior Auth
UVM Health Advantage Preferred 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
UVM Health Advantage Select PPO	Prior Auth
UVM Health Advantage Secure PPO	Prior Auth
UVM Health Advantage Preferred PPO	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

Duchenne Muscular Dystrophy

Type of Policy: **Drug Therapy**
Prior Approval Date: **11/01/2023**
Approval Date: **04/01/2024**
Effective Date: **04/01/2024**

Drug Requiring Prior Authorization (covered under the pharmacy benefit)

Emflaza

Deflazacort

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:

- Diagnosis of Duchenne muscular dystrophy (DMD) confirmed by genetic testing
- Patient 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 granted if the member shows all the following:

- Clinical benefit such as increase in muscle strength, pulmonary function tests or timed function tests
- Decrease in adverse effects experienced while receiving prednisone.

B. Medicaid Variation

- Medications that are a pharmacy benefit are covered and billed to New York State Fee-For-Service (FFS) program. They are defined as medications that go through a retail or specialty pharmacy, including self administered injectable products. Pharmacy medications are subject to FFS's clinical criteria including (but not limited to) coverage, quantity limit, step therapy, and prior authorization. Pharmacy benefit information can be found here: https://www.emedny.org/info/fullform.pdf
- Requests for Exondys 51, Vyondys 53, Amondys 45 and Viltepso will be reviewed when **ALL** the following criteria are met (based on New York State Department of Health Fee-For-Service criteria):
  - Member must have a diagnosis of Duchenne Muscular Disease (DMD) **AND**
  - Documentation of genetic testing must confirm the DMD gene mutation of the member is amenable to exon 45, 51, or 53 skipping **AND**
  - Documentation must confirm a stable dose of corticosteroids prior to starting therapy or a documented reason not to be on corticosteroids **AND**
  - Documentation indicates kidney function testing prior to starting therapy (except eteplirsen) **AND**
  - Member is not concurrently being treated with another exon skipping therapy for DMD
- Requests for Elevidys will be reviewed
  - Member must have a diagnosis of Duchenne Muscular Disease (DMD) **AND**

- Documentation of genetic testing must confirm the DMD gene mutation **AND**
- Confirmation that member is ambulatory **AND**
- Member is aged 4 through 5 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 indicated liver function, platelet counts and troponin-I prior to starting therapy **AND**
- Patient is not concurrently being treated with another exon skipping therapy for DMD

Exclusions

- Dosing, age, and/or frequency outside of the 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 all diagnoses including Duchenne muscular dystrophy, as the clinical benefit has not been confirmed.

References

1. Nayak S, Acharjya. Deflazacort versus other glucocorticoids: A comparison. Indian J Dematology. 2008;53(4):167-170
2. Griggs RC, Miller JP, Greenber CR, et al. Efficacy and safety of deflazacort vs prednisone and placebo for Duchenne muscular dystrophy. Neurology 2016; 87:2123-2131

3. Gloss DG, Moxley RT, Ashwal S, Oskoui M. Practice guideline update summary: Corticosteroid treatment of Duchenne muscular dystrophy. Neurology 2016; 86:465-472
4. Emflaza (deflazacort tablets/suspension). Prescribing Information. South Plainfiled, NJ. PTC Therapeutics
5. Exondys 51 (eteplirsen) injection. Prescribing Information. Cambridge, MA: Sarepta Therapeutics, Inc. September 2016.
6. Viltepso (viltolarsen) injection, for intravenous use. Prescribing Information. Paramus, NJ: NS Pharma. August 2020.
7. Amondys 45 (casimersen) injection. Prescribing Information. Cambridge, MA: Sarepta Therapeutics, Inc. February 2021.
8. New York State Medicaid Update. January 2022. Volume 38: Number 1. Medicaid Fee-For-Service Guidance for Duchenne Muscular Dystrophy Drugs. New York State Medicaid Update - January 2022 Volume 38 - Number 1 (ny.gov)
9. Elevidys. Package Insert - ELEVIDYS (fda.gov). Revised 10/2023.

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

UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
Healthy NY	Prior auth
MVP Premier	Prior auth
MVP Premier Plus	Prior auth
MVP Premier Plus HDHP	Prior auth
MVP Secure	Prior auth
MVP EPO	Prior auth
MVP EPO HDHP	Prior auth
MVP PPO	Prior auth
MVP PPO HDHP	Prior auth
Student Health Plans	Prior auth
ASO	See SPD
Vermont Products	
POS in Plan	Prior auth
POS OOP	Prior auth
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D
MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Select PPO	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Secure PPO	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D
MVP VT HMO	Prior auth
MVP VT Plus HMO	Prior auth
MVP VT HDHP HMO	Prior auth
MVP VT Plus HDHP HMO	Prior auth
MVP Secure	Prior auth
ASO	See SPD
♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).	
© 2024 MVP Health Plan, Inc. All rights reserved. Descriptions contained within MVP's Medical Policies are not a guarantee of coverage. Each MVP Group or Subscriber Contract contains specific limitations, exclusions and requirements that may affect a Policy. If there is any discrepancy between your Group or Subscriber Contract and a Policy, your Group or Subscriber Contract shall in all cases govern.	

***Medical Management Requirements**

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

MVP Health Care Medical Policy

Dupixent

Type of Policy: **Drug Therapy**
Prior Approval Date: **04/01/2023**
Approval Date: **04/01/2024**
Effective Date: **06/01/2024**
Related Policies: Xolair, Select Injectables for Asthma

Drugs Requiring Prior Authorization (covered under the pharmacy benefit)
Dupixent (dupilumab)

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

Overview

Dupixent is an interleukin-4 receptor alpha antagonist, which inhibits IL-4 and IL-13 cytokine-induced inflammatory response, including the release of proinflammatory cytokines, chemokines, nitric oxide, and IgE, which plays a role in the development of asthma. Dupixent has several FDA approved indications including nasal polyps, atopic dermatitis, asthma, puruigo nodularis and eosinophilic esophagitis.

Indication/Criteria

The use of Dupixent may be considered medically necessary if all the following criteria are met:

1. Chronic Rhinosinusitis with Nasal Polyps

   Dupixent may be considered for coverage for chronic rhinosinusitis with nasal polyps when the following criteria is met:

a. Confirmeddiagnosis of nasal polyps. Chart notes must document diagnosis confirmation by examination, endoscopy or sinus computed tomography (CT) scan.
b. Prescribed by or in consultation with an allergist, otolaryngologist or immunologist
c. Documented trial and failure of three (3) months to at least one intranasal corticosteroid indicated to treat nasal polyps
d. Documented failure, contraindication, intolerance, or allergy to other therapy used in the management of nasal polyps such as nasal saline irrigations, or antileukotriene agents (montelukast, zafirlukast, zileuton)
e. Documentation of prior oral corticosteroid therapy and/or sinus surgery

Dupixent will be add on maintenance in combination with an intranasal corticosteroid. **Initial coverage** will be for 6 months.

Continued authorization up to 12 months 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 is met:

a. Member has one of the following diagnoses:
    i. Documented diagnosis of asthma with eosinophilic phenotype with eosinophil count between ≥150 cells/mcL to ≤ 1500 cells/mcL in the past 12 months **OR** FeNO ≥ 25ppb **OR**
    ii. Documented diagnosis of oral corticosteroid dependent asthma with at least 1 month of daily oral corticosteroid use within the last 3 months **AND**

b. Member must be followed by an allergist, immunologist or pulmonologist **AND**
c. Documentation and claim history must identify that the member is compliant with the use of a high-dose inhaled corticosteroid (ICS) and a long-acting beta2-agonist (LABA) **AND**
d. Member still experiencing poor asthma control and has had at least two asthma exacerbations in the previous year

Initial approval will be for 6 months.

Continued authorization for up to 12 months will be considered if there is a documented decrease in asthma symptoms and exacerbations

3. Atopic Dermatitis
   Dupixent may be considered for coverage for atopic dermatitis when the following criteria is met:
   a. Chart notes documenting a confirmed diagnosis of moderate-to-severe atopic dermatitis (widespread areas of dry skin, severe limitation of everyday activities, nightly loss of sleep).
   b. Must have at least 10% BSA involvement at baseline documented in chart notes
   c. Chart notes documenting that symptom control has not been achieved with one of the following after an adequate trial:
      i. Medium or high potency topical corticosteroids **OR**
      ii. Topical calcineurin inhibitors (i.e. tacrolimus ointment, pimecrolimus cream)
   d. Must be prescribed by or in consultation with a dermatologist, allergist or immunologist

   Initial approval will be for 4 months. **Continued authorization** of 12 months must be accompanied by current chart notes identifying continued benefit and improvement in symptoms from baseline.

4. Eosinophilic Esophagitis
   Dupixent may be considered for coverage for eosinophilic esophagitis when the following criteria is met:
   a. Prescribed by or in consult with a gastroenterologist AND
   b. Member has a diagnosis of eosinophilic esophagitis confirmed by esophageal biopsy with the presence of ≥ 15 intraepithelial eosinophils per high-power field (eos/hpf) AND
   c. Secondary causes of eosinophilic esophagitis have been ruled out (such as food allergy and hypereosinophilic syndrome) AND
   d. Chart notes documenting symptoms (such as dysphagia, reflux, vomiting, food getting stuck in esophagus, trouble feeding).
   e. Documentation of a previous trial with a proton pump inhibitor, corticosteroids and dietary modifications OR

i. Documentation that a trial of a proton pump inhibitor, corticosteroids, and dietary modifications are not medically appropriate for the member.

Initial approval will be for 4 months. **Continued authorization** of 12 months must be accompanied by current chart notes identifying continued benefit and improvement in symptoms from baseline.

5. Pruruigo Nodularis
    a. Confirmed diagnosis of puruigo 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 4 months. **Continued authorization** of 12 months must be accompanied by current chart notes identifying continued benefit and improvement in symptoms from baseline.

Exclusions

- Off-label diagnosis.
- Dosing, age, and/or frequency outside of the FDA approved package labeling
- Dupixent is a self-administered product. Office or outpatient administration is not a covered benefit
- Treatment of acute bronchospasm or status asthmaticus
- Dual therapy with another monoclonal antibody is not a covered benefit

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References

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2. Eichenfield L, Tom W, Berger T, et al. Guidelines of care for the management of atopic dermatitis. Section 2. Management and treatment of atopic dermatitis with topical therapies. J Am Acad Dermatol 2014;71(1):116-32
3. Beck LA, Thaçi D, Hamilton JD, et al. Dupilumab treatment in adults with moderate-to-severe atopic dermatitis. N Engl J Med. 2014; 371:130-9
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Global Strategy for Asthma Management and Prevention. 2023 Update. GINA Main Report 2023 Front Cover (ginasthma.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.
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MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
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MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	
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MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD
♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).	

***Medical Management Requirements**

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

MVP Health Care Medical Policy

Enteral Therapy New York

(enteral, modified solid foods and medical foods)

Type of Policy: Drug Therapy
Prior Approval Date: 03/01/2023
Approval Date: 08/01/2023
Effective Date: 10/01/2023
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.[5] 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."

Medical foods are distinguished from the broader category of foods for special dietary use and from foods that make health claims by the requirement that medical foods be intended to meet distinctive nutritional requirements of a disease or condition, used under medical supervision and intended for the specific dietary management of a disease or condition. The term "medical foods" does not pertain to all foods fed to ill members. Medical foods are foods that are specially formulated and processed (as opposed to a naturally occurring foodstuff used in a natural state) for the patient who is seriously ill or who requires the product as a major treatment modality. 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.[3]

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.
- Coverage of enteral formulas provided through feeding tubes require that the member have a condition requiring tube feeding for at least three months and adequate nutrition is not possible by dietary adjustment and/or oral supplements.
- A nutritional consultation may be required prior to coverage.
- A prescription drug rider is required for coverage.

- 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.

The following formulas do not require prior authorization and will automatically adjudicate through the pharmacy benefits management system[9]. **All other products require prior authorization to determine medical necessity for all vendors.** This list is subject to change at any time.

ACERFLEX POW	MSUD 2 POW	PHENYL-FREE POW 1	UCD TRIO POW
BCAD 1 POW	MSUD AID POW	PHENYL-FREE POW 2	WND POW
BCAD 2 POW	MSUD ANALOG POW	PHENYL-FREE POW 2HP	WND 1 POW
CAMINO PRO POW BETTRMLK	MSUD COOLER LIQ	PHLEXY-10	WND 2 POW
CAMINO PRO15 LIQ	MSUD COOLER LIQ 20	PHLEXY-VITS	XLEU ANALOG POW
COMPLEX MSD POW JUNIOR	MSUD EXP20 PAK	PKU 2 POW	XLEU MAXAMAD POW
COMPLEX MSD POW VANILLA	MSUD EXPRESS PAK	PKU 3 POW	XLEU MAXAMUM POW
COMPLEX MSUD BAR AMINO AC	MSUD GEL PAK	PKU COOLER LIQ 15	XLYS XTRP POW ANALOG
COMPLEX MSUD POW	MSUD LOPHLEX LIQ LQ	PKU COOLR 10 LIQ	XLYS-XTRP POW MAXAMAID
CYCLINEX-1 POW	MSUD MAXAMAD POW	PKU COOLR 15 LIQ	XLYS-XTRP POW MAXAMUM
CYCLINEX-2 POW	MSUD MAXAMUM POW	PKU COOLR 20 LIQ	XMET ANALOG POW
GA POW	OA 1 POW	PKU EXP20 PAK	XMET MAXAMAD POW
GA DIET POW	OA 1 DIET POW	PKU EXPRESS POW	XMET MAXAMUM POW
GLUTAREX-1 POW	OA 2 POW	PKU GEL PAK	XMTVI ANALOG POW
GLUTAREX-2 POW	OA 2 DIET POW	PKU LOPHLEX LIQ LQ 20	XMTVI MAXAMD POW
GLYTACTIN	OS 2 POW	PKU TRIO POW	XMTVI MAXAMU POW
HCY 1 POW	PEPTAMEN JR LIQ	PORTAGEN POW	XPHE MAXAMAD POW
HCY 1 DIET POW	PERIFLEX POW ADVANCE	PROPIMEX-1 POW	XPHE MAXAMUM POW
HCY 2 POW	PERIFLEX POW INFANT	PROPIMEX-2 POW	XPHE-XTYR POW ANALOG
HOM 2 POW	PERIFLEX POW JUNIOR	TYR COOLER LIQ	XPHE-XTYR POW MAXAMAID
HOMINEX-1 POW	PERIFLEX LQ LIQ PKU	TYR COOLER LIQ 20	XPTM ANALOG POW
HOMINEX-2 POW	PERIFLEX LQ LIQ PKU	TYR EXP20 PAK	
I-VALEX-1 POW	PFD 1 POW	TYR EXPRESS PAK	
I-VALEX-2 POW	PFD 2 POW	TYR GEL PAK	
KETONEX-1 POW	PHENEX-1 POW	TYR LOPHLEX LIQ LQ	
KETONEX-2 POW	PHENEX-2 POW	TYREX-1 POW	
LANAFLEX PAK	PHENYLADE	TYREX-2 POW	
LMD POW	PHENYLADE POW ESSNTL	TYROS 1 POW	
LMD DIET POW	PHENYLADE POW MTE	TYROS 2 POW	

LOPHLEX POW	PHENYLADE40 POW	UCD 2 POW
LOPHLEX LQ LIQ 20	PHENYLADE60 POW	UCD ANAMIX POW JUNIOR
METHIONAID POW	PROMACTIN AA PLUS	

Exclusions/Limitations (See Medicare Variation)

- Any enteral, modified solid or medical foods, including nutritional supplements and herbal or natural compounds, whether or not a prescription is required, that are not disease specific. Examples include, but are not limited to, UltraClear®, Estrium®, Protrypsin®, glucosamine, and glucosamine/chondroitin.

- Any enteral, modified solid or medical foods whose use is not based on recognized scientific principles, including but not limited to, accepted standards of care, will be considered not medically necessary.

- Any enteral, modified solid or medical foods taken electively (i.e. to replace a missed meal in persons who have normal GI functioning) will be considered not medically necessary.

- Enteral nutrition is not covered for patients with a functioning gastrointestinal tract except when medical necessary criteria is met.

- Adequate nutrition must not be possible by dietary adjustment.

- Gluten-free solid foods used for the treatment of celiac disease do not meet coverage criteria.

- Components of medically prescribed diets (i.e. low residue or diverticular diets) do not meet coverage criteria.

- Formulas recommended as an alternative food source due to intolerance of standard formulas, but not as a specific treatment for an underlying disease process.

- Medical foods that replace or supplement standard drug treatment (i.e. Limbrel, Fosteum, Nicazel and Perative) for a specific disease or condition are not covered.

- Infants with colic without evidence of medical complications.

- 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. Enteral administration kits when the member does not have a disposable supply rider.

- Thickening agents that do not meet medical necessity criteria described above.

- Enzyme packed cartridges (e.g., Relizorb (Alcresta Pharmaceuticals)) for enzyme replacement in patients receiving enteral tube feedings are considered experimental/investigational and are not covered.

Medicare Variation

Enteral nutrition is covered under the prosthetic device benefit as per the Medicare Local Coverage Determination (LCD) for Enteral Nutrition (L38955) and the LCD-related Policy Article A58833. Please refer to this guidance for appropriate coverage.

Coverage of In-line digestive enzyme cartridges (ie. RELiZORB) is considered reasonable and necessary for the management of Medicare beneficiaries with a diagnosis of Exocrine Pancreatic Insufficiency (EPI) to maintain weight and strength commensurate with their overall health status. Please refer to LCD L38955.

Supplemental nutritional therapy including modified solid foods, medical foods, nutritional supplements, and enteral products administered orally or products that do not meet the Medicare definition of enteral therapy are not covered under Medicare Part B or Medicare Part D.

DSNP Variation (for MAP plans ONLY):–

Enteral nutrition for DSNP members is covered if it meets criteria outlined in the above Medicare Variation OR for the following conditions:

- Tube-fed individuals who cannot chew or swallow food and must obtain nutrition through formula via tube
- Individuals with rare inborn metabolic disorders requiring specific medical formulas to provide essential nutrients not available through any other means. Coverage of certain inherited disease of amino acid and organic acid metabolism shall include modified solid food products that are low-protein, or which contain modified protein.

Managed Medicaid Variation

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

ASO Variation

Enteral nutritional formulas will be limited to members who meet the criteria in this policy and:

1. Must be proven to be an effective treatment for individuals who, without this nutrition, would suffer from malnourishment, chronic disability, mental retardation, or death.

2. Treatment of GERD will require co-existing failure to thrive.

*Failure to thrive refers to infants who fail to grow at normal standards for growth velocity/rate. Thus, it does not include infants and young children with genetic short stature, constitutional growth delay, prematurity, or intrauterine growth restriction who have appropriate weight-for-length and normal growth velocity. Failure to thrive is diagnosed when a child's weight for age is below the fifth percentile or crosses two major percentile lines. It is recommended that the WHO growth charts be used for infants and toddlers who are less than 2 years old. The CDC growth charts can still be used for older children. Coverage of enteral nutrition varies by ASO group. For ASO groups that cover enteral nutrition, coverage may be through the pharmacy benefit or the medical benefit. Group-specific coverage can be determined by using the MVP Benefit Check List reference documents.

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15. Enteral Nutrition – Policy Article (A58833). Effective Date: 09/05/2021.

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 Secure HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP Medicare WellSelect PPO	Prior Auth
MVP Medicare WellSelect Plus PPO	Prior Auth
MVP Medicare Patriot Plan PPO	Prior Auth
MVP DualAccess D-SNP HMO	Prior Auth
MVP DualAccess Complete D-SNP HMO	Prior Auth

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UVM Health Advantage Select PPO	Prior Auth
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UVM Health Advantage Preferred 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	N/A
POS OOP	N/A
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
UVM Health Advantage Select PPO	Prior Auth
UVM Health Advantage Secure PPO	Prior Auth
UVM Health Advantage Preferred PPO	Prior Auth
MVP VT HMO	N/A
MVP VT Plus HMO	N/A
MVP VT HDHP HMO	N/A
MVP VT Plus HDHP HMO	N/A
MVP Secure	Prior Auth
ASO	See SPD
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***Medical Management Requirements**

Prior Auth	Prior Authorization Required
Potential for Retrospective Review	No Prior Authorization Required. May be subject to Retrospective Review.
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 Vermont
(enteral, modified solid foods and medical foods)

Type of Policy: **Medical Therapy**
Prior Approval Date: **06/01/2022**
Approval Date: **10/01/2023**
Effective Date: **12/01/2023**
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

Request for coverage of Enteral nutrition must include:

- Medical diagnosis to support the request of an enteral formula or low protein food.
- Is indicated to treat 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
- A nutritional consultation may be required prior to 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
- Coverage of enteral formulas provided through feeding tubes require that the member have a condition requiring tube feeding for at least three months and adequate nutrition is not possible by dietary adjustment and/or oral supplements.
- 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

.

Diseases screened for by the State of Vermont are: [1]:

- 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 loss (HEAR)
- 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[2]. **All other products require prior authorization to determine medical necessity for all vendors.** This list is subject to change at any time.

ACERFLEX POW	MSUD 2 POW	PHENYL-FREE POW 1	UCD TRIO POW
BCAD 1 POW	MSUD AID POW	PHENYL-FREE POW 2	WND POW
BCAD 2 POW	MSUD ANALOG POW	PHENYL-FREE POW 2HP	WND 1 POW
CAMINO PRO POW BETTRMLK	MSUD COOLER LIQ	PHLEXY-10	WND 2 POW
CAMINO PRO15 LIQ	MSUD COOLER LIQ 20	PHLEXY-VITS	XLEU ANALOG POW
COMPLEX MSD POW JUNIOR	MSUD EXP20 PAK	PKU 2 POW	XLEU MAXAMAD POW
COMPLEX MSD POW VANILLA	MSUD EXPRESS PAK	PKU 3 POW	XLEU MAXAMUM POW
COMPLEX MSUD BAR AMINO AC	MSUD GEL PAK	PKU COOLER LIQ 15	XLYS XTRP POW ANALOG

COMPLEX MSUD POW	MSUD LOPHLEX LIQ LQ	PKU COOLR 10 LIQ	XLYS-XTRP POW MAXAMAID
CYCLINEX-1 POW	MSUD MAXAMAD POW	PKU COOLR 15 LIQ	XLYS-XTRP POW MAXAMUM
CYCLINEX-2 POW	MSUD MAXAMUM POW	PKU COOLR 20 LIQ	XMET ANALOG POW
GA POW	OA 1 POW	PKU EXP20 PAK	XMET MAXAMAD POW
GA DIET POW	OA 1 DIET POW	PKU EXPRESS POW	XMET MAXAMUM POW
GLUTAREX-1 POW	OA 2 POW	PKU GEL PAK	XMTVI ANALOG POW
GLUTAREX-2 POW	OA 2 DIET POW	PKU LOPHLEX LIQ LQ 20	XMTVI MAXAMD POW
GLYTACTIN	OS 2 POW	PKU TRIO POW	XMTVI MAXAMU POW
HCY 1 POW	PEPTAMEN JR LIQ	PORTAGEN POW	XPHE MAXAMAD POW
HCY 1 DIET POW	PERIFLEX POW ADVANCE	PROPIMEX-1 POW	XPHE MAXAMUM POW
HCY 2 POW	PERIFLEX POW INFANT	PROPIMEX-2 POW	XPHE-XTYR POW ANALOG
HOM 2 POW	PERIFLEX POW JUNIOR	TYR COOLER LIQ	XPHE-XTYR POW MAXAMAID
HOMINEX-1 POW	PERIFLEX LQ LIQ PKU	TYR COOLER LIQ 20	XPTM ANALOG POW
HOMINEX-2 POW	PERIFLEX LQ LIQ PKU	TYR EXP20 PAK	
I-VALEX-1 POW	PFD 1 POW	TYR EXPRESS PAK	
I-VALEX-2 POW	PFD 2 POW	TYR GEL PAK	
KETONEX-1 POW	PHENEX-1 POW	TYR LOPHLEX LIQ LQ	
KETONEX-2 POW	PHENEX-2 POW	TYREX-1 POW	
LANAFLEX PAK	PHENYLADE	TYREX-2 POW	
LMD POW	PHENYLADE POW ESSNTL	TYROS 1 POW	
LMD DIET POW	PHENYLADE POW MTE	TYROS 2 POW	
LOPHLEX POW	PHENYLADE40 POW	UCD 2 POW	
LOPHLEX LQ LIQ 20	PHENYLADE60 POW	UCD ANAMIX POW JUNIOR	
METHIONAID POW	PROMACTIN AA PLUS		

Exclusions (See Medicare Variation)

- No coverage for the Vermont HDHP POS out-of-plan contract.
- The prescription drug rider is **not** required for Vermont for enteral formula, modified solid foods or medical foods that meet the medical criteria.
- Coverage is for up to a maximum of six months at a time.
- Disposable supply kits are not covered unless the member has a disposable rider
- Enzyme packed cartridges (e.g., Relizorb (Alcresta Pharmaceuticals)) for enzyme replacement in patients receiving enteral tube feedings are considered experimental/investigational and are not covered.
- Any enteral, modified solid or medical foods, including nutritional supplements and herbal or natural compounds, whether or not a prescription is required, that are not disease specific. Examples include, but are not limited to, UltraClear®, Estrium®, Protrypsin®, glucosamine, glucosamine/chondroitin.

- Any enteral, modified solid or medical foods whose use is not based on recognized scientific principles, including but not limited to, accepted standards of care, will be considered not medically necessary.
- Any enteral, modified solid or medical foods taken electively (i.e. to replace a missed meal in persons who have normal GI functioning) will be considered not medically necessary.
- Enteral nutrition is not covered for patients with a functioning gastrointestinal tract except when medical necessity criteria is met.
- Adequate nutrition must not be possible by dietary adjustment.
- Gluten-free solid foods used for the treatment of celiac disease do not meet coverage criteria.
- Components of medically prescribed diets (i.e. low residue or diverticular diets) do not meet coverage criteria.
- Formulas recommended as an alternative food source due to intolerance of standard formulas, but not as a specific treatment for an underlying disease process.
- Medical foods that replace or supplement standard drug treatment (i.e. Limbrel, Fosteum, Nicazel and Perative) for a specific disease or condition are not covered.
- Enteral supplies (including but not limited to enteral feeding kits, pumps and poles) and/or nursing and home services when the formula is determined to be not medically necessary. MVP shall review all claims retrospectively for services and supplies, including but not limited to nursing services, per diem charges, pumps, poles and feeding bags, associated with enteral formulas.
- Thickening agents that do not meet medical necessity criteria described above.

Medicare Variation

Enteral nutrition is covered under the prosthetic device benefit as per the Medicare Local Coverage Determination (LCD) for Enteral Nutrition (L38955) and the LCD-related Policy Article A58833. Please refer to this guidance for appropriate coverage.

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 commensurate 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.

References

1. Vermont Law Title 8 Banking and Insurance 4089e, Treatment of Inherited Metabolic Diseases.
2. Michigan Department of Community Health Bulletin November 1, 2011,
3. Vermont Department of Health. Early Identification of Infants with Potentially Serious Condition. Accessed July 23, 2021. Newborn Screening | Vermont Department of Health (healthvermont.gov)
4. National Coverage Determination for Enteral and Parenteral Nutritional Therapy (180.2). Effective Date: 7/11/1984
5. Local Coverage Determination for Enteral Nutrition (L38955). Effective Date: 01/01/2022.
6. Enteral Nutrition – Policy Article (A58833). Effective Date: 09/05/2021.

Member Product	Medical Management Requirements*
New York Products	
HMO	Prior Auth
PPO in Plan	Prior Auth
PPO OOP	Prior Auth
POS in Plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Child Health Plus	Prior Auth
MVP Harmonious Health Care Plan	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP Medicare WellSelect PPO	Prior Auth
MVP Medicare WellSelect Plus PPO	Prior Auth
MVP Medicare Patriot Plan PPO	Prior Auth

MVP DualAccess D-SNP HMO	Prior Auth
MVP DualAccess Complete D-SNP HMO	Prior Auth
MVP DualAccess Plus D-SNP HMO	Prior Auth
UVM Health Advantage Select PPO	Prior Auth
UVM Health Advantage Secure PPO	Prior Auth
UVM Health Advantage Preferred 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	N/A
POS OOP	N/A
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
UVM Health Advantage Select PPO	Prior Auth
UVM Health Advantage Secure PPO	Prior Auth
UVM Health Advantage Preferred PPO	Prior Auth
MVP VT HMO	N/A
MVP VT Plus HMO	N/A
MVP VT HDHP HMO	N/A
MVP VT Plus HDHP HMO	N/A
MVP Secure	Prior Auth
ASO	See SPD
♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).	
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***Medical Management Requirements**

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

MVP Health Care Medical Policy

Medicare Part B: ENTYVIO (vedolizumab)

Type of Policy:	**Drug/Medical Therapy**
Prior Approval Date:	**N/A**
Approval Date:	**1/01/2024**
Effective Date:	**01/01/2024**

Related Policies:

Inflammatory Biologic Drug Therapy

Experimental or Investigational Procedures

Infliximab

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

Drugs Requiring Prior Authorization (covered under the medical benefit)

J3380 Entyvio (vedolizumab, injection 1mg)

Overview/Summary of EvidenceENTYVIO is an integrin receptor antagonist indicated for adult ulcerative colitis and adult Crohn's disease. Prior to initiating treatment with ENTYVIO, all patients should be brought up to date with all immunizations according to current immunization guidelines. ENTYVIO is not recommended in patients with active, severe infections until the infections are controlled. Providers should consider withholding treatment in patients who develop a severe infection while on treatment with ENTYVIO. Providers should perform screening for tuberculosis (TB) according to the local practice.

Indications/Criteria

Coverage is provided in the following conditions:

Universal Criteria:

- Patient is at least 18 years of age; AND

- Must be prescribed by, or in consultation with, a specialist in gastroenterology; AND

- Patient is not on concurrent treatment with another TNF-inhibitor, biologic response modifier, natalizumab products or other non-biologic agent (i.e., apremilast, tofacitinib, baricitinib, upadacitinib, etc.);

- Coverage duration (unless otherwise specified for applicable indication)
    - Initial coverage up to 3 months
    - Continuation of coverage 12 months

For the treatment of **Crohn's disease**:

Documented moderate to severe active disease; AND
• Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum (3) month trial on previous therapy with a TNF modifier such as adalimumab, certolizumab, or infliximab

Continuation of therapy will require documentation of:

Disease response as indicated by improvement in signs and symptoms compared to baseline such as endoscopic activity, number of liquid stools, presence and severity of abdominal pain, presence of abdominal mass, body weight compared to IBW, hematocrit, presence of extra intestinal complications, use of anti-diarrheal drugs, tapering or discontinuation of corticosteroid therapy, and/or an improvement on a disease activity scoring tool [e.g., an improvement on the Crohn's Disease Activity Index (CDAI) score or the Harvey-Bradshaw Index score].

For the treatment of **Ulcerative Colitis**:

Documented moderate to severe active disease; AND
• Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum (3) month trial of corticosteroids or immunomodulators (e.g., azathioprine, 6-mercaptopurine, or methotrexate); OR

• Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum (3) month trial on previous therapy with a TNF modifier such as adalimumab, golimumab, or infliximab
- Requests for patients with moderately severe UC, who are naïve to biologic therapies will be reviewed on a case-by-case basis consistent with the AGA guidelines.

Continuation of therapy will require documentation of:

Disease response as indicated by improvement in signs and symptoms compared to baseline such as stool frequency, rectal bleeding, and/or endoscopic activity, tapering or discontinuation of corticosteroid therapy, and/or an improvement on a disease activity scoring tool [e.g., an improvement on the Ulcerative Colitis Endoscopic Index of Severity (UCEIS) score or the Mayo Score].

Management of **Immune Checkpoint Inhibitor-Related Diarrhea/Colitis**:

• Patient has been receiving therapy with an immune checkpoint inhibitor (e.g., nivolumab, pembrolizumab, atezolizumab, avelumab, durvalumab, cemiplimab, etc.); AND

• Patient has moderate (grade 2) to severe (grade 3-4) diarrhea or colitis related to their immunotherapy

Continuation of therapy will require documentation of:

May not be renewed

Exclusions

Age, dose, frequency outside of FDA approved labeling

References

1. Entyvio [package insert]. Lexington, MA 02421; Takeda Pharmaceuticals America, Inc; August 2021. Accessed September 2021.
2. 2. Lichtenstein GR, Loftus EV, Isaacs K, et al. American College of Gastroenterology Clinical Guideline: Management of Crohn's Disease in Adults. Am J Gastroenterol. 2018;113: 481-517. doi: 10.1038/ajg.2018.27; published online 27 March 2018.
3. 3. Kornbluth A, Sachar DB; Practice Parameters Committee of the American College of Gastroenterology. Ulcerative colitis practice guidelines in adults: American College Of Gastroenterology, Practice Parameters Committee. Am J Gastroenterol. 2010 Mar;105(3):501-23.
4. 4. Dignass A, Lindsay JO, Sturm A, et al. Second European evidence-based consensus on the diagnosis and management of ulcerative colitis part 2: current management. J Crohns Colitis. 2012 Dec;6(10):991-1030.
5. 5. Terdiman JP, Gruss CB, Heidelbaugh JJ, et al. American Gastroenterological Association Institute guideline on the use of thiopurines, methotrexate, and anti-TNF-α biologic drugs for the induction and maintenance of remission in inflammatory Crohn's disease. Gastroenterology. 2013 Dec;145(6):1459-63. doi: 10.1053/j.gastro.2013.10.047.
6. 6. Gomollón F, Dignass A, Annese V, et al. EUROPEAN Evidence-based consensus on the diagnosis and management of Crohn's disease 2016: Part 1: Diagnosis and medical management. J Crohns Colitis. 2016 Sep 22. pii: jjw168.
7. 7. Harbord M, Eliakim R, Bettenworth D, et al. Third European Evidence-based Consensus on Diagnosis and Management of Ulcerative Colitis. Part 2: Current Management. J Crohns Colitis. 2017 Jan 28. doi: 10.1093/ecco-jcc/jjx009.
8. 8. National Institute for Health and Care Excellence. NICE 2012. Crohn's Disease: Management. Published 10 October 2012. Clinical Guideline [CG152]. https://www.nice.org.uk/guidance/cg152/resources/crohns-disease-management-pdf-35109627942085.
9. 9. Lewis JD, Chuai S, Nessel L, et al. Use of the Non-invasive Components of the Mayo Score to Assess Clinical Response in Ulcerative Colitis. Inflamm Bowel Dis. 2008 Dec; 14(12): 1660–1666. doi: 10.1002/ibd.20520
10. 10. Paine ER. Colonoscopic evaluation in ulcerative colitis. Gastroenterol Rep (Oxf). 2014 Aug; 2(3): 161–168.
11. 11. Walsh AJ, Bryant RV, Travis SPL. Current best practice for disease activity assessment in IBD. Nature Reviews Gastroenterology & Hepatology 13, 567–579 (2016) doi:10.1038/nrgastro.2016.128
12. 12. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG clinical guideline: ulcerative colitis in adults. Am J Gastroenterol. 2019 Mar;114(3):384-413.

13. 13. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) vedolizumab. National Comprehensive Cancer Network, 2021. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL
14. ACG Clinical Guidline: Ulcerative Colitis in Adults. The American Journal of Gastroenterology: March 2019 - Volume 114 - Issue 3 - p 384-413 doi: 10.14309/ajg.0000000000000152. Accessed: ACG Clinical Guideline: Ulcerative Colitis in Adults : Official journal of the American College of Gastroenterology | ACG (lww.com)

MVP Health Care Medical Policy

Epinephrine Autoinjector

Type of Policy: Drug Therapy
Prior Approval Date: 08/01/2022
Approval Date: 08/01/2023
Effective Date: 10/01/2023

Related Policies: Quantity Limits

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

Table 1 Epinephrine autoinjector products:

Drug Name	Chemical Name	Quantity limit per 30 days	Prior Authorization
Adrenaclick 0.15mg/0.15ml	Epinephrine	2	Yes
Adrenaclick 0.3mg/0.3ml	Epinephrine	2	Yes
Epinephrine 0.15mg/0.15ml	Epinephrine	2	No (quantity limit only)
Epinephrine 0.3mg/0.3ml	Epinephrine	2	No (quantity limit only)
Epi-pen Jr. 0.15mg/0.3ml	Epinephrine	2	No (quantity limit only)
Epi-pen 0.3mg/0.3ml	Epinephrine	2	No (quantity limit only)
Symjepi	Epinephrine	2	No (quantity limit only)

Overview

Auto-Injectors are indicated in the emergency treatment of allergic reactions (Type I) including anaphylaxis to stinging insects (e.g., order Hymenoptera, which include bees, wasps, hornets, yellow jackets and fire ants) and biting insects (e.g., triatoma, mosquitos), allergen immunotherapy, foods, drugs, diagnostic testing substances (e.g., radiocontrast media) and other allergens, as well as idiopathic anaphylaxis or exercise-induced anaphylaxis. Auto-Injectors are intended for immediate administration in patients, who are determined to be at increased risk for anaphylaxis, including individuals with a history of anaphylactic reactions. Selection of the appropriate dosage strength is determined according to patient body weight. Such reactions may occur within minutes after exposure and consist of flushing, apprehension, syncope, tachycardia, thready or unobtainable pulse associated with a fall in blood pressure, convulsions, vomiting, diarrhea and abdominal cramps, involuntary voiding, wheezing, dyspnea due to laryngeal spasm, pruritus,

rashes, urticaria or angioedema. Auto-Injectors are intended for immediate self-administration as emergency supportive therapy only and are not a substitute for immediate medical care.[1]

Indications/Criteria

To prevent anaphylactic shock for individuals who have had life-threatening reactions to insect stings, foods, drugs or other allergens:

- Non-formulary epinephrine autoinjector agents will require documented prior use of preferred epinephrine autoinjectors or medical justification why alternative therapies are not appropriate. Please refer to Table 1 above for agents that require prior authorization.
- Case-by-case consideration will be made for situations involving pediatrics or members with special needs.

Exclusions

- Auvi-Q is excluded from coverage

References

1. Epi-pen and Epi-pen Jr. Autoinjector. Prescribing information. Basking Ridge, NJ: Mylan, Inc., August 2016.

Member Product	Medical Management Requirements*
New York Products	
HMO	Prior Authorization
PPO in Plan	Prior Authorization
PPO OOP	Prior Authorization
POS in Plan	Prior Authorization
POS OOP	Prior Authorization
Essential Plan	Prior Authorization
MVP Medicaid Managed Care	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Child Health Plus	Prior Authorization
MVP Harmonious Health Care Plan	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Medicare 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 Authorization
MVP Premier	Prior Authorization
MVP Premier Plus	Prior Authorization
MVP Premier Plus HDHP	Prior Authorization
MVP Secure	Refer to Part D Coverage
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 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 Authorization
MVP VT Plus HMO	Prior Authorization
MVP VT HDHP HMO	Prior Authorization
MVP VT Plus HDHP HMO	Prior Authorization
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).	

***Medical Management Requirements**

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

MVP Health Care Medical Policy

Erythropoiesis Stimulating Agents (ESAs)

Type of Policy: **Drug Therapy**
Prior Approval Date: **10/01/2022**
Approval Date: **10/01/2023**
Effective Date: **12/01/2023**

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

1. Retacrit [package insert]. Lake Forest, IL; Hospira, Inc; May 2018. Accessed May 2018.
2. Aranesp [package insert]. Thousand Oaks, CA; Amgen; June 2011. Accessed March 2019.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) epoetin alfa. National Comprehensive Cancer Network, 2018. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc." To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed May 2018.
4. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Cancer-and Chemotherapy-Induced Anemia Version 2.2018. National Comprehensive Cancer Network, 2017. 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 March 2018.
5. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Myelodysplastic Syndrome Version 2.2018. National Comprehensive Cancer Network, 2017. 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 March 2018.
6. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Myeloproliferative Neoplasms Version 2.2018. National Comprehensive Cancer Network, 2017. 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 March 2018.

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8. Pincus T, Olsen NJ, Russell IJ, et al. Multicenter study of recombinant human erythropoietin in correction of anemia in rheumatoid arthritis. Am J Med 1990; 89:161-8.
9. Saag, MS, Bowers, P, Leitz, GJ, Levine, AM. Once-weekly epoetin alfa improves quality of life and increases hemoglobin in anemic HIV+ patients. AIDS Res Hum Retroviruses 2004; 20:1037.
10. Grossman, HA, Goon, B, Bowers, P, Leitz, G. Once-weekly epoetin alfa dosing is as effective as three times-weekly dosing in increasing hemoglobin levels and is associated with improved quality of life in anemic HIV-infected patients. J Acquir Immune Defic Syndr 2003; 34:368.
11. Afdhal, NH, Dieterich, DT, Pockros, PJ, et al. Epoetin alfa maintains ribavirin dose in HCV-infected patients: a prospective, double-blind, randomized controlled study. Gastroenterology 2004; 126:1302.
12. Cervantes F, Alvarez-Laran A, Hernandez-Boluda JC, et al. Erythropoietin treatment of the anaemia of myelofibrosis with myeloid metaplasia: results in 20 patients and review of the literature. British Journal of Haematology, 127: 399–403. doi:10.1111/j.1365-2141.2004.05229.x
13. Shaffer CL, Ransom JL. Current and theoretical considerations of erythropoietin use in anemia of bronchopulmonary dysplasia. J of Pediatric Pharmacy Practice 1996; 1:23-29.
14. Reiter PD, Rosenberg AA, Valuck RJ. Factors associated with successful epoetin alfa therapy in premature infants. Ann Pharmacother 2000; 34:433-439.

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	Potential for Retrospective Review
MVP Child Health Plus	Potential for Retrospective Review
MVP Harmonious Health Care Plan	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
UVM Health Advantage Secure PPO	Potential for Retrospective Review
UVM Health Advantage Preferred 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
UVM Health Advantage Select PPO	Potential for Retrospective Review
UVM Health Advantage Secure PPO	Potential for Retrospective Review
UVM Health Advantage Preferred PPO	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).	

***Medical Management Requirements**

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

MVP Health Care Medical Policy

Etanercept

Type of Policy:	**Drug/Medical Therapy**
Prior Approval Date:	**10/01/2023**
Approval Date:	**02/01/2024**
Effective Date:	**04/01/2024**
Related Policies:	**Apremilast**
	Adalimumab
	Infliximab
	Risankizumab
	Secukinumab
	Tofacitinib
	Upadacitinib
	Ustekinumab
	Zeposia

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

Drugs Requiring Prior Authorization under the pharmacy benefit

Enbrel (J1438, etanercept)

Overview

Etanercept is a subcutaneously administered tumor necrosis factor (TNF) blocker that is a soluble TNF receptor. Like other TNF blockers, etanercept is useful in a variety of inflammatory disorders such as rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and psoriasis. Etanercept carries a black box warning for infection and

malignancy. Members should be screened for immunologic and infectious disease prior to initiating therapy. **Medicare Variation**

- Refer to the Medicare Part D formulary for drugs that may be covered under the Part D benefit.
- Medicare Part B variation: Step through therapy is NOT required for medical drugs.

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

Indications/Criteria

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

- Prescription drugs covered under the pharmacy benefit must be self-administered. If office administration is being requested documentation must be provided identifying why the member or caregiver is unable to administer the medication
- Must be ordered by or with consult from an appropriate specialist: rheumatologist/immunologist/dermatologist
- Must be prescribed for an FDA approved indication

B. Ankylosing Spondylitis

Etanercept may be considered for coverage for Ankylosing Spondylitis when:

- Chart notes documenting failure of at least one NSAIDS at maximum tolerated dose unless the member has contraindications to NSAID therapy such as cardiovascular disease, peptic ulcer disease or renal disease **AND**
- Documented significant clinical symptoms such as fatigue, spinal pain, arthralgia, inflammation of joints and tendons, morning stiffness duration and therapy **AND**

- Insufficient response to at least one local corticosteroid injection in patients with symptomatic peripheral arthritis **AND**
- **Members with pure axial manifestations** do not have to have a trial of nonbiologic disease modifying anti-rheumatic drugs (DMARDs)

Initial approval will be for 6 months

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

C. Psoriasis

Etanercept may be considered for coverage for Psoriasis when:

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

Initial approval for **6 months**.

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

D. Psoriatic Arthritis

Etanercept may be considered for coverage for Psoriatic Arthritis when:

- Member has a diagnosis of moderate to severe psoriatic arthritis as indicated by three or more tender joints AND three or more swollen joints on two separate occasions at least one month apart
- Chart notes documenting a failure of at least one NSAIDS at maximum tolerated dose unless the member has contraindications to NSAID therapy such as cardiovascular disease, peptic ulcer disease or renal disease **AND**
- Chart notes documenting a failure to respond to an adequate trial of at least one of the following nonbiologic disease modifying anti-rheumatic drugs (DMARDs): leflunomide, sulfasalazine, or methotrexate.

    - **Members with pure axial manifestations** do not have to have a trial of nonbiologic disease modifying anti-rheumatic drugs (DMARDs)
    - If a trial of methotrexate is not appropriate due to alcohol use and both leflunomide and sulfasalazine are not clinically appropriate, chart notes must be provided indicating that the patient has been counseled on the need to abstain from alcohol use while taking methotrexate and is unwilling to abstain from alcohol use.

Initial approval will be for 6 months

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

E. Rheumatoid Arthritis

Etanercept may be considered for coverage for Rheumatoid Arthritis when:

- Member has a diagnosis of moderate to severe active adult **rheumatoid arthritis** as defined by persistent or recurrent symptoms with documented synovitis and morning stiffness of significant duration to inhibit activities of daily living **AND**
- Chart notes documenting a failure to respond to one or more nonbiologic disease modifying anti-rheumatic drugs (DMARDs), one of which includes a three-month trial of maximally tolerated dose of methotrexate.

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

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

Initial approval will be for 6 months

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

F. Juvenile Idiopathic Arthritis

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

Initial approval will be for 6 months

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

Exclusions

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

- Dosing/age and/or frequency outside of the FDA approved package labeling.
- Etanercept in combination with other biologics is excluded from coverage
- Combination therapy that is not supported by guidelines
- History of Multiple Sclerosis

References

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2. Etanercept. Clinical Pharmacology powered by ClinicalKey. Philadelphia (PA): Elsevier. C2021 - [cited 2023 Aug 21]. Available from: http://www.clinicalkey.com.

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

UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
Healthy NY	Prior Authorization
MVP Premier	Prior Authorization
MVP Premier Plus	Prior Authorization
MVP Premier Plus HDHP	Prior Authorization
MVP Secure	Prior Authorization
MVP EPO	Prior Authorization
MVP EPO HDHP	Prior Authorization
MVP PPO	Prior Authorization
MVP PPO HDHP	Prior Authorization
Student Health Plans	Prior Authorization
ASO	Prior Authorization
Vermont Products	
POS in Plan	Prior Authorization
POS OOP	Prior Authorization
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D
MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Select PPO	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Secure PPO	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D
MVP VT HMO	Prior Authorization
MVP VT Plus HMO	Prior Authorization
MVP VT HDHP HMO	Prior Authorization
MVP VT Plus HDHP HMO	Prior Authorization
MVP Secure	Prior Authorization
ASO	Prior Authorization
♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).	

***Medical Management Requirements**

Prior Auth	Prior Authorization Required
Potential for Retrospective Review	No Prior Authorization Required. May be subject to Retrospective Review.
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: 04/01/2022
Approval Date: 03/01/2023
Effective Date: 04/01/2023
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 (for 2-tier closed formulary plans) 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 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 patient 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.

NY Commercial, NY Exchange, VT Exchange turnaround time

a. Standard Review. We will make a formulary exception determination within 72 hours of provider receipt and documentation.

b. 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 N/A

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

GABA-Receptor Modulators

Type of Policy:	**Drug Therapy**
Prior Approval Date:	**11/01/2022**
Approval Date:	**11/01/2023**
Effective Date:	**01/01/2024**
Related Policies:	**Quantity Limits for Prescription Drugs**
	Obstructive Sleep Apnea: Diagnosis

Drugs Requiring Prior Authorization

Xyrem® (sodium oxybate)

Sodium Oxybate solution

Xywav® (Calcium Oxybate, Magnesium Oxybate, Potassium Oxybate, Sodium Oxybate)

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

Overview

Narcolepsy is a chronic neurological disorder caused by the brain's inability to regulate sleep-wake cycles normally. At various times throughout the day people with narcolepsy experience fleeting urges to sleep. If the urge becomes overwhelming, patients fall asleep for periods lasting from a few seconds to several minutes. In rare cases, some people may remain asleep for an hour or longer. In addition to the most common symptom excessive daytime sleepiness (EDS), three other major symptoms frequently characterize narcolepsy: cataplexy (the sudden loss of voluntary muscle tone); vivid hallucinations during sleep onset or upon awakening; and brief episodes of total paralysis at the beginning or end of sleep. EDS can result from a wide range of medical conditions, including other sleep disorders such as sleep apnea, various viral or bacterial infections, mood disorders such as depression, and painful chronic illnesses such as congestive heart failure and rheumatoid arthritis that disrupt normal sleep patterns. Various medications can also lead to EDS, as can consumption of caffeine, alcohol, and nicotine. Finally, sleep deprivation has become one of the most common causes of EDS among Americans. This lack of specificity increases the difficulty of arriving at an

accurate diagnosis based on a consideration of symptoms alone. Specialized tests are essential in confirming a diagnosis of narcolepsy.[1]
Xyrem® (sodium oxybate) is GHB (gamma-hydroxybutyrate), a known drug of abuse. Xyrem is indicated for the treatment of excessive daytime sleepiness and cataplexy in patients with narcolepsy. In Xyrem clinical trials, approximately 80% of patients maintained concomitant stimulant use. The package label black box warns that Xyrem is a central nervous system (CNS) depressant with abuse potential, and it should not be used with alcohol or other CNS depressants. Xyrem is only available through the Xyrem REMS Program, using a centralized pharmacy.[2]
Xywav® is a mixture of oxybate salts, including calcium, magnesium, potassium, and sodium oxybates. The Xywav product differs from Xyrem, a sodium oxybate formulation, in that the oxybate electrolytes are balanced in the Xywav formulation, eliminating the need for monitoring in patient populations requiring a low sodium diet. [6] In addition, to the indication for treatment of cataplexy or EDS in patients with narcolepsy, Xyway is indicated for the treatment of idiopathic hypersomnia (IH). IH is a rare and typically chronic neurologic sleep disorder and is unique from other disorders that also cause EDS. Furthermore, people with IH still experience EDS during the day despite sleeping a normal or longer than normal amount of time each night.[6,7,8,9] Xywav is only available through the Xywav REMS Program, using a certified pharmacy.[5]

Indications/Criteria

The use of Xyrem® or Xywav for the treatment of cataplexy and EDS in patients with narcolepsy may be considered medically necessary if all of the following criteria are met:

- Definitive diagnosis of narcolepsy based upon objective sleep studies; **AND**
- Patient 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) [3]
            - modafinil 200mg daily or solriamfetol (Sunosi) 150mg dailyor armodafinil 150mg daily; **AND** formulary amphetamine product
    - For Pediatric patients 7 years old up to 17 years old

- For excessive daytime sleepiness (EDS) [3]
    - modafinil

The use of Xywav for the treatment of IH may be considered for coverage when the following criteria is met:

- 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 including narcolepsy type 1 and 2, insufficient sleep syndrome, obstructive sleep apnea, depression, and delayed sleep phase syndrome.[9]
- Documentation of clinical feature(s) supportive of IH[6,9]
    - 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[10,11]
    - Epworth Sleepiness Scale (ESS) of ≥ 10 and/or idiopathic hypersomnia severity scale (IHSS).

Initial approval: up to 3 months.

For members with a diagnosis of narcolepsy, continued therapy will be considered at 6-month intervals 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, 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; [2]
- History of GHB abuse
- Diagnosis of narcolepsy based solely on symptoms
- Doses greater than 9 grams per night

- Age, dose, and/or frequency outside of the FDA approve package labeling

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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
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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 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).	

***Medical Management Requirements**

Prior Auth	Prior Authorization Required
Potential for Retrospective Review	No Prior Authorization Required. May be subject to Retrospective Review.
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:	**11/01/2022**
Approval Date:	**11/01/2023**
Effective Date:	**01/01/2024**
Related Policies:	**N/A**

Drug Requiring Prior Authorization (covered under the pharmacy benefit)

Gralise® (gabapentin)

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. RLS coverage for Horizant will be considered when ALL of the following criteria are met:
   1. Adults with a documented diagnosis of moderate to severe primary (idiopathic) RLS
   2. A score of 11 or greater on the International Restless Legs Syndrome Rating Scale
   3. Patient must fail a 1-month trial or have a contraindication or intolerance to one of the following:
      a. Ropinirole
      b. Pramipexole

Initial approval will be for 6 months at a dose of 600mg per day. Subsequent requests will be considered up to 12 months, if there is documentation that the patient has a 50% or greater improvement in score on the International Restless Legs Syndrome Rating Scale.

B. PHN coverage for Horizant or Gralise will be considered when ALL of the following criteria are met:
   1. PHN has persisted for at least three months after the rash and/or blisters have healed; AND
   2. 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);
   3. Contraindication, intolerance, or failure to a trial of each of the following medications:
      - gabapentin immediate release at 1800mg in divided dose three times a day;
      - tricyclic antidepressant (TCA) (examples include amitriptyline, nortriptyline).
      - Lidocaine 5% patch

Initial approval will be limited to 3 months. Subsequent requests will be considered up to 6 months if there is documentation of adequate pain relief.

Exclusions

1. Not within FDA approved age, dosing or frequency.

2. RLS secondary to other conditions (iron deficiency anemia, pregnancy, ESRD, etc.)
3. Patients with a movement disorder other than RLS, including periodic limb movement disorder
4. Patients with a neurological disease
5. Gralise
    a. Creatinine Clearance less than 30ml/min
    b. Patients on hemodialysis
    c. Doses greater than 1,800mg per day
6. Horizant for RLS
    a. Doses greater than 600mg per day
    b. Combination therapy with dopamine agonists
7. Horizant for PHN-doses greater than 1,200mg per day
8. For diagnosis of RLS: Currently receiving drugs that may cause movement disorders including atypical antipsychotics, tricyclic antidepressants, selective serotonin reuptake inhibitors, antiemetics such as metoclopramide and droperidol, or sedating antihistamines; unless the movement disorder has been ruled out as a side effect from medication and RLS has been definitively diagnosed.
9. For a diagnosis of PHN: Non-compliance with gabapentin and/or tricyclic antidepressants unless contraindicated

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References

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11. Gralise (gabapentin). Prescribing Information. Newark, CA: Depomed, Inc. April 2020. Revised 04/2023.
12. Charles E. Argoff (2011) Review of Current Guidelines on the Care of Postherpetic Neuralgia, Postgraduate Medicine, 123:5, 134-142, DOI: 10.3810/pgm.2011.09.2469

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 Policies
MVP Medicare Secure HMO POS	Refer to Part D Policies
MVP Medicare Secure Plus HMO POS	Refer to Part D Policies
MVP Medicare WellSelect PPO	Refer to Part D Policies
MVP Medicare WellSelect Plus PPO	Refer to Part D Policies
MVP Medicare Patriot Plan PPO	Refer to Part D Policies
MVP DualAccess D-SNP HMO	Refer to Part D Policies
MVP DualAccess Complete D-SNP HMO	Refer to Part D Policies
MVP DualAccess Plus D-SNP HMO	Refer to Part D Policies
UVM Health Advantage Select PPO	Refer to Part D Policies
UVM Health Advantage Secure PPO	Refer to Part D Policies
UVM Health Advantage Preferred PPO	Refer to Part D Policies
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 Policies
MVP EPO	Prior Auth
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 Policies
MVP Medicare Secure Plus HMO POS	Refer to Part D Policies
UVM Health Advantage Select PPO	Refer to Part D Policies
UVM Health Advantage Secure PPO	Refer to Part D Policies
UVM Health Advantage Preferred PPO	Refer to 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	Refer to Part D Policies
ASO	See SPD
♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).	
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***Medical Management Requirements**

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

MVP Health Care Medical Policy

Ganaxolone

Type of Policy: **Drug/Medical Therapy**
Prior Approval Date: **02/01/2023**
Approval Date: **02/01/2024**
Effective Date: **04/01/2024**

Related Policies: **NA**

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

Drugs Requiring Prior Authorization under the pharmacy benefit

Ztalmy (ganaxolone) suspension

Overview

Ganaxolone is a neuroactive steroid gamma-aminobutyric acid (GABA) A receptor positive modulator indicated for the treatment of seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD) in patients 2 years and older. CDD is a rare developmental epileptic encephalopathy (DEE) that causes both epileptic activity and severe developmental impairment, impacting cognitive, motor, speech, and visual function.

Indications/Criteria

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

- Ordered by or in consult with a neurologist.
- Member has a documented diagnosis of seizures associated with cyclin-dependent kinase like 5 deficiency disorder (CDD)
- Confirmed CDKL5 gene mutation
- Documentation of baseline monthly seizure frequency
- Documentation of a failure of at least two previous antiepileptic therapies

Initial approval will be for 6 months.

Extension requests will be approved for up to 12 months if the member has a continued benefit to therapy and documentation of reduction in monthly seizure frequency compared to baseline.

Exclusions

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

- Dosing, age, and/or frequency outside of the FDA approved package labeling

References

1. Clinical Pharmacology. Ztalmy 50mg/ml suspension. Revised 03/29/2022. Accessed 01/07/2023.

Member Product	Medical Management Requirements*
New York Products	
HMO	Prior Auth
PPO in Plan	Prior Auth
PPO OOP	Prior Auth
POS in Plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Child Health Plus	Prior Auth
MVP Harmonious Health Care Plan	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Medicare Gold Giveback	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Secure HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare WellSelect PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare WellSelect Plus PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Patriot Plan PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess Complete D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.

MVP DualAccess Plus D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Select PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Secure PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	
POS in Plan	Prior Auth
POS OOP	Prior Auth
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D
MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Select PPO	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Secure PPO	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D
MVP VT HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD
♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).	

***Medical Management Requirements**

Prior Auth	Prior Authorization Required
Potential for Retrospective Review	No Prior Authorization Required. May be subject to Retrospective Review.
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:	**03/01/2023**
Approval Date:	**10/01/2023**
Effective Date:	**12/01/2023**
Related Policies:	**N/A**

Codes Requiring Prior Authorization (covered under the medical benefit)

J1786 Cerezyme® (imiglucerase, 10 units)

J3385 Vpriv™ (Injection, velaglucerase alfa, 100 units)

J3060 Elelyso (Injection, taliglucerase alfa, 10 units)

Drug Requiring Prior Authorization (covered under the pharmacy benefit)

Cerdelga (eliglustat 84 mg oral capsules)

Zavesca® (miglustat 100 mg oral capsules)

Miglustat 100mg oral capsules

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

Overview

Gaucher disease is an inherited metabolic disorder in which harmful quantities of a fatty substance called glucocerebroside accumulate in the spleen, liver, lungs, bone marrow, and sometimes in the brain. There are three types of Gaucher disease. **Type 1** is the most common. Patients in this group usually bruise easily and experience fatigue due to anemia and low blood platelets. They also have an enlarged liver and spleen, skeletal disorders, and, in some instances, lung and kidney impairment. There are no signs of brain involvement. Symptoms can appear at any age. In **Type 2**, liver and spleen enlargement are apparent by 3 months of age. Patients have extensive and progressive brain damage and usually die by 2 years of age. In **Type 3**, liver and spleen enlargement is variable, and signs of brain involvement such as seizures gradually become apparent.

All Gaucher patients exhibit a deficiency of an enzyme called glucocerebrosidase that is involved in the breakdown and recycling of glucocerebroside. The buildup of this fatty material within cells prevents the cells and organs from functioning properly. Enzyme replacement therapy may reverse many of the complications of the disease in patients with Type 1 disease.[5] The agents identified in this policy are FDA approved only in type 1 Gaucher disease.

Medications that reverse or halt the clinical symptoms of Gaucher's Disease Type 1 are Cerezyme® (imiglucerase), Vpriv™ (velaglucerase alfa) and Elelyso® (taliglucerase alfa). Cerdelga (eliglustat) is a glucosylceramide synthase inhibitor approved for the long-term treatment of adults with Gaucher's disease type 1, whose dose is determined by establishing the patient's CYP2D6 phenotype. Zavesca® (miglustat) is a glucosylceramide synthase inhibitor approved for adult patients 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

Coverage criteria for **imiglucerase (Cerezyme)**, **velaglucerase alfa (Vpriv)** and **taliglucerase alfa (Elelyso)** are as follows:

- 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:
    1. Documented skeletal disease (osteopenia, avascular osteosclerosis, marrow infiltration, lytic lesions)
    2. 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)
    3. Thrombocytopenia (platelet count less than or equal to 120,000/mm^3
    4. Hepatomegaly or splenomegaly

Coverage criteria for **eliglustat (Cerdelga)** is as follows:

- 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

Coverage criteria for **miglustat** is as follows:

- 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 one 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:

- dosing, age, and/or frequency outside of the 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:

- renal Impairment: extensive metabolizers with end stage renal disease (Creatinine Clearance (CrCl) less than 15ml/minute)
- intermediate and poor metabolizers with any degree of renal impairment
- hepatic impairment or cirrhosis
- CYP2D6 ultra-rapid metabolizer as detected by an FDA-cleared test
- pre-existing cardiac disease, long QT syndrome, or concomitant use of Class IA and Class III antiarrhythmics

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References

1. Cerezyme® (imiglucerase). Prescribing Information. Cambridge, MA: Genzyme Corporation; Apr 2018. Revised Dec 2022.
2. Zavesca® (miglustat). Prescribing Information. South San Francisco, CA: Actelion Pharmaceuticals, Inc. Jan 2021.
3. Grabowski GA, Barton NW, Pastores G, et al.. Enzyme therapy in type 1 Gaucher disease: Comparative efficacy of mannose-terminated glucocerebriosidase from natural and recombinant sources. Ann Intern Med. 1995;122(1):33-9
4. National Institutes of Health Consensus Development Conference Report. Gaucher Disease: Current issues in diagnosis and treatment. 1995.
5. National Institute of Neurological Disorders and Stroke. National Institutes of Health, Gaucher's Disease information page. http://www.ninds.nih.gov/disorders/gauchers/gauchers.htm.
6. Vpriv® (velaglucerase alfa for injection) Lexington, MA: Shire Human Genetic Therapies, Inc.; Dec 2020. Revised Sept 2021.
7. Elelyso® (taliglucerase alfa). Prescribing Information. New York, NY: Pfizer Labs. Jul 2021. Revised May 2023.
8. Grabowski GA. Phenotype, diagnosis, and treatment of Gaucher's disease. *Lancet*. Oct 4, 2008;372(9645):1263-71.

9. Cerdelga (eliglustat capsules). Prescribing Information. Waterford, Ireland: Genzyme Ltd. Aug 2018. Revised Dec 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 Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP Medicare WellSelect PPO	Prior Auth
MVP Medicare WellSelect Plus PPO	Prior Auth
MVP Medicare Patriot Plan PPO	Prior Auth
MVP DualAccess D-SNP HMO	Prior Auth
MVP DualAccess Complete D-SNP HMO	Prior Auth
MVP DualAccess Plus D-SNP HMO	Prior Auth
UVM Health Advantage Select PPO	Prior Auth
UVM Health Advantage Secure PPO	Prior Auth
UVM Health Advantage Preferred 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
UVM Health Advantage Select PPO	Prior Auth
UVM Health Advantage Secure PPO	Prior Auth
UVM Health Advantage Preferred PPO	Prior Auth
MVP VT HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD
♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).	

***Medical Management Requirements**

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

MVP Health Care Medical Policy

GLP-1 Receptor Agonists (prospective)

Type of Policy:	**Drug/Medical Therapy**
Prior Approval Date:	**NA**
Approval Date:	**08/01/2023**
Effective Date:	**08/01/2023**
Related Policies:	**NA**

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

Drugs Requiring Prior Authorization under the pharmacy benefit

Adlyxin

Ozempic

Rybelsus

Trulicity

Victoza

Mounjaro

Byetta

Bydureon/ Bydureon BCISE

Overview

Glucagon-like peptide-1 receptor agonists (GLP-1) is a class of anti-diabetic medications that exert their main effect by stimulating glucose-dependent insulin release from the pancreatic islets. Per current American Diabetic Association guidelines, they are considered additive therapy to metformin and lifestyle modifications (such as diet and exercise). There are specific GLP-1 agonists with an indication for weight loss (rather than Type 2 diabetes) which include Saxenda and Wegovy.

Indications/Criteria

GLP-1 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 "Weight loss products" criteria in the 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 Authorization
PPO in Plan	Prior Authorization
PPO OOP	Prior Authorization
POS in Plan	Prior Authorization

POS OOP	Prior Authorization
Essential Plan	Prior Authorization
MVP Medicaid Managed Care	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Child Health Plus	Prior Authorization
MVP Harmonious Health Care Plan	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Medicare 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 Authorization
MVP Premier	Prior Authorization
MVP Premier Plus	Prior Authorization
MVP Premier Plus HDHP	Prior Authorization
MVP Secure	Refer to Part D Coverage
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 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 Authorization
MVP VT Plus HMO	Prior Authorization
MVP VT HDHP HMO	Prior Authorization
MVP VT Plus HDHP HMO	Prior Authorization
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

Golimumab

Type of Policy:	**Medical Therapy**
Prior Approval Date:	**03/01/2023**
Approval Date:	**02/01/2024**
Effective Date:	**04/01/2024**
Related Policies:	**Apremilast, Adalimumab, Infliximab, Risankizumab, Secukinumab, Tofacitinib, Upadacitinib, Ustekinumab, Ozanimod, Abatacept, Tocilizumab, Certolizumab**

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

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

Drugs Requiring Prior Authorization under the pharmacy benefit

Simponi SQ (golimumab) is non-preferred under the pharmacy benefit

Drugs Requiring Prior Authorization under the medical benefit

J1602 Simponi Aria (injection, golimumab)

Overview

Golimumab is a TNF-alpha blocker (TNF blocker) available in both intravenous and subcutaneous formulations. It is FDA approved to treat moderately to severely active rheumatoid arthritis (RA), psoriatic arthritis (PsA), ankylosing spondylitis (AS), and polyarticular juvenile idiopathic arthritis (pJIA). Members should be screened for immunologic and infectious disease prior to initiating therapy.

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

Indications/Criteria

A. For all indications, Simponi SQ (golimumab) is non-formulary and will only be considered for **pharmacy** coverage when:
   - Documented failure, contraindication or ineffective response to all preferred/formulary therapies for the specific indication.

B. For all indications, Simponi Aria (injection, golimumab) may be considered for **medical** coverage when:
   - Must be prescribed for an FDA approved indication **AND**
   - Must be ordered by or with consult from a rheumatologist/immunologist **AND**
   - Documentation identifies failure of **preferred** self-administered biologic therapies to treat the condition **AND**
     Rationale and documentation is provided identifying why member or caregiver is unable to self-administer

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

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 September 2019.
3. Simponi ARIA (golimumab) injection. Prescribing information. Janssen Biotech, Inc. Horsham, PA. Revised February 2021.
4. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis & Rheumatology Vol. 71, No. 1, January 2019, pp 5–32 DOI 10.1002/art.40726. 2018 American College of Rheumatology/ National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis
5. 2021 American College of Rheumatology Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Oligoarthritis, Temporomandibular Joint Arthritis, and Systemic Juvenile Idiopathic Arthritis. Arthritis and Rheumatology. Vol 74 No. 4 April 2022, pp553-569. Available at: https://www.rheumatology.org/Portals/0/Files/ACR-JIA%20Guideline-Oligo-TMJ-sJIA-EarlyView.pdf
6. Fraenkel et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care & Research Vol. 73, No. 7, July 2021, pp 924–939 DOI 10.1002/acr.24596. Available at: 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis (contentstack.io).
7. Ward Michael, Atul Deodhar et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondylosrthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing

Spondylitis and Nonradiographic Axial Spondyloarthritis. Arthritis and Rheumatology. Vol 71 (No. 10). October 2019, pp 1599-1613. Available at: https://www.rheumatology.org/Portals/0/Files/AxialSpA-Guideline-2019.pdf

8.

Member Product	Medical Management Requirements*
New York Products	Prior Auth
HMO	Prior Auth
PPO in Plan	Prior Auth
PPO OOP	Prior Auth
POS in Plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Child Health Plus	Prior Auth
MVP Harmonious Health Care Plan	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Medicare Gold Giveback	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Secure HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare WellSelect PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare WellSelect Plus PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Patriot Plan PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess Complete D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess Plus D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Select PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Secure PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD

Vermont Products	
POS in Plan	Prior Auth
POS OOP	Prior Auth
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D
MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Select PPO	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Secure PPO	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D
MVP VT HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD
♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).	
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***Medical Management Requirements**

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

MVP Health Care Medical Policy

Medicare Part B: Golimumab

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

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

Drugs Requiring Prior Authorization under the medical benefit

J1602 Simponi Aria (injection, golimumab)

Overview/Summary of Evidence

Golimumab is a TNF-alpha blocker (TNF blocker) available in both intravenous and subcutaneous formulations. It is FDA approved to treat moderately to severely active rheumatoid arthritis (RA), psoriatic arthritis (PsA), ankylosing spondylitis (AS), and polyarticular juvenile idiopathic arthritis (pJIA). Members should be screened for immunologic and infectious disease prior to initiating therapy.

Indications/Criteria

A. For all indications, Simponi Aria (injection, golimumab) may be considered for **medical** coverage when:
   - Must be prescribed for an FDA approved indication **AND**
   - Must be ordered by or with consult from a rheumatologist/immunologist **AND**

- Member has coverage under Medicare Part B and meets the criteria below for a provider administered drug identified in this policy.

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

Initial approval for **6 months**.

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

C. **Ankylosing Spondylitis**
Golimumab may be considered for coverage for Ankylosing Spondylitis when the above criteria is met **AND**:
    - Member has a diagnosis of moderate to severe AS
    - Chart notes documenting failure of at least one NSAID at maximum tolerated dose AND documented significant clinical symptoms such as fatigue, spinal

pain, arthralgia, inflammation of joints and tendons, morning stiffness duration and therapy AND insufficient response to at least one local corticosteroid injection in patients with symptomatic peripheral arthritis
    - **For members with pure axial manifestations** do not have to have a trial of nonbiologic disease modifying anti-rheumatic drugs (DMARDs)

Initial approval for **6 months**.

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

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

Initial approval for **6 months**.

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

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

Initial approval for **6 months**.

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

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Exclusions

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

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

References

1. Clinical Pharmacology: Golimumab. Revised 09/30/2022. Accessed 01/05/2023.
2. Simponi ARIA (golimumab) injection. Prescribing information. Janssen Biotech, Inc. Horsham, PA. Revised February 2021.
3. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis & Rheumatology Vol. 71, No. 1, January 2019, pp 5–32 DOI 10.1002/art.40726. 2018 American College of Rheumatology/ National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis
4. 2021 American College of Rheumatology Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Oligoarthritis, Temporomandibular Joint Arthritis, and Systemic Juvenile Idiopathic Arthritis. Arthritis and Rheumatology. Vol 74 No. 4 April 2022, pp553-569. Available at:

https://www.rheumatology.org/Portals/0/Files/ACR-JIA%20Guideline-Oligo-TMJ-sJIA-EarlyView.pdf

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MVP Health Care Medical Policy

Gout Treatments

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

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

Codes Requiring Prior Authorization (covered under the medical benefit)

J2507 Injection, pegloticase, 1 mg (Krystexxa™)

Drugs Requiring Prior Authorization (covered under the pharmacy benefit)
Colcrys™ (colchicine tablets) if quantity exceeds 2 tablets per day
Gloperba (colchicine oral solution) if quantity exceeds 10mL per day
Mitigare (colchicine capsules) if quantity exceeds 2 capsules per day
Colchicine tablets/capsules if quantity exceeds 2 tablets/capsules per day
Uloric® (febuxostat) tablets (only brand Uloric requires prior authorization)

Overview

Gout is a complex form of arthritis characterized by sudden, severe flares of pain, redness, and tenderness in joints caused by urate crystals accumulating around the joint, causing inflammation and intense pain. Urate crystals can form when there are high levels of uric acid in the blood (hyperuricemia = uric acid levels of >6.8 mg/dL). Normally uric acid dissolves in the blood and passes through the kidneys into the urine but sometimes the body either produces too much uric acid or the kidneys excrete too little uric acid. There are two different therapies for treating gout; treating the acute attack and treating hyperuricemia associated with gout. For mild/moderate acute gout, monotherapy treatment is recommended with one of the following: non-steroidal anti-inflammatory drugs (NSAIDS), oral colchicine, or systemic corticosteroids. Combination

therapy can be considered for a severe acute attack. For the treatment of hyperuricemia associated with gout, it is recommended to start with allopurinol (or probenecid if adequate renal function and intolerant to allopurinol), febuxostat, and lastly, pegloticase (Krystexxa).

Colcrys, Gloperba (colchicine): A pain reliever that effectively reduces gout pain that is generally reserved for patients who cannot take NSAIDs. It is dosed 1.2 mg at first sign of flare and then 0.6 mg one hour later. Colchicine can cause intolerable side effects such as nausea, vomiting, or diarrhea. Colchicine may be effective for prophylaxis against acute flares when beginning urate lowering treatment[6]. Colcrys is also indicated for familial Mediterranean fever (FMF).

Allopurinol: A xanthine oxidase inhibitor indicated for the management of patients with signs and symptoms of primary or secondary gout. Dosing for patients with a creatinine clearance down to 10mL/min is available.

Uloric (febuxostat): A xanthine oxidase inhibitor indicated for the chronic management of hyperuricemia in patients with gout. It is dosed 40 mg or 80 mg orally once daily continuously for frequent gouty flares and to prevent complications. Dosing for patients with a creatinine clearance less than 15mL/min is not available.

Krystexxa (pegloticase): A PEGylated uric acid specific enzyme which works by catalyzing the oxidation of uric acid to allantoin (an inert, water-soluble purine metabolite that is readily eliminated by renal excretion) and therefore lowers serum uric acid. It is indicated for the treatment of chronic gout (hyperuricemia) in adult patients who are inadequately controlled with xanthine oxidase inhibitors at the maximum dose or for whom these drugs are contraindicated. Administered as an 8 mg intravenous infusion every 2 weeks in a healthcare setting given over at least 120 minutes.

Indications/Criteria

Colcrys (colchicine) will be allowed up to the FDA labeled dose for up to 2 tablets per day. Gloperba (colchicine oral solution) will be allowed up to the FDA labeled dose for up to 10mL per day. Doses exceeding 2 tablets per day or 10mL per day for gout will not be covered. Doses exceeding 2 tablets per day for Familial Mediterranean fever (FMF) will require prior authorization.

ALL the following criteria must be met for coverage for **Uloric (brand** febuxostat):

- Recurrent acute gout flares; symptomatic gout with at least 2 gout flares in the previous 12 months or at least 1 gout tophus or gouty arthritis or radiographic damage due to gout

- CrCl >15 mL/min
- Failure of 90-day continuous trial of allopurinol and a trial of generic febuxostat therapy at the maximum medically appropriate dose or an intolerance to allopurinol or when treatment with allopurinol is advised against
- Serum uric acid level ≥ 6 mg/dL
- Consideration of cardiovascular health as there is a higher rate of cardiovascular death associated with febuxostat use in those with cardiovascular disease

ALL the following criteria must be met for coverage for **Krystexxa**:

- Failure of 90-day continuous trial of each of the following: allopurinol (dosed ≥ 600mg/day) AND Uloric/Febuxostat.
    - If either allopurinol or Uloric/febuxostat is contraindicated, failure of a 90-day continuous trial of probenecid (dosed ≥500mg twice a day) AND documentation of specific contraindication to allopurinol and Uloric/febsuxostat must be submitted in place of a trial.
- Recurrent acute gout flares[6]: symptomatic gout with at least 3 gout flares in the previous 18 months or at least 1 gout tophus or gouty arthritis
- Serum uric acid level ≥6 mg/dL
- If not used in combination with methotrexate, documentation confirming why methotrexate cannot be used is required. If a trial of methotrexate is not appropriate due to alcohol use, chart notes must be provided indicating that the patient has been counseled on the need to abstain from alcohol use while taking methotrexate and is unwilling to abstain from alcohol use
- Glucose-6-phosphate dehydrogenase (G6PD) Deficiency: Before starting Krystexxa, patients at higher risk for G6PD deficiency (e.g., those of African and Mediterranean ancestry) should be screened due to the risk of hemolysis and methemoglobinemia. Krystexxa is contraindicated in patients with G6PD deficiency

Initial approval up to 6 months. Continuation of therapy for brand Uloric, and Krystexxa for up to 12 months may be considered if documentation identifies improvement in symptoms and uric acid levels are less than 6mg/dL.

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

Exclusions

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling Uloric/Febuxostat in combination with azathioprine, mercaptopurine, or theophylline
- Uloric/Febuxostat used for the treatment of asymptomatic hyperuricemia
- If uric acid level increases to above 6 mg/dL after initiating treatment, continuation of Krystexxa is not a covered benefit due to an increased risk of anaphylaxis and infusion reactions particularly when 2 consecutive levels are observed
- Re-treatment with Krystexxa after stopping treatment for longer than 4 weeks is not covered due to immunogenicity and increased risk of anaphylaxis and infusion reactions

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2. Probenecid Tablets. Prescribing Information. Corona, CA: Watson Laboratories, Inc. July 2003.
3. Wallace SL, Robinson H, Masi AT, Decker JL, McCarty DJ, Yü T-F. Preliminary criteria for the classification of the acute arthritis of primary gout. Arthritis Rheum 1977; 20:895---900.
4. Colcrys™ (colchicine) Tablets. Prescribing Information. Philadelphia, PA: AR Scientific, Inc. July 2009.
5. Zhang w, Doherty M, Pascual E, et al. EULAR evidence-based recommendations for gout. Part I: Diagnosis. Report of a task force of the Standing Committee for International Clinical Studies Including Therapeutics (ESCISIT). Ann Rheum Dis. 2006 Oct;65(10):1301-1311.
6. Zhang w, Doherty M, Bardin T, et al. EULAR evidence-based recommendations for gout. Part II: Management. Report of a task force of the EULAR. Ann Rheum Dis 2006; 65:1312–1324.
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Member Product	Medical Management Requirements*
New York Products	
HMO	Prior Auth
PPO in Plan	Prior Auth
PPO OOP	Prior Auth
POS in Plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Child Health Plus	Prior Auth
MVP Harmonious Health Care Plan	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Medicare Gold Giveback	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Secure HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare WellSelect PPO	Refer to the MVP website for the Medicare Part B and Part D policies.

MVP Medicare WellSelect Plus PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Patriot Plan PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess Complete D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess Plus D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Select PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Secure PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	
POS in Plan	Prior Auth
POS OOP	Prior Auth
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D
MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Select PPO	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Secure PPO	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D
MVP VT HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD
♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).	

***Medical Management Requirements**

Prior Auth	Prior Authorization Required
Potential for Retrospective Review	No Prior Authorization Required. May be subject to Retrospective Review.
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: **03/01/2023**
Approval Date: **12/01/2023**
Effective Date: **02/01/2024**
Related Policies: **Enteral Therapy- New York**

Codes: N/A

Overview

Child Health Plus and select Essential Plans cover certain OTC drugs and supplies as listed in this policy. Coverage for these products will be allowed at a participating pharmacy.

Indications/Criteria

- Subject to applicable copayment
- Prescription must be filled by a participating pharmacy.
- A prescription for an OTC product described above must be written by a participating provider
- Coverage of OTC medications and quantities follow the New York State Medicaid Program Pharmacy Fee Schedule (4.1) for the MVP Medicaid, Child Health Plus and select Essential Plan products.
- A prescription for an OTC product described below must be written by a practitioner licensed and authorized to prescribe medications.
- The over-the-counter medications in the following classes are covered for Child Health Plus and select Essential Plan members:

  Enteral Nutrition*
  ANALGESIC AND ANTIPYRETIC
  ANTACID
  ANTI-DIARRHEAL
  ANTIHISTAMINE
  ANTI-VERTIGO
  ARTIFICIAL TEARS AND OCCULAR/ORAL LUBRICANTS
  CHRONIC RENAL DISEASE

COUGH AND COLD
DERMATOLOGICAL
FAMILY PLANNING
FECAL SOFTENER AND LAXATIVE
HEMATINIC
INSULIN
INSULIN, BIOSYNTHETIC HUMAN
PEDICULOCIDE
SMOKING CESSATION AGENTS
VITAMIN/MINERAL

**May require prior authorization per MVP Benefit Interpretation*
[q]Quantity Limits may apply

For detailed information on covered non-prescription/OTC drugs refer to the New York State
Medicaid Pharmacy List of Reimbursable Drugs available at:
https://www.emedny.org/info/formfile.aspx

- Certain -over the counter supplies are covered at the pharmacy based on the NYS Medicaid Pharmacy Services Fee Schedule. Examples of coverage are listed below and the full list is available at: Pharmacy_Fee_Schedule.xls (live.com)
    - Contraceptive Condoms
    - Diabetic supplies
    - Humidifiers/Vaporizers
    - Nebulizers and supplies
    - Ostomy supplies
    - Peak Flow meters
    - Spacers
    - Incontinence supplies
    - Diapers
    - Wound dressings
    - Enteral supplies
    - Breast pumps

Exclusions/Limitations

- Humidifiers and vaporizers are limited to 1 unit per year
- Nebulizers are limited to 1 unit per year. There are no limits on nebulizer supplies (i.e. masks)
- Peak Flow meters are limited to 1 unit every 6 months
- Spacers are limited to 1 unit every 6 months. There is no limit to replacement bags for certain products

- Requests for OTC products other than those listed as covered in the subscriber contract will be denied as a non-covered benefit.

References

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2. New York State Pharmacy Fee Schedule October 12, 2022. Accessed on October 27, 2022. Available at: Pharmacy_Fee_Schedule.xls (live.com)

3. New York State Medicaid Fee-For-Service Program Pharmacy Manual Policy Guidelines. October 2022; Version 2022-2. Accessed on October 27, 2022. Available at: Pharmacy Policy Guidelines (emedny.org)

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 Gold Giveback	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Secure HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare WellSelect PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare WellSelect Plus PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Patriot Plan PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess Complete D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
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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	Not Covered

MVP Premier	Not Covered
MVP Premier Plus	Not Covered
MVP Premier Plus HDHP	Not Covered
MVP Secure	Not Covered
MVP EPO	Not Covered
MVP EPO HDHP	Not Covered
MVP PPO	Not Covered
MVP PPO HDHP	Not Covered
Student Health Plans	Not Covered
ASO	See SPD
Vermont Products	
POS in Plan	Not Covered
POS OOP	Not Covered
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D
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	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).	

***Medical Management Requirements**

Prior Auth	Prior Authorization Required
Potential for Retrospective Review	No Prior Authorization Required. May be subject to Retrospective Review.
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: **02/01/2024**
Approval Date: **04/01/2024**
Effective Date: **06/01/2024**
Related Policies: **N/A**

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

Drugs Requiring Prior Authorization (covered under the pharmacy benefit)

Genotropin/Miniquick (somatropin)

Norditropin/Flexpro (somatropin)

Humatrope (somatropin)

Nutropin AQ/Nuspin (somatropin)

Increlex (mecasermin)

Serostim (somatropin)

Zomacton (somatropin)

Omnitrope (somatropin)

Voxzogo (vosoritide)

Overview

Growth failure may be the result of growth hormone deficiency or primary insulin-like growth factor-1 (IGF-1) deficiency in children. The administration of growth hormone to children results in an acceleration in linear growth. Growth hormone deficiency in children ranges from complete absence of the hormone resulting in severe growth restriction, to a partial deficiency resulting in slightly short stature. Progressive weight loss and inappropriate deletion of lean body mass with paradoxical sparing of total body fat characterize HIV-associated wasting. If this condition is identified early, alternative treatments can be started, and growth hormone therapy may be avoided.

Voxzogo (vosoritide) is a C type natriuretic peptide (CNP) analog approved for increasing linear growth in pediatric patients 5 years and older with achondroplasia and open epiphyses. Achondroplasia is a genetic condition that causes short stature and disproportionate growth.

Indications/Criteria

Nutropin AQ/Nuspin and Norditropin/Flexpro 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 (for growth velocity)	Growth velocity < 25% for bone age and bone age less than 14 years (for growth velocity)	X	
C. Lack of response to two different growth hormone provocative tests defined as a serum GH level of less than 10 ng/ml	X			X	Normal or elevated growth hormone **AND** basal IGF-1 standard deviation score ≤ - 3.0

in children and adolescents; OR lack of response to one GH test AND IGF-I and IGF-BP3 levels more than 2 SD below the mean for bone age and gender..					
D. Genetic testing confirming diagnosis.				X	

GHD = growth hormone deficiency; CRI = Growth restriction due to chronic renal insufficiency in children; TS = Turner's Syndrome in children; PWS = Prader-Willi Syndrome in children; IGF-1 = Severe Primary IGF-1 Deficiency in children.

- For pediatric members with confirmed Prader-Willi syndrome, documentation must include that the member does not have special risk factors such as severe obesity, history of respiratory impairment or sleep apnea or unidentified respiratory infection. Growth hormone therapy is contraindicated in these members.

  Initial approval will be up to 12 months

  Extension requests will be up to 12 months. Dose increases require a new prior authorization request. Dose increases will be considered only if the height and growth velocity is below normal for age/gender after a minimum of 6 months of therapy at a previously authorized dose.

B. <u>Voxzogo (vosoritide)</u>

- Voxzogo therapy may be considered for coverage when the following criteria is met:
- Documentation indicating a diagnosis of achondroplasia confirmed through genetic testing with results significant for a mutation of the GlyArg mutation of the FGFR3 gene such as c.1138G>A or c.1138G>CDocumentation of recent annualized growth velocity (AGV)
- Member is 5 years of age or older
- Must have open growth plates and a current AGV ≥ 1.5cm/year
- Member has not received previous treatment with growth hormone, insulin-like growth factor 1 or anabolic steroids in the last 6 months

- Member does not have a planned limb lengthening surgery. If the member had a limb lengthening surgery, it must have occurred at least 18 months prior to the Voxzogo request
- Must be ordered by or with consult from an endocrinologist, geneticist, or skeletal dysplasia specialist

Initial requests will be approved up to 6 months

Extension requests will be approved up to 12 months if documentation is provided indicating all the following:

- The member has open growth plates
- Current AGV ≥ 1.5cm/year and an increase in AGV
- Attestation that the member will not have limb lengthening surgery while take Voxzogo.

C. <u>Small for Gestational Age (SGA)/Intrauterine Growth Restriction (IUGR)</u>

Growth Hormone therapy may be considered for coverage for SGA/IUGR when the following criteria is met:

-
- Member's birth weight is less than 10th percentile for gestational age and gender or birth weight and/or length < - 2 standard deviation score (SDS) (≤ 3rd 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 ageMember is at least two years of age and prepubertal at start of therapy
- Must be ordered by or with consult from an endocrinologist
- Must have open growth plates

Initial approval will be up to 12 months

Extension requests will be up to 12 months when documentation of prior height and current height with dates is provided. Dose increases require a new prior authorization request. Dose increases will be considered only if the height and growth velocity is below normal for age/gender after a minimum of 6 months of therapy at a previously authorized dose.

D. <u>Adults with growth hormone deficiency</u>

Growth Hormone therapy for adults with growth hormone deficiency may be considered for coverage when the following criteria is met:

- Documented diagnosis of growth hormone deficiency of adult onset from
    - hypopituitarism/pituitary disease,
    - hypothalamic disease,
    - pituitary hormone deficiencies (Adrenocorticotripic, thyroid-stimulating hormone, gonadotropin deficiency, prolactin)
    - pituitary surgery,
    - radiation, tumor,
    - brain injury

      OR
    - Documented congenital or genetic defect
- Documented low serum insulin-like growth factor-1 (adjusted for age and gender)
- Lack of response to two separate growth hormone provocative tests
    - Defined as a serum GH level ≤4 mcg/L on the GHRH/arginine test and ≤ 5 mcg/L for the gold standard insulin tolerance test (ITT).
    - When GHRH is not available and an ITT is either contraindicated or not practical in a given patient, the glucagon stimulation test can be used (criteria defined by GH level ≤3 mcg/L)

OR

- Patients with irreversible hypothalamic-pituitary structural lesions and those with panhypopituitarism (≥3 pituitary hormone deficiencies) and serum IGF-I levels below the age- and sex-appropriate normal range when off GH therapy for at least 1 month. These patients should be deemed GH deficient and do not require further GH stimulation testing.

AND all the following must be met for coverage:

- Baseline IGF-1 level required with initial request.
- Current IGF-1 required for continuation of therapy.
- Must be ordered by an endocrinologist.
- Adults with childhood-onset GHD previously treated with GH replacement in childhood should be retested after final height is achieved and GH therapy discontinued for at least 1 month to establish their GH status before considering restarting GH therapy.

Initial approval will be up to 12 months

Extension requests will be up to 12 months and considered if dosing is adjusted to target an IGF-1 level within the age-adjusted reference range.

E. Adults with AIDS Wasting/Cachexia (Serostim)

Growth Hormone therapy for adults with AIDS Wasting/Cachexia may be considered for coverage when the following criteria is met:

- Documentation of HIV diagnosis and current antiretroviral therapy.
    - Member is currently receiving highly active antiretroviral therapy (HAART) for at least one month with viral load reduced to <10,000 copies/ml.

- Must be ordered by physicians specializing in treating HIV patients.

- Documented unintentional weight loss of at least *10%* from baseline premorbid weight**,** or weight and amount that indicates significant weight loss has occurred (BMI <20kg/m^2)and wasting is not the result of an active, HIV-related opportunistic infection, TB or cancers or other preventable causes of weight loss. Member should be free from infection for 4-8 weeks before initiation of therapy.

- Currently receiving at least 100% of estimated caloric requirement on current nutritional regimen. Individuals receiving assisted enteral or parenteral nutrition must be weight stable for at least 2 months or have persistent weight loss despite such interventions

- Member has a trial, contraindication or intolerance to the following therapies: cyproheptadine, dronabinol and/or megestrol.

- Documentation that the member does not have the following:

    - Evidence of GI bleeding, obstruction, or malabsorption.
    - Experiencing acute critical illness due to complications following open heart or abdominal surgery, multiple accidental trauma, or acute respiratory failure
    - Active malignancy.
    - Systemic chemotherapy, interferon, anabolic steroids, or investigational agents within 30 days. Individuals with documented hypogonadism may

be on replacement therapy with gonadal steroids if this was started at least 2 months prior.
    - Diabetes mellitus, diabetic retinopathy, or history of significant glucose intolerance which for the purposes of the protocol will be defined as a fasting blood glucose >200 mg/dl.

Initial approval will be limited to a 12-week period at a dose of no more than 6mg/day.

Extension requests will require that the weight has stabilized or there has been no further weight loss and that the member is currently on antiretroviral therapy.

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
- Any indication, dose, frequency, age outside of the FDA approved 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.

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

UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
Healthy NY	Prior Authorization
MVP Premier	Prior Authorization
MVP Premier Plus	Prior Authorization
MVP Premier Plus HDHP	Prior Authorization
MVP Secure	Prior Authorization
MVP EPO	Prior Authorization
MVP EPO HDHP	Prior Authorization
MVP PPO	Prior Authorization
MVP PPO HDHP	Prior Authorization
Student Health Plans	Prior Authorization
ASO	See SPD
Vermont Products	
POS in Plan	Prior Authorization
POS OOP	Prior Authorization
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D
MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Select PPO	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Secure PPO	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D
MVP VT HMO	Prior Authorization
MVP VT Plus HMO	Prior Authorization
MVP VT HDHP HMO	Prior Authorization
MVP VT Plus HDHP HMO	Prior Authorization
MVP Secure	Prior Authorization
ASO	See SPD
♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).	

***Medical Management Requirements**

Prior Auth	Prior Authorization Required
Potential for Retrospective Review	No Prior Authorization Required. May be subject to Retrospective Review.
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/Medical Therapy**
Prior Approval Date: **03/01/2023**
Approval Date: **10/01/2023**
Effective Date: **12/01/2023**
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 pharmacy benefit
Temfya (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).

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, or colorectal surgeon
- Must be prescribed for an FDA approved indication
- Providers should perform screening for tuberculosis (TB) according to the local practice.

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 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 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 are provided 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.

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 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:

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

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References

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Member Product	Medical Management Requirements*
New York Products	
HMO	Prior Auth
PPO in Plan	Prior Auth
PPO OOP	Prior Auth
POS in Plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Child Health Plus	Prior Auth
MVP Harmonious Health Care Plan	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Medicare 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).	

***Medical Management Requirements**

Prior Auth	Prior Authorization Required
Potential for Retrospective Review	No Prior Authorization Required. May be subject to Retrospective Review.
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:	03/01/2023
Approval Date:	10/01/2023
Effective Date:	12/01/223
Related Policies:	Hemophilia Gene 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.

Codes Requiring Retrospective Review (must be obtained from Accredo Specialty Pharmacy, covered under the medical benefit)*

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

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.

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.

Exclusions

- Child Health Plus: blood factors prior to 04/01/2014 are not covered

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References

1. HCPCS Level II. Ingenix. 2011
2. Clinical Pharmacology: Accessed 10/30/2013
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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 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
UVM Health Advantage Secure PPO	Potential for retrospective review
UVM Health Advantage Preferred 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
UVM Health Advantage Select PPO	Potential for retrospective review
UVM Health Advantage Secure PPO	Potential for retrospective review
UVM Health Advantage Preferred PPO	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).	

***Medical Management Requirements**

Prior Auth	Prior Authorization Required
Potential for Retrospective Review	No Prior Authorization Required. May be subject to Retrospective Review.
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:	**N/A**
Approval Date:	**11/01/2023**
Effective Date:	**01/01/2024**
Related Policies:	**N/A**

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

Codes Requiring 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

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).

Prior authorization and medical justification is required for factor products obtained or administered in other outpatient settings.

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

Medicare Part B: Hemophilia Factor

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

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

Codes Requiring 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

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).

Prior authorization and medical justification is required for factor products obtained or administered in other outpatient settings.

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:	**NA**
Approval Date:	**10/01/2023**
Effective Date:	**10/01/2023**
Related Policies:	**Hemophilia Factor**

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

Drugs Requiring Prior Authorization under the medical benefit

J1411 Hemgenix (injection, etranacogene dezaparvovec-drlb)

J3590 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 XI 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 detected by an FDA-approved test. 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.
The recommended dose of Roctavian is 6 X 1013 vector genomes per kilogram (vg/kg) body weight, administered as a single intravenuous infusion. Roctavian is administered using an infusion pump rate of 1 mL/min, which can be increased every 30 minutes by 1 mL/min up to a maximum rate of 4mL/min.

Indications/Criteria

A. Hemophilia A

Roctavian may be considered for coverage when ALL of the following criteria is met:

- Member is biologically male
- Chart notes documenting that member has a confirmed diagnosis of hemophilia A (hereditary factor VIII deficiency).
- Current chart notes documenting the **ALL** of the following tests:
    - Pre-existing antibodies to AAV5 using FDA approved companion diagnostic. Roctavian must NOT be administered to members with a positive test for antibodies to AAV5.
    - Factor VIII inhibitor titer testing
        - Roctavian must NOT be administered to members with a positive test for Factor VIII inhibitor
    - 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 that the evaluation for thrombosis and cardiovascular risk factors has been completed with the member and will be monitored after Roctavian infusion.

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:

- Member is biologically male
- Chart notes documenting that member has a confirmed diagnosis of hemophilia B (hereditary factor IX deficiency).
- Current chart notes documenting the **ALL** of the following tests:
    - Factor IX inhibitor titer testing
        - If initial test is positive, there must be documentation of a re-test within 2 weeks. If both the initial test and re-test results are positive, Hemgenix cannot be administered.
    - Documentation of liver health assessments including:
        - Enzyme testing [alanine aminotransferase (ALT), asparate aminotransferase (AST), alkaline phosphatase (ALP) and total bilirubin).
        - Hepatic ultrasounds and elastography
- Current chart notes documents one of the following:
    - Current use of Factor IX prophylaxis OR
    - Member has a current or historical life-threatening hemorrhage OR
    - Member as had repeated, serious spontaneous bleeding episodes
- Provider attestation
    - For members with pre-existing risk factors for hepatocellular carcinogenicity, 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

- 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
- Hemgenix
    - Member has active hepatitis C infection
    - Member has uncontrolled HIV infection
    - Member has cirrhosis

References

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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)

Member Product	Medical Management Requirements*
New York Products	
HMO	Prior Authorization
PPO in Plan	Prior Authorization
PPO OOP	Prior Authorization
POS in Plan	Prior Authorization
POS OOP	Prior Authorization
Essential Plan	Prior Authorization
MVP Medicaid Managed Care	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Child Health Plus	Prior Authorization
MVP Harmonious Health Care Plan	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Medicare Preferred Gold HMO POS	Prior Authorization
MVP Medicare Secure HMO POS	Prior Authorization
MVP Medicare Secure Plus HMO POS	Prior Authorization
MVP Medicare WellSelect PPO	Prior Authorization
MVP Medicare WellSelect Plus PPO	Prior Authorization
MVP Medicare Patriot Plan PPO	Prior Authorization

MVP DualAccess D-SNP HMO	Prior Authorization
MVP DualAccess Complete D-SNP HMO	Prior Authorization
MVP DualAccess Plus D-SNP HMO	Prior Authorization
UVM Health Advantage Select PPO	Prior Authorization
UVM Health Advantage Secure PPO	Prior Authorization
UVM Health Advantage Preferred PPO	Prior Authorization
Healthy NY	Prior Authorization
MVP Premier	Prior Authorization
MVP Premier Plus	Prior Authorization
MVP Premier Plus HDHP	Prior Authorization
MVP Secure	Prior Authorization
MVP EPO	Prior Authorization
MVP EPO HDHP	Prior Authorization
MVP PPO	Prior Authorization
MVP PPO HDHP	Prior Authorization
Student Health Plans	Prior Authorization
ASO	See SPD
Vermont Products	
POS in Plan	Prior Authorization
POS OOP	Prior Authorization
MVP Medicare Preferred Gold HMO POS	Prior Authorization
MVP Medicare Secure Plus HMO POS	Prior Authorization
UVM Health Advantage Select PPO	Prior Authorization
UVM Health Advantage Secure PPO	Prior Authorization
UVM Health Advantage Preferred PPO	Prior Authorization
MVP VT HMO	Prior Authorization
MVP VT Plus HMO	Prior Authorization
MVP VT HDHP HMO	Prior Authorization
MVP VT Plus HDHP HMO	Prior Authorization
MVP Secure	Prior Authorization
ASO	See SPD
♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).	
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***Medical Management Requirements**

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

MVP Health Care Medical Policy

Hepatitis C Treatment

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

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
- **Harvoni**-Genotypes 1, 4, 5, 6
- **Mavyret**-Genotype 1-6
- **Vosevi**-Genotypes 1-6

Indications/Criteria

The following information must be provided for all drugs:

- Test results identifying HCV-antibody, quantitative HCV PCR level (viral load), HCV genotype, and fibrosis score must be provided
- Documentation identifying if patient 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
- Doses above or indications not supported in 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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1. Sovaldi™ Capsules. Prescribing Information. Foster City, CA: Gilead Science, Inc. December 2013.
2. Olysio™ Capsules. Prescribing Information. Titusville, NJ: Janssen Therapeutics, LP; November 2013.
3. Epclusa Tablets. Prescribing Information. Foster City, CA: Gilead Sciences, Inc. June 2016
4. Treatment regimens for chronic hepatitis C virus genotype 1: UpToDate, Inc. 2014
5. 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
6. AASLD/IDSA/IAS-USA. Recommendations for testing, managing, and treating Hepatitis C. http://www.hcvguidelines.org. Accessed November, 2017
7. 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
8. Harvoni Tablets. Prescribing Information. Foster City, CA: Gilead Science, Inc.; October 2014
9. 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
10. 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):26-31
11. Vosevi Tablets. Prescribing Information. Foster City, CA: Gilead Science, Inc. July 2017
12. Mavyret Tablets. Prescribing Information. North Chicago, IL. August 2017
13. New York State Department of Health: Hepatitis C (www.health.ny.gov/communicable/hepatitis/hepatitis_c)
14. Hepatitis C - FAQs, Statistics, Data, & Guidelines | CDC
15. What's New, Updates and Changes to the Guidance | HCV Guidance (hcvguidelines.org)
16. HCV Testing and Linkage to Care | HCV Guidance (hcvguidelines.org). Last updated October 24, 2022.
17. Epclusa. Prescribing Information. Foster City, CA: Gilead Sciences, Inc. Last updated April 2022
18. Harvoni. Prescribing Information. Foster City, CA: Gilead Science, Inc. Last updated March 2020
19. Sovaldi™. Prescribing Information. Foster City, CA: Gilead Science, Inc. Last updated March 2020.

20. Mavyret Tablets. Prescribing Information. North Chicago, IL: AbbVie Inc. Last updated October 2023
21. Vosevi Tablets. Prescribing Information. Foster City, CA: Gilead Science, Inc. Last updated November 2019
22. Peg-Intron®. Prescribing Information. Whitehouse Station, NJ: Merck Sharp & Dohme Corp ., a subsidiary of Merck & Co.. Last updated August 2019
23. Pegasys®. Prescribing Information. South San Francisco, CA: Hoffmann-La Roche, Inc. c/o Genentech, Inc.. Last updated March 2021

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

MVP PPO	Prior Authorization
MVP PPO HDHP	Prior Authorization
Student Health Plans	Prior Authorization
ASO	See SPD
Vermont Products	
POS in Plan	Prior Authorization
POS OOP	Prior Authorization
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D
MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Select PPO	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Secure PPO	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D
MVP VT HMO	Prior Authorization
MVP VT Plus HMO	Prior Authorization
MVP VT HDHP HMO	Prior Authorization
MVP VT Plus HDHP HMO	Prior Authorization
MVP Secure	Prior Authorization
ASO	See SPD
♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).	
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***Medical Management Requirements**

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

MVP Health Care Medical Policy

Hereditary Angioedema

Type of Policy: **Drug/Medical Therapy** *(administered by the pharmacy department)*
Prior Approval Date: **03/01/2023**
Approval Date: **10/01/2023**
Effective Date: **12/01/2023**
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.

Codes Requiring Prior Authorization (covered under the medical benefit)
J0598 Cinryze® Injection, C1 esterase inhibitor (human), 10 units. (B/D coverage for Medicare dependent upon place of service)
J0597 Berinert® Injection, C1 esterase inhibitor (human), 10 units
J1290 Kalbitor® Injection, ecallantide, 1mg
J0596 Ruconest Injection, C1 esterase inhibitor recombinant), 10 units

Drugs Requiring Prior Authorization (covered under the pharmacy benefit)
Firazyr® (icatibant) – self-administered
Haegarda (C1 esterase inhibitor, human) –self administered
Takhzyro (lanadelumab-flyo)- self administered

Overview

Hereditary angioedema (HAE) is a genetic disorder caused by a deficiency or defective plasma protein C1 inhibitor. HAE is a chronic disease that is associated with acute attacks of swelling. Swelling can occur in the face, larynx, gastrointestinal tract, and limbs. The frequency and severity of attacks can vary significantly.

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

Indications/Criteria

Brand Name	Berinert®	Cinryze®	Firazyr®	Haegarda	Kalbitor®	Ruconest	Takhzyro

Chemical Name	C1 esterase inhibitor	C1 esterase inhibitor	icatibant	C1 esterase inhibitor	ecallantide	C1 esterase inhibitor	Lanadelumab-flyo
Indication specific for HAE	acute abdominal, facial, or laryngeal attacks	prophylaxis	acute attacks	prophylaxis	acute attacks	acute nonlaryngeal attacks	prophylaxis
Administration	IV	IV	SC (self adm only – RX benefit)	SC (self adm only – RX benefit)	SC (Physician adm only – medical benefit)	IV	SC (self adm only – RX benefit)
Age restrictions	≥ 12 years	≥ 6 years	≥ 18 years	≥ 6 years	≥ 12 years	≥ 13 years	≥ 12 years
Recommended Dose	20 units/kg IV	≥ 12 years 1,000 Units IV every 3 or 4 days 6-11 years 500 units IV every 3 or 4 days	30mg SC x1. MDD=3 inj/24hrs	60 units/kg SC twice weekly (every 3 or 4 days)	30mg SC x1. MDD=60mg/ 24hrs	<84 kg: 50 units/kg IV >84 kg: 4200 units IV MDD=2inj/24hrs	300mg SC every 2 weeks Consider dosing once every 4 weeks when patient is attack free for > 6 months
Initial authorization & subsequent authorizations	3 months (1 injection per visit at recommended dose)	3 months [10 doses (20 vials) per month for ≥ 12 years] or [10 doses (10 vials) per month for 6-11 years	3 months [3 doses (3 prefilled syringes) per RX]	3 months [10 doses per month]	3 months (2 doses per visit)	3 months (2 doses per visit)	3 months [2 doses (4 vials) per month].

Cinryze, Berinert, Firazyr, Haegarda, Kalbitor, Takhzyro and Ruconest may be considered for coverage if all of the following criteria are met:

- Ordered by an allergist, immunologist, or hematologist;
- Indication as listed in the table on page 1 of this policy;
- Laboratory data provided confirms diagnosis of HAE (i.e.C1-INH activity and serum complement factor 4 level below the reference range; serum C1q level within normal reference range);

- For short-term prophylaxis therapy, triggers (e.g. surgery, major dental work, etc.) of attacks have been prophylactically treated appropriately and severe HAE attacks* persist; OR contraindication (such as pregnancy or lactating) or severe intolerance to attenuated androgens (e.g. danazol);
- Provide family history of angioedema status;
- Provide current prescription history. (Medications that may trigger or worsen angioedema and should be avoided are estrogen contraceptives, hormone replacement therapy, and ACE-Inhibitors)[11];
- For medications indicated for prophylaxis, provider has documented the benefits of a prophylactic treatment strategy in addition to on-demand treatment considering individualized patient factors OR provider has documented plans for as-needed use of short-term prophylaxis before medical procedures or other events at high risk of triggering HAE attacks.

*Severe attacks are defined as attacks that compromise the airway, compromise activities of daily living for at least 5 days per month, or last more than 72 hours.

Continued authorization may be provided for Cinryze, Takhzyro and Haegarda if the number of emergency room visits or hospitalizations due to a severe HAE attack has diminished. Continued authorization may be provided for Firazyr, Kalbitor, Ruconest or Berinert if documentation identifies diminished symptoms, decreased severity of attack, reduced duration of attacks, and decreased hospitalizations.

Exclusions

- Other types of angioedema are not covered (e.g. allergic, acquired, and medication-induced);
- More than one acute agent per authorization period;
- Refill of medication prior to use of current supply (i.e. stockpiling of medication is not covered);
- Medications that may trigger or worsen angioedema are currently being administered
- For Ruconest patients with laryngeal attacks

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 Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP Medicare WellSelect PPO	Prior Auth
MVP Medicare WellSelect Plus PPO	Prior Auth
MVP Medicare Patriot Plan PPO	Prior Auth
MVP DualAccess D-SNP HMO	Prior Auth
MVP DualAccess Complete D-SNP HMO	Prior Auth
MVP DualAccess Plus D-SNP HMO	Prior Auth
UVM Health Advantage Select PPO	Prior Auth
UVM Health Advantage Secure PPO	Prior Auth
UVM Health Advantage Preferred 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
UVM Health Advantage Select PPO	Prior Auth
UVM Health Advantage Secure PPO	Prior Auth
UVM Health Advantage Preferred PPO	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

Select Hypnotics

Type of Policy: Drug Therapy
Prior Approval Date: 11/01/2022
Approval Date: 04/01/2023
Effective Date: 04/01/2023
Related Policies: Refer to the MVP Medicare website for the Medicare Part D formulary and policies for drugs covered under the Part D benefit.

Drugs Requiring Prior Authorization (if step edit is not met and/or quantity limits are exceeded)

Brand Name Non-benzodiazepines*	Chemical/ Generic Name
Ambien®	zolpidem
Ambien CR®	Zolpidem ER
Edluar™	zolpidem
Intermezzo®	zolpidem
Sonata®	zaleplon
Lunesta®	eszopiclone
Rozerem®	ramelteon
Zolpimist™	zolpidem
Brand Name Orexin Receptor Antagonist	**Chemical/Generic Name**
Belsomra	suvorexant
Dayvigo	lemborexant
Quviviq	Daridorexant

Drugs Requiring Prior Authorization if quantity limits are exceeded

Brand Name benzodiazepines for insomnia*	Chemical/ Generic Name
Dalmane®	flurazepam

Doral®	quazepam
Halcion®	triazolam
Prosom®	estazolam
Restoril®	temazepam

Drugs Requiring Prior Authorization

Brand Name	Chemical/Generic Name
Hetlioz	tasimelteon
Silenor®	doxepin

Overview

Hypnotics should generally be limited to 7 to 10 days of use and reevaluation of the patient is recommended if therapy is to exceed more than 2 to 3 weeks. Hypnotic labeling does not address duration of treatment however for many patients 2-4 weeks may be appropriate followed by re-evaluation of treatment. (Journal of Clinical Sleep Medicine. Clinical Guideline for the Evaluation and Management of Chronic Insomnia in Adults. 2017.)

An expert panel convened by the NIH in June 2005 noted that newer benzodiazepine receptor agonist medications have been developed that have fewer and less severe effects than other medications, and show promise for long-term use, but this requires further evaluation [1]. There is no evidence that treatment effects persist on termination of pharmacotherapy.[2]

Failure of insomnia to remit after 7 to 10 days of therapy may indicate the presence of primary psychiatric disorder or medical illness that should be evaluated. Insomnia usually appears in the presence of at least one other disorder. Particularly common comorbidities are major depression, generalized anxiety, substance abuse, attention deficit/hyperactivity in children, dementia, and a variety of physical problems. Behavioral and cognitive-behavioral therapies (CBT's) have demonstrated efficacy in randomized controlled clinical trials.[1]

Behavioral methods include relaxation training, stimulus control, sleep restriction, maintaining consistent bedtime and arising time, and reassociating bedtime with rapid sleep onset by curtailing sleep-incompatible activities. Cognitive therapy methods include cognitive restructuring, in which anxiety-producing beliefs and erroneous beliefs about sleep and sleep loss are specifically targeted. This is to assist patients in recognizing and changing distorted sleep cognitions. CBTs are a combination of cognitive methods and behavioral methods.[1,2]

Documentation should reflect that CBTs have been evaluated. Insomnia is often transient and intermittent; therefore, prolonged administration is generally not recommended. There is no clear evidence that improved sleep leads to meaningful changes in daytime well-being or performance. The National Cancer Institute (NCI) guidelines state that when sleep disturbances are not resolved with nonpharmacologic therapies, the use of sleep medications on a short-term or intermittent basis may be helpful.

Indications/Criteria

All **brand name** oral prescription **non-benzodiazepine** hypnotics and orexin receptor antagonists require step therapy. These include Ambien, Ambien CR, Edluar, Intermezzo, Lunesta, Sonata, Rozerem, Zolpimist, Belsomra, Dayvigo and Quviviq. Both brand Intermezzo and the generic zolpidem sublingual are subject to step edit. The use of a brand name non-benzodiazepine select hypnotics, zolpidem sublingual, Dayvigo, Belsomra or Quviviq may be medically necessary if:

- The member has experienced treatment failure or significant intolerance (e.g. sensitivity, drug allergy, adverse effect) to at least one generic non-benzodiazepine prescription select hypnotics not subject to the step edit at the appropriate dose.
- Quantity limits apply.
- Previous history of at least one claim of a generic non-benzodiazepine hypnotic not subject to the step edit in the past 365 days will be allowed through an automatic edit process.

The use of brand name **Silenor** may be medical necessary when:

- The member has a documented failure or intolerance to all formulary non-benzodiazepine sleep medications (e.g zaleplon, zolpidem, zolpidem CR, eszopliclone, ramelteon, doxepin (generic Silenor)).

The use of **Hetlioz** capsules* may be medically necessary ifthe following are met:

- Diagnosis of Non-24-Hour Sleep-Wake Disorder (Non-24), Circadian rhythm sleep-wake disorder, Non-24 sleep wake type or Circadian rhythm sleep disorder, free running type AND
    - Patient is 18 years or older AND
    - Patient is totally blind AND
    - Sleep disturbance cannot be explained by other current sleep disorder, medical or neurological disorder, mental disorder, medication use or substance use disorder AND
    - At least 3-month history of insomnia, excessive daytime sleepiness or both, which alternate with asymptomatic episodes AND
    - Documented daily sleep logs (and/or actigraphy) over at least 14 days must demonstrate a pattern of sleep and wake times that typically delay each day, with a circadian period that is usually longer than 24 hours OR
- Diagnosis of Smith-Magenis Syndrome (SMS) with Nighttime Sleep Disturbances AND
  Patient 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
- Patient is 3-15 years of age

*Please note, Hetlioz capsules and Hetlioz LQ Oral Suspension are not substitutable

All products **identified in this policy** and their corresponding generics, are limited to 30 dosage units every 30 days. Prior authorization is required for quantities exceeding this limit.

Quantity Limit exceptions may be granted when all criteria below are met:

- Member has been evaluated for underlying conditions that may be causing insomnia and reversible conditions have been addressed

- Sleeplessness must have a negative impact on normal activities of everyday living such as work performance impairment and ability to drive due to excessive sleepiness caused by insomnia
- Documented failure supported by chart notes and prescription history of a trial of allowable quantities (e.g. 30 dosage units every 30 days) of formulary agents in combination with non-pharmacologic therapies such as stimulus control, appropriate sleep hygiene, sleep restriction, muscle relaxation, cognitive behavioral therapy, etc.
- For tier 3 drugs: chart notes and prescription history must identify failure of an adequate trial of all formulary **non-benzodiazepine** prescription sleep agents at 30 units per 30 days and the requested drug at 30 units per 30 days.
- Member must have documented symptoms, including at least one of the following, despite adequate opportunity for sleep:
  - difficulty falling asleep
  - difficulty staying asleep
  - waking up too early in the morning

Additional consideration may be given to the following:

- Use within treatment regimen for primary psychiatric disorder or other medical illness. Appropriate documentation is required.
- If the sleep disorder is secondary to a chronic and irreversible physical and/or psychological cause, documentation of appropriate evaluations and/or consults are required to identify that physical and psychiatric disorders have been evaluated and are being treated.
- If insomnia is due to chronic pain, appropriate evaluations addressing pain control must be documented and optimal pain management is currently being received.
- Exceptions may be granted up to 3 months for an acute situational event (i.e. death of a close family member, etc.) that has occurred within the past 30 days.
- Initial quantity limit exceptions may be granted up to 3 months for psychiatric disorders that are not resolved with adequate psychoactive medications and chronic irreversible conditions such as Parkinson's disease and multiple sclerosis.

Initial authorization for quantity limits and/or brand name select hypnotics will be up to 3 months.

Extensions of therapy will be considered for up to a maximum of 6 months if documentation provided identifies continued benefit from therapy.

Requests for continued authorization must be substantiated by an evaluation that identifies continued need and prescription history identifies consistent use. Extensions will not be granted solely because of efficacy and patient satisfaction. Documentation must demonstrate that despite attempts to correct the underlying illness, insomnia persists. Documented attempts to taper daily use, outcome of a dose reduction attempt or contraindication to a dose reduction must be provided with initial request and may also be required, if appropriate, with continued authorization requests.

Exclusions

- Members who are documented as current drug or alcohol abusers.

- Members that use the drug for patient convenience to overcome lack of opportunity for sleep (i.e. shift work /works double shift), sleeps in noisy environment.
- 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.
- Doses exceeding the FDA approved package labeling maximum recommended dose.
- 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
- Over-the-counter medications are not covered
- Members who do not fall within the FDA approved age ranges
- Hypnotics are not covered for the indication of anxiety without meeting the criteria in this policy.
- 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.)
- Orexin Receptor Antagonists (i.e. Belsomra, Dayvigo and Quviviq): not covered for Members with diagnosis of narcolepsy
- Hetlioz
    - Not covered for patients with severe hepatic impairment

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Member Product	Medical Management Requirements*
New York Products	
HMO	Prior Authorization
PPO in Plan	Prior Authorization
PPO OOP	Prior Authorization
POS in Plan	Prior Authorization
POS OOP	Prior Authorization
Essential Plan	Prior Authorization
MVP Medicaid Managed Care	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Child Health Plus	Prior Authorization
MVP Harmonious Health Care Plan	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Medicare 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 Authorization
MVP Premier	Prior Authorization
MVP Premier Plus	Prior Authorization
MVP Premier Plus HDHP	Prior Authorization
MVP Secure	Refer to Part D Coverage
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 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 Authorization
MVP VT Plus HMO	Prior Authorization
MVP VT HDHP HMO	Prior Authorization

MVP VT Plus HDHP HMO	Prior Authorization
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).	

***Medical Management Requirements**

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

MVP Health Care Medical Policy

Idiopathic Pulmonary Fibrosis

Type of Policy: **Drug Therapy**
Prior Approval Date: **07/01/2023**
Approval Date: **07/01/2024**
Effective Date: **09/01/2024**
Related Policies: **NA**

Drugs Requiring Prior Authorization

Pirfenidone tablets

Esbriet (pirfenidone) capsules/tablets

Ofev (nintedanib) capsules

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

Overview

Idiopathic pulmonary fibrosis (IPF) is a chronic, progressive fibrotic interstitial lung disease of unknown origin[1]. The tissue deep in the lungs becomes thick and scarred, resulting in an irreversible loss of the tissue's ability to transport oxygen. The most common symptoms are shortness of breath and cough. As the disease progresses, members can experience rapid, shallow breathing, unintended weight loss, fatigue or malaise, aching muscles and joints and clubbing of the fingers or toes.[2] IPF causes the same type of scarring and symptoms as other lung diseases, making it difficult to diagnose.

Esbriet and Ofev are both indicated for the treatment of IPF. Esbriet is a pyridone with an unknown mechanism of action.[3] Ofev is a kinase inhibitor, which inhibits multiple receptors implicated in the pathogenesis of IPF.[4]

Indications/Criteria

Esbriet/Ofev will be considered medically necessary for Idiopathic Pulmonary Fibrosis when **ALL** the following criteria are met:

- Documented diagnosis of IPF with HRCT (high resolution computed tomography) **OR** pathological lung biopsy
    - Must rule out other causes of interstitial lung disease such as domestic and occupational environmental exposures, connective tissue disease, drug toxicity and/or infection.
- Liver function test prior to initiating treatment indicating AST/ALT and bilirubin are less than 5x ULN
- Prescribed by or in consultation with a pulmonologist
- FVC greater than or equal to 50% of predicted and a carbon monoxide diffusing capacity of 30 to 79% of predicted, prior to start of therapy

Initial coverage will be for 6 months. For continuation of therapy up to 12 months, documentation must identify improvement or maintenance of disease (less than a 10% decline in FVC) and LFTs within allowed bounds.

Ofev will be considered medically necessary for **Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD)** when **ALL** the following criteria are met:

- Confirmed diagnosis of SSc-ILD such as with HRCT (high resolution computed tomography) **AND**
- Prescribed by or in consultation with a pulmonologist

Ofev will be considered medically necessary for **Chronic Fibrosing Interstitial Lung Diseases (ILD) with a Progressive Phenotype** when **ALL** the following criteria are met:

- Confirmed diagnosis of Chronic Fibrosing ILD such as with HRCT (high resolution computed tomography) **AND**
- Presenting with clinical signs of progression (defined as FVC decline ≥ 10%, FVC decline ≥ 5% and < 10% with worsening symptoms or imaging, or worsening symptoms and worsening imaging all in the 24 months prior to screening) **AND**
- Prescribing physician is a pulmonologist or prescribed in consult with a pulmonologist

Initial coverage will be for 6 months. For continuation of therapy up to 12 months, must identify improvement or maintenance of disease and LFTs within allowed bounds.

Exclusions

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

References

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Member Product	Medical Management Requirements*
New York Products	
HMO	Prior Auth
PPO in Plan	Prior Auth
PPO OOP	Prior Auth
POS in Plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Child Health Plus	Prior Auth
MVP Harmonious Health Care Plan	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Medicare Gold Giveback	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Secure HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare WellSelect PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare WellSelect Plus PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Patriot Plan PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess Complete D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess Plus D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Select PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Secure PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	
POS in Plan	Prior Auth
POS OOP	Prior Auth
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D 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).**

***Medical Management Requirements**

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

MVP Health Care Medical Policy

Immunoglobulin Therapy

Type of Policy: Medical Therapy
Prior Approval Date: 06/01/2023
Approval Date: 04/01/2024
Effective Date: 06/01/2024

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

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

Drugs Requiring Prior Authorization under the medical benefit

Billing Code(s)	Medication
J1459	Injection, immune globulin (Privigen), intravenous, non-lyophilized (e.g. liquid), 500 mg
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 ≤ 5 consecutive days) for the treatment of:
    - Management of acute bleeding due to severe thrombocytopenia (platelet counts less than 30,000/µl; **or**
    - To increase platelet counts prior to splenectomy; **or**Severe thrombocytopenia (platelets less than 20,000/microliters) in members considered at risk for intracerebral hemorrhage.

- Chronic refractory ITP:
    - Prior treatment with corticosteroids and splenectomy; **and**
    - Duration of illness≥ 3 months; **and**
    - Age of 10 years or older; **and**
    - No concurrent illness/disease explaining thrombocytopenia **and**
    - Platelet count < 30,000/mcL **OR** Platelet count <50,000/mcL and significant bleeding symptoms or rapid increase in platelets is required **and**
    -

3. Chronic lymphocytic leukemia with associated hypogammaglobulinemia criteria:

Intravenous Immunoglobulin may be considered for coverage for Chronic lymphocytic leukemia with associated hypogammaglobulinemia when the following criteria is met

- IVIG is being prescribed for prophylaxis of bacterial infection AND

- IgG level is less than 500mg/dL **OR**
- Documentation of specific antibody deficiency **AND** the presence or repeated bacterial infections within the past 12 months.

4. **Symptomatic human immunodeficiency virus (HIV)**
   Intravenous Immunoglobulin may be considered for coverage for HIV when the following criteria is met:
   - Chart notes identifying a HIV diagnosis
   - Documentation of recurrent infections
   - Documentation of IgG level <500mg/dl
   -
5. **Bone marrow transplant**
   Intravenous Immunoglobulin may be considered for coverage for bone marrow transplant when the following criteria is met:

   - Member is seropositive for cytomegalovirus (CMV) before transplantation or the patient and donor were seronegative and were undergoing allogeneic transplantation for hematologic neoplasms.
   - Documentation that member has a current IgG level <500mg/dL
   - May be covered up to 90 days only.

6. **Solid organ transplantation**
   Intravenous Immunoglobulin may be considered for coverage for solid organ transplant when the following criteria is met:

   - Chart notes identifying of a solid organ transplantation

7. **Kawasaki Disease (mucocutaneous lymph node syndrome)**
   Intravenous Immunoglobulin may be considered for coverage for Kawasaki Disease the following criteria is met:

   - Chart notes identifying a diagnosis of Kawasaki Disease

8. **Immune thrombocytopenic purpura in pregnancy.**
   For Immune thrombocytopenic purpura in pregnancy, Intravenous immunoglobulin is covered for any of the following:
      - Pregnant members who have previously delivered infants with autoimmune thrombocytopenia

- Pregnant members who have platelet counts less than 50,000/mm^3 during the current pregnancy
- Pregnant members with past history of splenectomy.

9. Autoimmune mucocutaneous blistering diseases

Intravenous Immunoglobulin may be considered for coverage for autoimmune mucocutaneous blistering diseases when the following criteria is met:

- Chart notes identifying that diagnosis has been confirmed by biopsy and pathology report
- Documentation that the condition is rapidly progressing, extensive and/or debilitating
- Documentation of a failure of standard therapy (i.e. corticosteroids, immunosuppressant agents)
- Approval will cover short-term use. Maintenance therapy is not a covered benefit.

10. Scleromyxedema

Intravenous Immunoglobulin may be considered for coverage for Scleromyxedema when the following criteria is met:

- Documentation of a diagnosis of scleromyxedema

11. Humoral or vascular allograft rejection

Intravenous Immunoglobulin may be considered for coverage for Humoral or vascular allograft rejection when the following criteria is met:

- Documentation of Humoral or vascular allograft rejection

12. Hemolytic anemia

Intravenous Immunoglobulin may be considered for coverage for Hemolytic anemia when the following criteria is met:

- Member is 18 years of age or younger
- Chart notes identifying a diagnosis of hemolytic anemia
- Members with hepatomegaly or hepatosplenomegaly will be considered for coverage on a case-by-case basis

13. Polymyositis and dermatomyositis

Intravenous Immunoglobulin may be considered for coverage for Polymyositis and dermatomyositis when the following criteria is met:

- Chart notes identifying that diagnosis is confirmed by objective test results such as electromyogram (EMG), muscle biopsy, and blood analysisDocumentation of a failure, contraindication, adverse effects or ineffective response to steroids or immunosuppressants
-
- Documentation that IVIG will be used to decrease the doses of other drugs that are needed for treatment.

14. Sensitized renal cell transplant

Intravenous Immunoglobulin may be considered for coverage for Sensitized renal cell transplant when the following criteria is met:

- Chart notes identifying renal cell transplant

15. Stiff-person syndrome

Intravenous Immunoglobulin may be considered for coverage for Stiff-person syndrome when the following criteria is met:

-
- Chart notes identifying diagnosis of stiff-person syndrome
- Documentation of inadequate response to first-line treatment (benzodiazepines/baclofen)

16. Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

Intravenous Immunoglobulin may be considered for coverage for CIDP when the following criteria is met:

- Chart notes identifying a diagnosis of CIDP confirmed by electrodiagnostic studies
- Documentation of progressive or relapsing/remitting disease
- Documentation of moderate to severe functional disability

17. Other supported diagnoses (such as acute and chronic inflammatory demyelinating polyradiculoneuropathy (CIDP), Guillain-Barre syndrome, myasthenia gravis, multifocal motor neuropathy (MMN))

- The request must meet the Experimental/Investigational policy and if appropriate:
    - Documentation of difficulty with venous access for plasmapheresis; **or**

- Documentation is provided that other therapy has failed or is contraindicated such as steroids; **or**
- Documentation of rapidly progressive disease

Initial approval will be up to one treatment every 28-30 days up to 3 months unless otherwise noted for the diagnosis

Extension requests will be approved up to 6 months if the member has documentation of ALL the following:

- Current documentation that the member has continued benefit to therapy
- Current documentation demonstrating objective improvement
- Current documentation of appropriate laboratory reports

B. <u>Subcutaneous Immune Globulin (SCIG): Gammaked, Gammagard, Gamunex-C, Hizentra, HyQvia, Cutaquig, and Xembify</u>

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

- Member meets the diagnosis criteria above AND subcutaneous IG is indicated for their diagnosis
- Current documentation indicating that intravenous IVIG is inappropriate
- Documentation that the member has a serum IgA level > 0.05g/L
- Documentation of no known antibodies to IgA
    a. Subcutaneous Immunoglobulin is contraindicated for IgA deficient patients with antibodies against IgA
- Attestation that the member does not have a history of severe systemic response to immune globulin preparations and
- Subcutaneous immunoglobulin is to be administered in the home setting, with the exception of the first dose, which may be given in a supervised outpatient setting.
    a. Chart notes must be provided documentation medical necessity for administering intravenous immunoglobulin in places of service other than the home.
    b. IVIG and SCIG must be obtained from a preferred contracted IVIG vendor.

- Please see Medicaid, Child Health Plus and Vermont Variation regarding place of service and where to obtain.

Initial approval will be up to one treatment every 28-30 days up to 3 months unless otherwise noted for the diagnosis

Extension requests will be approved up to 6 months if the member has documentation of ALL the following:

- Current documentation that the member has continued benefit to therapy
- Current documentation demonstrating objective improvement
- Current documentation of appropriate laboratory reports

Medicaid Variation:

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

Child Health Plus Variation : Members are not required to receive IVIG in the home setting.

Vermont Variation: Members are not required to receive IVIG in the home setting

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Exclusions

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling
- Diagnosis not supported by FDA approved package labeling or "MVP Health Care Experimental or Investigational Procedures, Behavioral Health Services, Drugs and Treatments, Off-Label use of FDA approved Drugs, and Clinical Trials" policy

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16. Cutaquig (Immune Globulin Subcutaneous (Human) – hipp) 16.5% solution. Prescribing Information. Octapharma USA Inc. Hoboken, NJ. November 2021.
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19. Centers for Medicare & Medicaid Services. Local Coverage Determination (LCD) for External Infusion Pumps (L33794) Original Effective Date 10/01/2015. Revision Effective Date 04/01/2023.
20. Centers for Medicare & Medicaid Services. External Infusion Pumps – Policy Article (A52507). Original Effective Date 10/01/2015. Revision Effective Date 04/01/2023.
21. Stiff-Person Syndrome: A Treatment Update and New Directions - PMC (nih.gov)

Member Product	Medical Management Requirements*
New York Products	
HMO	Prior Auth
PPO in Plan	Prior Auth
PPO OOP	Prior Auth
POS in Plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Child Health Plus	Prior Auth
MVP Harmonious Health Care Plan	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Medicare Gold Giveback	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Secure HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare WellSelect PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare WellSelect Plus PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Patriot Plan PPO	Refer to the MVP website for the Medicare Part B and Part D policies.

MVP DualAccess D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess Complete D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess Plus D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Select PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Secure PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	Prior Auth
Vermont Products	
POS in Plan	Prior Auth
POS OOP	Prior Auth
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D
MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Select PPO	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Secure PPO	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D
MVP VT HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	Prior Auth
♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).	

***Medical Management Requirements**

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

MVP Health Care Medical Policy

Medicare Part B: Immunoglobulin Therapy

Type of Policy:	**Medical Therapy**
Prior Approval Date:	**01/01/2024**
Approval Date:	**04/01/2024**
Effective Date:	**06/01/2024**

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

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

Drugs Requiring Prior Authorization under the medical benefit

Billing Code(s)	Medication
J1459	Injection, immune globulin (Privigen), intravenous, non-lyophilized (e.g. liquid), 500 mg
J1554	Injection, immune globulin (Asceniv), 500 mg
J1556	Injection, immune globulin (Bivigam), 500mg
J1555	Injection, immune globulin (Cuvitru)
J1557	Injection, immune globulin, (Gammaplex), intravenous, non-lyophilized (e.g. liquid), 500mg
J1561	Injection, immune globulin (Gamunex-C, Gammaked), intravenous, non-lyophilized (e.g. liquid), 500 mg
J1566	Injection, immune globulin, intravenous, lyophilized (e.g. powder), not otherwise specified, 500 mg (Only Carimune NF and Gammagard S/D should be billed using this code)
J1568	Injection, immune globulin, (Octagam), intravenous, non-lyophilized (e.g. liquid), 500 mg

J1569	Injection, immune globulin, (Gammagard), intravenous, non-lyophilized, (e.g. liquid), 500 mg
J1572	Injection, immune globulin, (Flebogamma/Flebogamma DIF), intravenous, non-lyophilized (e.g. liquid), 500 mg
J1559	Injection, immune globulin, (Hizentra), subcutaneous, 100 mg
J1575	Injection, immune globulin, (HyQvia), subcutaneous 100 mg
J1576	Injection, immune globulin,intravenuous, non-lyophilized (e.g. liquid), not otherwise specified, 500mg (Panzyga)
J1551	Immune globulin (SCIg) (Cutaquig), subcutaneous, 100mg
J1558	immune globulin (Xembify), subcutaneous, 100mg

(**Common Procedure Codes**
CPT Codes: 96365, 96366, 96367, 96368, 96374, 96375, 90284

Overview/Summary of Evidence

Intravenous Immunoglobin Therapy (IVIG)
The administration of Intravenous Immunoglobulin Therapy (IVIG) is used to provide antibodies in people who are susceptible to diseases for which there are no immunizations or who are immune deficient.

Immune Globulin Subcutaneous (Human)
The administration of Immune Globulin Subcutaneous (Human) is for the treatment of primary immune deficiency. Immune Globulin Subcutaneous (Human) supplies a broad spectrum of opsonizing and neutralizing IgG antibodies against a wide variety of bacterial agents.

This policy does not address other immunoglobulin preparations that at are used for pre or post exposure prophylaxis for specific infectious diseases, such as tetanus, rabies, hepatitis B, or cytomegalovirus.

Indications/Criteria

Intravenous Immunoglobulin

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- This policy is a supplement to Medicare National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs). Refer to the applicable NCD or LCD at www.cms.gov for the most up to date coverage guidance.
- IVIG and SCIG must be obtained from a preferred contracted IVIG vendor.

Medicare Coverage:

- Please refer to the current coverage guidelines at www.cms.gov.
- IVIG is covered under the Part B benefit in all treatment settings for Primary Immunodeficiency. Refer to LCD L33610 for Intravenous Immune Globulin and the accompanying Policy Article A52509 for coverage guidance.
    - Conditions not addressed in this policy will be reviewed on a case-by-case basis and must meet criteria for Experimental & Investigational therapies for coverage under Part B.
- Part B coverage of subcutaneous immune globulin administered in the home setting follows Medicare guidance under LCD 33794 for External Infusion Pumps. Please refer to LCD 33794 and the accompanying Policy Article A52507 for coverage guidance.
- Refer to the Medicare Part D formulary for drugs that may be covered under the Part D benefit.
- Medicare members are not required to receive IVIG in the home setting.

Initial Coverage

Initial coverage period will be for up to 3 months

Extension of Therapy

Continuation of therapy requests must be submitted along with documentation of all pertinent laboratory reports and objective evidence of improvement. Extensions of therapies will be for up to 6 months.

Exclusions

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

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MVP Health Care Medical Policy

Infertility Drug Therapy (Commercial/Marketplace)

Type of Policy: Drug Therapy
Prior Approval Date: 02/01/2023
Approval Date: 02/01/2024
Effective Date: 04/01/2024
Related Policies:

Infertility (Advanced Services) and In Vitro Fertilization (IVF)
Infertility Services (Basic)
Fertility Preservation Services
Infertility Drug Therapy (Medicaid/HARP)
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
- S0122/J3590 Menopur, Repronex (Injection, menotropins, 75 IU)
- S0126/J3490 Gonal-F (Injection, follitropin alfa, 75 IU)
- S0128/J3590 Follistim AQ (Injection, follitropin beta, 75 IU)
- S0132/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. **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). Follistim AQ is the preferred recombinant FSH. **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

- 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
- Doses exceeding those listed in the FDA-approved prescribing information
- Days' supply in excess of member's benefit
- Medication use in any cycle that exceeds the generally accepted standards of care per pregnancy
- 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.
- Exclusion for FSH-containing infertility drugs for serum FSH levels above 19 mIU/ml on day 3 of any menstrual cycle
- Quantities of injectable infertility drugs requiring prior authorization exceeding 4 cartridges/pens or 3600 Units/month whichever is greater
- Infertility treatments that have a low chance of success unless supporting documentation is submitted.

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***Medical Management Requirements**

Prior Auth	Prior Authorization Required
Potential for Retrospective Review	No Prior Authorization Required. May be subject to Retrospective Review.
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: **08/01/2023**
Approval Date: **12/01/2023**
Effective Date: **02/01/2024**

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 patient status.

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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**
- Documented significant clinical symptoms such as fatigue, spinal pain, arthralgia, inflammation of joints and tendons, and morning stiffness duration **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 Infliximab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

B. <u>Crohn's Disease</u>

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:

-
- Documented failure or inadequate response to a 12-week trial of adalimumab **OR** <18 years old* **OR** rationale and documentation is provided identifying why member or caregiver is unable to self-administer adalimumab.
- If step therapy is not appropriate, rationale for medical necessity of infliximab before other agents 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 Crohn's disease requests will be reviewed on a case-by-case basis.

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 failure during a 3-month period of a 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 a failure ailed 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 the 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 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 at least 12.5mg/week of methotrexate or maximum dose tolerable for the patient, 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:

- Documentation identifying 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 step 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 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**:

• Patient has been receiving therapy with an immune checkpoint inhibitor (e.g., nivolumab, pembrolizumab, atezolizumab, avelumab, durvalumab, cemiplimab, etc.); AND

• Patient has moderate (grade 2) to severe (grade 3-4) diarrhea or colitis related to their immunotherapy

Continuation of therapy will require documentation of:

May not be renewed

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

***Medical Management Requirements**

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

- Member has had an inadequate response or intolerance to pharmacologic treatment with methotrexate, cyclosporine, or acitretin

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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

MVP Health Care Medical Policy

Intestinal Antibiotics

Type of Policy:	**Drug Therapy**
Prior Approval Date:	**10/01/2022**
Approval Date:	**10/01/2023**
Effective Date:	**12/01/2023**
Related Policies:	**NA**

Drugs Requiring Prior Authorization

Aemcolo (rifamycin) 194mg tablets

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

Overview

Aemcolo is indicated for travelers' diarrhea caused by noninvasive strains of Escherichia coli. Untreated bacterial diarrhea lasts 3–5 days. Antibiotic selection is based on the likelihood that an invasive organism is present and on antibiotic resistance patterns. These factors are determined largely by travel destination. First-line antibiotics for treatment or as empiric therapy include those of the quinolone class, such as ciprofloxacin or levofloxacin. An alternative to quinolones in known resistance locations (e.g., Thailand) is azithromycin. Since it is often difficult for travelers to distinguish between invasive and noninvasive diarrhea, the overall usefulness of rifamycin as empiric self-treatment remains to be determined. At this time, prophylactic antibiotics should not be recommended for most travelers.

Indications/Criteria

1. Traveler's diarrhea

- Aemcolo may be covered for the treatment of traveler's diarrhea when all the following criteria are met:
    - Members ≥18 years old
    - Moderate to severe distressing symptoms of travelers' diarrhea are present and proven or strongly suspected to be caused by Escherichia coli based upon symptoms and travel destination. (When culture and susceptibility information are available, culture must identify E. coli and susceptible to rifamycin.); **AND**
    - Failure or intolerance to at least one quinolone such as ciprofloxacin or levofloxacin; **OR**
    - If contraindication or resistance to quinolones, then failure of azithromycin is required unless contraindicated.
    - Initial approval limited to 1 month, 12 tablets.

Exclusions

- For travelers' diarrhea:
    1. Dose/frequency exceeding the package label.
    2. Diarrhea complicated by fever or blood in the stool or diarrhea due to pathogens other than Escherichia coli.
    3. Excludes diarrhea associated with antibiotics
    4. Prophylactic use
    5. Travel purposes
    6. Aemcolo: more than 12 tablets per episode

Dosing and/or frequency exceeding the FDA approved package labeling

- Non-FDA approved use

References

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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
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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	
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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:	**10/01/2022**
Approval Date:	**10/01/2023**
Effective Date:	**12/01/2023**
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[1]:

- 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 patients 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 patients of the female sex with severe IBS-D. It should only be used in patients who have been experiencing diarrhea as their main symptom and have had inadequate response to other treatments. Alosetron should not be used in patients of the male sex as it is seen to be ineffective. It should not be initiated in patients with constipation, used in patients 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:

- Member must have a diagnosis of IBS, as defined by the Rome IV criteria, and sub-classified as diarrhea-predominant IBS (IBS-D) using the Bristol Stool Form Scale **AND**
- Use of conventional therapy is not appropriate or **one** conventional agent was ineffective **AND** Conventional therapy includes:
    - Antidiarrheal agents (Loperamide)
    - Antispasmodics (dicyclomine, hyoscyamine)
    - Tricyclic Antidepressants (amitriptyline, nortriptyline, or imipramine)
- Must be prescribed by or in consultation with a gastroenterologist

Additional coverage criteria for **Viberzi (**eluxadoline) are as follows:

- Must have failed or have a contraindication to a 14-day trial of Xifaxan

Additional coverage criteria for **alosetron** are as follows:

- Diagnosed with severe IBS (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**
- Patient must be of the female sex **AND**
- Member must have tried and failed a 14-day trial of Xifaxan **AND** Viberzi **OR**
- Use of **BOTH** Xifaxan and Viberzi is inappropriate (confirmed with documentation) OR
- Use of Xifaxan **OR** Viberzi is inappropriate (confirmed with documentation) **AND** the other has been tried and failed
- 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

- Dosing, age, and/or frequency outside of the FDA approved package labeling
- Any non-FDA approved indication
- None of the medications identified in this policy will be covered when used in combination with one another.
- Viberzi:
    - Member taking concurrent narcotic or opioid agents
- Alosetron:
    - Member taking concurrent fluvoxamine

References

1. Lacy BE. Diagnosis and treatment of diarrhea-predominant irritable bowel syndrome. Int J Gen Med. 2016; 9:7-17.
2. Xifaxan® (rifaximin) Tablets. Prescribing Information. Morrisville, NC: Salix Pharmaceuticals, Inc. November 2010.
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4. Weinberg DS, Smalley W, Heidelbaugh JJ, et al. American Gastroenterological Association Institute Guideline on the pharmacological management of irritable bowel syndrome. Gastroenterology. 2014;147(5):1146-8.
5. Pimental, M. Evidence- Based Management of Irritable Bowel Syndrome with Diarrhea. Am J Manag Care. Jan 25, 2018;24: -S0
6. 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.
7. Rome IV Criteria Section C1 Irritable Bowel Syndrome Diagnostic Criteria. Rome IV Criteria - Rome Foundation (theromefoundation.org). 2021. Accessed 8/8/2023.

Member Product	Medical Management Requirements*
New York Products	
HMO	Prior Auth
PPO in Plan	Prior Auth
PPO OOP	Prior Auth
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Essential Plan	Prior Auth
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ASO	See SPD
♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).	
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***Medical Management Requirements**

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

MVP Health Care Medical Policy

Izervay

Type of Policy:	**Drug Therapy**
Prior Approval Date:	**NA**
Approval Date:	04/01/2024
Effective Date:	04/01/2024
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 is met:

- Chart notes confirming a diagnosis of geographic atrophy secondary to age-related macular degeneration
- Prescribed and administered by an ophthalmologist
- Baseline best-corrected visual acuity (BCVA) is between 20/25 and 20/320
- Member is not currently utilizing any other intravitreal complement inhibitor therapies confirmed by claims history

Initial approval for 6 months

Extension requests for Izervay may be covered for an additional 6 months after initial approval for the following situations. Izervay may not be used for more than 12 months of total therapy (12 doses max per eye):

- 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)
- Member has not received greater than 12 total months of therapy
- 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 younger than 18 years of age
- Members with ocular or periocular infections
- Members with active intraocular inflammation
- Dosing, age, and/or frequency exceeding the FDA approved package labeling.

- Member has already received 12 months of therapy. Izervay may not be used for more than 12 months of total therapy (12 doses max per eye)
- GA secondary to a condition other than AMD such as Stargardt disease in either eye
- Member is currently utilizing another intravitreal compliment inhibitor

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References

1. Avacincaptad Pegol. In: Specific Lexicomp Online Database [database on the Internet]. Hudson (OH): Lexicomp Inc.: publication year [updated 9 Feb. 2024; cited 14 Feb. 2024]. Available from: http://online.lexi.com. Subscription required to view.
2. Izervay (avacincaptad pegol intravitreal solution) NDA 217225. FDA. Revised 8/2023. label (fda.gov)
3. Gaffe GJ, Westby K, Csaky KG, et al. C5 Inhibitor avacincaptad pegol for geographic atrophy due to age related macular degeneration: a randomized pivotal phase 2/3 trial. Ophthalmology. 2021; 128: 576-586.

Member Product	Medical Management Requirements*
New York Products	Prior Authorization
HMO	Prior Authorization
PPO in Plan	Prior Authorization
PPO OOP	Prior Authorization
POS in Plan	Prior Authorization
POS OOP	Prior Authorization
Essential Plan	Prior Authorization
MVP Medicaid Managed Care	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Child Health Plus	Prior Authorization
MVP Harmonious Health Care Plan	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Medicare Gold Giveback	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Secure HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.

MVP Medicare WellSelect PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
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MVP Premier	Prior Authorization
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POS in Plan	Prior Authorization
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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).**

***Medical Management Requirements**

Prior Auth	Prior Authorization Required
Potential for Retrospective Review	No Prior Authorization Required. May be subject to Retrospective Review.
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:	**N/A**
Approval Date:	**04/01/2024**
Effective Date:	**04/01/2024**
Related Policies:	Syfovre

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

Drugs Requiring Prior Authorization under the medical benefit

J2782 Izervay (Avacincaptad Pegol) Solution for Intravitreal Injection

Overview/Summary of Evidence

Izervay (Avacincaptad Pegol) solution for intravitreal injection is a complement C5 inhibitor which is FDA approved for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD).

Indications/Criteria

Geographic atrophy (GA) secondary to age-related macular degeneration (AMD)

Izervay may be considered for coverage for Geographic atrophy (GA) secondary to age-related macular degeneration (AMD) when all of following criteria is met:

- Chart notes confirming a diagnosis of geographic atrophy secondary to age-related macular degeneration
- Prescribed and administered by an ophthalmologist

- 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 an additional 6 months after initial approval for the following situations. Izervay may not be used for more than 12 months of total therapy (12 doses max per eye):

- 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)
- Member has not received greater than 12 total months of therapy
- Extension requests where Izervay did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing

---

Exclusions

Geographic atrophy (GA) secondary to age-related macular degeneration (AMD)

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

- Members with ocular or periocular infections
- Members with active intraocular inflammation
- Dosing, age, and/or frequency exceeding the FDA approved package labeling.
- Member has already received 12 months of therapy. Izervay may not be used for more than 12 months of total therapy (12 doses max per eye)
- GA secondary to a condition other than AMD such as Stargardt disease in either eye
- Member is currently utilizing another intravitreal complement inhibitor

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References

1. Avacincaptad Pegol. In: Specific Lexicomp Online Database [database on the Internet]. Hudson (OH): Lexicomp Inc.: publication year [updated 9 Feb. 2024; cited 14 Feb. 2024]. Available from: http://online.lexi.com. Subscription required to view.
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3. Gaffe GJ, Westby K, Csaky KG, et al. C5 Inhibitor avacincaptad pegol for geographic atrophy due to age related macular degeneration: a randomized pivotal phase 2/3 trial. Ophthalmology. 2021; 128: 576-586.
4. Izervay (avacincaptad pegol intravitreal solution). Prescribing Information. Iveric Bio, Inc. Parsippany, NJ. Revised 8/2023.

MVP Health Care Medical Policy

Jynarque

Type of Policy:	**Drug Therapy**
Prior Approval Date:	**02/01/2023**
Approval Date:	**02/01/2024**
Effective Date:	**04/01/2024**
Related Policies:	**Genetic and Molecular Diagnostic Testing**

Drugs Requiring Prior Authorization (covered under the pharmacy benefit)

Jynarque (tolvaptan oral tablets)

Overview

Tolvaptan is an oral selective vasopressin V2-receptor antagonist. Jynarque is FDA approved to slow kidney function decline in patients with rapidly progressing autosomal dominant polycystic kidney disease (ADPKD). For ADPKD, Jynarque requires routine liver function monitoring and is available through the Jynarque REMs program.

Indications/Criteria

Patient must meet all the following criteria for initiating therapy:

- Prescribed by or in consult with a nephrologist
- Diagnosis of autosomal dominant polycystic kidney disease (ADPKD) confirmed by ultrasound OR genetic testing if imaging is not available or adequate.
- Total kidney volume (TKV) classification of 1C or higher by Mayo Clinical Imaging Classification Criteria
- Documentation of eGFR between 25 and 65ml/min/1.73m^2 .
- Chart notes identifying symptoms of ADPKD (such as hypertension and flank pain)

- Documentation of the following labs:
  - Blood sodium concentration
  - ALT
  - AST
  - Bilirubin

Initial approval will be for a duration of 3 months.

Subsequent extensions for 6 months will be granted if the following are met**:**

- Documentation of continued monitoring of AST, ALT and bilirubin monthly for the first 18 months and every 3 months thereafter.
- Documentation of stability of eGFR level above 25 mL/min/1.73 m2
- Documentation that patient has not initiated dialysis

Exclusions

- Age, dose, frequency, outside of the FDA package label.
- Previous history, signs or symptoms of significant liver impairment or injury (not including uncomplicated polycystic liver disease).
- Combination use with strong CYP3A inhibitors
- Inability to sense or respond to thirst
- Uncorrected abnormal blood sodium concentrations, hypovolemia
- Urinary outflow obstruction
- Anuria
- Patients 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
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3. Belibi FA, Edelstein CL. Unified ultrasonographic diagnostic criteria for polycystic kidney disease. J Am Soc Nephrol. 2009;20(1):6-8

Member Product	Medical Management Requirements*
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PPO OOP	Prior Authorization

POS in Plan	Prior Authorization
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Healthy NY	Prior Authorization
MVP Premier	Prior Authorization
MVP Premier Plus	Prior Authorization
MVP Premier Plus HDHP	Prior Authorization
MVP Secure	Prior Authorization
MVP EPO	Prior Authorization
MVP EPO HDHP	Prior Authorization
MVP PPO	Prior Authorization
MVP PPO HDHP	Prior Authorization
Student Health Plans	Prior Authorization
ASO	Prior Authorization
Vermont Products	
POS in Plan	Prior Authorization
POS OOP	Prior Authorization
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D
MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Select PPO	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Secure PPO	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D
MVP VT HMO	Prior Authorization
MVP VT Plus HMO	Prior Authorization
MVP VT HDHP HMO	Prior Authorization
MVP VT Plus HDHP HMO	Prior Authorization
MVP Secure	Prior Authorization
ASO	Prior Authorization
♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).	

***Medical Management Requirements**

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

MVP Health Care Medical Policy

Lenmeldy

Type of Policy:	Medical Therapy (administered by the pharmacy department)
Prior Approval Date:	NA
Approval Date:	06/01/2024
Effective Date:	06/01/2024
Related Policies:	Orphan Drug(s) and Biologicals

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

Drugs Requiring Prior Authorization under the medical benefit

J3490 Lenmeldy (Atidarsagene Autotemcel)

Overview

Lenmeldy is an autologous hematopoietic stem cell-based gene therapy indicated for the treatment of children with pre-symptomatic late infantile (PSLI), pre-symptomatic early juvenile (PSEJ) or early symptomatic early juvenile (ESEJ) metachromatic leukodystrophy (MLD). MLD is a rare, autosomal recessive, life-limiting lysosomal storage disease. It is caused by mutations in the arylsulfatase A (ARSA) gene or sphingolipid activator protein B (SAPB) gene which leads to accumulation of sulfatides throughout the body. Sulfatides accumulation is toxic to the nervous system and leads to gait abnormalities, speech regression, functional loss, cognitive loss, and seizures. Atidarsagene autotemcel is intended for one time administration to add functional copies of the ARSA gene into the patient's own hematopoietic stem cells (HSCs).

Indications/Criteria

Metachromatic Leukodystrophy

Lenmeldy may be considered for coverage when:

- Member has a confirmed diagnosis of pre-symptomatic late infantile (PSLI) or pre-symptomatic early juvenile (PSEJ) or early symptomatic early juvenile (ESEJ) metachromatic leukodystrophy (MLD). Diagnosis is confirmed by:
    - Genetic confirmation of mutation in ARSA gene
    - Biochemical testing
        - Sulfatase enzyme activity
        - Urinary sulfatide excretion
    - Brain MRI
        - An MRI can show the presence and absence of myelin. Brain injury accumulates as the disease progresses. An initial MRI in pediatric members can appear normal. Pediatric cases with an initial normal MRI will be reviewed on a case-by-case basis.
- Prescribed by or in consultation with Neurologist or Geneticist
- Chart notes documenting that the member does not have liver or renal impairment which is documented with current renal and liver function tests
- Documentation that the member will not receive live vaccines 6 weeks prior to myeloablative conditioning for Lenmeldy and until hematological recovery following treatment with Lenmeldy
- For female members, a negative serum pregnancy test must be confirmed
- Provider confirmation that member will not use prophylactic HIV anti-retroviral medications at least one month prior to mobilization or for the expected direction of time needed for the elimination of the medications.
    - Note: Anti-retroviral medications may interfere with the manufacturing of Lenmeldy
    - Note: if a child requires anti-retrovirals for HIV prophylaxis, initiation of Lenmeldy treatment should be delayed until confirmation of a negative test for HIV.
- Treatment centers administering Lenmeldy must be appropriately certified to do so. Please see link for treatment centers: LENMELDY(TM) (atidarsagene autotemcel) – Now Available
- Provider confirmation that the manufacturer requirement for a collection of unmanipulated back-up $CD34^+$ cells of at least 2.0×10^6 $CD34^+$ 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).	

***Medical Management Requirements**

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

MVP Health Care Medical Policy

Medicare Part B: Lenmeldy

Type of Policy:	Medical Therapy (administered by the pharmacy department)
Prior Approval Date:	NA
Approval Date:	06/01/2024
Effective Date:	06/01/2024
Related Policies:	Medicare Part B: Orphan Drug(s) and Biologicals

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

Drugs Requiring Prior Authorization under the medical benefit

J3490 Lenmeldy (Atidarsagene Autotemcel)

Overview

Lenmeldy is an autologous hematopoietic stem cell-based gene therapy indicated for the treatment of children with pre-symptomatic late infantile (PSLI), pre-symptomatic early juvenile (PSEJ) or early symptomatic early juvenile (ESEJ) metachromatic leukodystrophy (MLD). MLD is a rare, autosomal recessive, life-limiting lysosomal storage disease. It is caused by mutations in the arylsulfatase A (ARSA) gene or sphingolipid activator protein B (SAPB) gene which leads to accumulation of sulfatides throughout the body. Sulfatides accumulation is toxic to the nervous system and leads to gait abnormalities, speech regression, functional loss, cognitive loss, and seizures. Atidarsagene autotemcel is intended for one time administration to add functional copies of the ARSA gene into the patient's own hematopoietic stem cells (HSCs).

Indications/Criteria

Metachromatic Leukodystrophy

Lenmeldy may be considered for coverage when:

- Member has a confirmed diagnosis of pre-symptomatic late infantile (PSLI) or pre-symptomatic early juvenile (PSEJ) or early symptomatic early juvenile (ESEJ) metachromatic leukodystrophy (MLD). Diagnosis is confirmed by:
    - Genetic confirmation of mutation in ARSA gene
    - Biochemical testing
        - Sulfatase enzyme activity
        - Urinary sulfatide excretion
    - Brain MRI
        - An MRI can show the presence and absence of myelin. Brain injury accumulates as the disease progresses. An initial MRI in pediatric members can appear normal. Pediatric cases with an initial normal MRI will be reviewed on a case-by-case basis.
- Prescribed by or in consultation with Neurologist or Geneticist
- Chart notes documenting that the member does not have liver or renal impairment which is documented with current renal and liver function tests
- Documentation that the member will not receive live vaccines 6 weeks prior to myeloablative conditioning for Lenmeldy and until hematological recovery following treatment with Lenmeldy
- For female members, a negative serum pregnancy test must be confirmed
- Provider confirmation that member will not use prophylactic HIV anti-retroviral medications at least one month prior to mobilization or for the expected direction of time needed for the elimination of the medications.
    - Note: Anti-retroviral medications may interfere with the manufacturing of Lenmeldy
    - Note: if a child requires anti-retrovirals for HIV prophylaxis, initiation of Lenmeldy treatment should be delayed until confirmation of a negative test for HIV.
- Treatment centers administering Lenmeldy must be appropriately certified to do so. Please see link for treatment centers: LENMELDY(TM) (atidarsagene autotemcel) – Now Available
- Provider confirmation that the manufacturer requirement for a collection of unmanipulated back-up $CD34^+$ cells of at least 2.0×10^6 $CD34^+$ 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:	**04/01/2023**
Approval Date:	**04/01/2024**
Effective Date:	**06/01/2024**
Related Policies:	**N/A**

Drug Requiring Prior Authorization (covered under the medical benefit)

J3398 Luxturna (voretigene neparvovec-rzyl) intraocular suspension

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

Overview

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
- Patient is at least 12 months of age but not greater than 64 years of age
- Patient 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
- Patient 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 patient 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://mysparkgeneration.com/hcp-support.html#TreatmentCenters

If approved, coverage will be provided for a maximum of 1 injection per eye per lifetime. Coverage of lost, damaged, or mishandled product will not be covered. Coverage is contingent on eligibility at the time of administration.

Exclusions

- Dose and/or frequency exceeding the package label
- Patient is pregnant
- Patient 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 patient must have a retinal dystrophy due to confirmed mutations (on genetic testing) in both copies of the RPE65 gene
- The patient must have viable retinal cells as determined by the treating physician(s)
- The patient must be 12 months of age or olderTreatment 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 patient 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://mysparkgeneration.com/hcp-support.html#TreatmentCenters

References

1. Luxturna (voretigene neparvovec-ryzel) prescribing information. Philadelphia, PA: Spark Therapeutics, Inc. 2017. Revised 05/2022.

2. A Safety and Efficacy Study in Subjects with Leber Congenital Amaurosis (LCA) Using Adeno-Associated Viral Vector to Deliver the Gene for Human RPE65 to the Retinal Pigment Epithelium (RPE) [AAV2-hRPE65v2-301]. Available online at: https://www.clinicaltrials.gov/ct2/show/NCT00999609?term=voretigene+neparvovec-rzyl&rank=1

3. New York State Medicaid Update. March 2018; Vol 34: Number 3. Available at: New York Medicaid Update, Volume 34 Number 3, March 2018 (ny.gov)

4. Russel S, Bennet J, Wellman JA, et al. Efficacy and safety of voretigene neparvovec (AAV2-hRPE65v2) in patients with RPE65-mediated inherited retinal dystrophy: a randomized, controlled, open-label phase 3 trial. Lancet 2017; 390:849-860.

Member Product	Medical Management Requirements*
New York Products	
HMO	Prior Auth
PPO in Plan	Prior Auth
PPO OOP	Prior Auth
POS in Plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Child Health Plus	Prior Auth
MVP Harmonious Health Care Plan	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Medicare Gold Giveback	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Secure HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare WellSelect PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare WellSelect Plus PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Patriot Plan PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.

MVP DualAccess Complete D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess Plus D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Select PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Secure PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	
POS in Plan	Prior Auth
POS OOP	Prior Auth
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D
MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Select PPO	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Secure PPO	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D
MVP VT HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD
♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).	

***Medical Management Requirements**

Prior Auth	Prior Authorization Required
Potential for Retrospective Review	No Prior Authorization Required. May be subject to Retrospective Review.
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:	**11/01/2023**
Approval Date:	**04/01/2024**
Effective Date:	**06/01/2024**
Related Policies:	**N/A**

Drug Requiring Prior Authorization (covered under the medical benefit)

J3398 Luxturna (voretigene neparvovec-rzyl) intraocular suspension

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

Overview/Summary of Evidence

Luxturna is an adeno-associated virus vector-based gene therapy indicated as an orphan drug for the treatment of patients with confirmed biallelic *RPE65* mutation-associated retinal dystrophy. Treatment with Luxturna includes one dose per eye per lifetime.

Indications/Criteria

Luxturna will be considered for coverage when ALL the following are met:

- Prescribed and administered by an ophthalmologist or retinal surgeon with experience providing sub-retinal injections
- Patient is at least 12 months of age but not greater than 64 years of age
- Patient 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
- Patient 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 patient 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://mysparkgeneration.com/hcp-support.html#TreatmentCenters

If approved, coverage will be provided for a maximum of 1 injection per eye per lifetime. Coverage of lost, damaged, or mishandled product will not be covered. Coverage is contingent on eligibility at the time of administration.

Exclusions

- Dose and/or frequency exceeding the package label
- Patient is pregnant
- Patient has previous administration of gene therapy vector
- Use of retinoid compounds or precursors that could potentially interact with the biochemical activity of the *RPE65* enzyme (individuals must discontinue use of these compounds for 18 months prior to Luxturna administration)
- Prior intraocular surgery within 6 months

References

1. Luxturna (voretigene neparvovec-ryzel) prescribing information. Philadelphia, PA: Spark Therapeutics, Inc. 2017. Revised 05/2022.

2. A Safety and Efficacy Study in Subjects with Leber Congenital Amaurosis (LCA) Using Adeno-Associated Viral Vector to Deliver the Gene for Human RPE65 to the Retinal Pigment Epithelium (RPE) [AAV2-hRPE65v2-301]. Available online at: https://www.clinicaltrials.gov/ct2/show/NCT00999609?term=voretigene+neparvovec-rzyl&rank=1

3. 3. Russel S, Bennet J, Wellman JA, et al. Efficacy and safety of voretigene neparvovec (AAV2-hRPE65v2) in patients with RPE65-mediated inherited retinal dystrophy: a randomized, controlled, open-label phase 3 trial. Lancet 2017; 390:849-860.

MVP Health Care Medical Policy

Lyfgenia (Lovotibeglogene Autotemcel)

Type of Policy:	Drug Therapy (administered by the pharmacy department)
Prior Approval Date:	NA
Approval Date:	06/01/2024
Effective Date:	06/01/2024
Related Policies:	Casgevy, Adakveo

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

Drugs Requiring Prior Authorization under the medical benefit

J3590 Lyfgenia (Lovotibeglogene Autotemcel)

Overview

Lyfgenia (Lovotibeglogene Autotemcel)as is an intravenous, one-time autologous genome edited hematopoietic stem cell-based gene therapy for patients with sickle cell disease suffering from vaso-occlusive crisis. A vaso occlusive crisis is a potentially life-threatening complication caused when sickled red blood cells hinder blood flow causing pain, and lack of oxygen delivery to tissue. Lyfgenia is manufactured specifically for an individual using their own blood stem cells. The treatment course consists of multiple phases including cell mobilization and apheresis to collect CD34+ cells for manufacturing, myeloablative conditioning, and finally the modified cells are returned to

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)

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

Member Product	Medical Management Requirements*
New York Products	
HMO	Prior Auth

PPO in Plan	Prior Auth
PPO OOP	Prior Auth
POS in Plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Child Health Plus	Prior Auth
MVP Harmonious Health Care Plan	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Medicare Gold Giveback	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Secure HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
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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
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MVP VT HDHP HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD

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

***Medical Management Requirements**

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

MVP Health Care Medical Policy

Medicare Part B: Lyfgenia (Lovotibeglogene Autotemcel)

Type of Policy:	Drug Therapy (administered by the pharmacy department)
Prior Approval Date:	NA
Approval Date:	06/01/2024
Effective Date:	06/01/2024
Related Policies:	Casgevy, Adakveo

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

Drugs Requiring Prior Authorization under the medical benefit

J3590 Lyfgenia (Lovotibeglogene Autotemcel)

Overview

Lyfgenia (Lovotibeglogene Autotemcel)as is an intravenous, one-time autologous genome edited hematopoietic stem cell-based gene therapy for patients with sickle cell disease suffering from vaso-occlusive crisis. A vaso occlusive crisis is a potentially life-threatening complication caused when sickled red blood cells hinder blood flow causing pain, and lack of oxygen delivery to tissue. Lyfgenia is manufactured specifically for an individual using their own blood stem cells. The treatment course consists of multiple phases including cell mobilization and apheresis to collect CD34+ cells for manufacturing, myeloablative conditioning, and finally the modified cells are returned to

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)

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
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- Member is pregnant or planning to become pregnant
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Member Product	Medical Management Requirements*
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Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	
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MVP Secure	Prior Auth
ASO	See SPD

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

***Medical Management Requirements**

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

MVP Health Care Medical Policy

Lyme Disease/IV Antibiotic Treatment

Type of Policy: **Medical Therapy**
Prior Approval Date: **03/01/2023**
Approval Date: **12/01/2023**
Effective Date: **02/01/2024**
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 patients 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 patient 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:

1. 18 kDa
2. 21 kDa (OspC)*
3. 28 kDa
4. 30 kDa
5. 39 kDa (BmpA)
6. 41 kDa (Fla)

7. 45 kDa
8. 58 kDa (not GroEL)
9. 66 kDa
10. 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:

1. 24 kDa (OspC)*
2. 39 kDa (BmpA)
3. 41 kDa (Fla)

C. 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 with clinical and laboratory evidence (e.g. lymphocytic cerebrospinal fluid pleocytosis, CSF elevation) or radiculopathy[5]
2. Carditis (early Lyme disease): Atrioventricular (AV) heart block and/or myopericarditis associated with early Lyme disease.
3. Lyme arthritis with persistent joint swelling after a course of oral antibiotic therapy, and if PCR results of a synovial fluid is negative for B. burgdorferi nucleic acids, should be treated symptomatically, reserving IV antibiotics for patients who have failed to improve, or their symptoms have worsened.
4. 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.

D. Contraindication or intolerance to all appropriate first-line oral antibiotic therapy at recommended maximum dosages, except for meningitis, radiculopathy, late stage central or peripheral nervous system disease. Refer to the IDSA guidelines Table 2 and Table 3 at http://cid.oxfordjournals.org/content/43/9/1089.full.);

E. Chart notes from appropriate specialists (e.g. rheumatologist, cardiologist, neurologist), in the absence of neurologic or cardiac manifestations, that have ruled out underlying conditions that may have the similar symptoms as Lyme disease.

F. Treatment with IV antibiotics is supported by medical guidelines or peer reviewed literature and meets MVP Clinical Coverage Criteria for medical necessity.

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

Exclusions

- Additional or prolonged courses of antibiotic therapy have not been demonstrated to benefit individuals and may expose them to significant risk from adverse effects of the medications.
- Intravenous antibiotic therapy in excess of 28 days.
- The following medications are not recommended for treatment of patients with any manifestation of Lyme disease[5]:
    - first-generation cephalosporins
    - fluoroquinolones
    - carbapenems
    - vancomycin
    - metronidazole
    - tinidazole
    - amantadine
    - ketolides
    - isoniazid
    - trimethoprim/sulfamethoxazole
    - fluconazole
    - benzathine penicillin G
    - antimicrobial combinations
    - pulse-doses antibiotics
    - IVIG
- Patients 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)[6,7].
- Chronic subjective symptoms (i.e. greater than 6 months) after treatment regimen completed. (Symptomatic therapy is recommended)[6,7].
- Prophylaxis of Lyme disease in the absence of clinical symptoms.
- Treatment with IV antibiotics for non-specific symptoms (fatigue, headache, etc.)

References

1. HAYES Directory: Long-term antibiotic therapy for chronic lyme disease, December 2010. Available: www.hayesinc.com.
2. Wormser, Gary, P. MD, Early Lyme Disease, N Engl J Med 2006: 354:2794-801.
3. Centers for Disease Control and Prevention (CDC). Recommendations for test performance and interpretation from the Second National Conference on serologic diagnosis of lyme disease. MMWR Morb Mortal Wkly Report. 1995 Aug 11;44(31):590-1.
4. 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.
5. Wormser GP, Dattwyler RJ, Shapiro ED, et. al. The clinical assessment, treatment, and prevention of lyme disease, human granulocytic anaplasmosis, and babesiosis: clinical practice guidelines by the Infectious Diseases Society of America. Clin Infect Dis 2006 Nov1;43(9):1089-134.
6. HAYES Directory: Intravenous Antibiotic Treatment for Late-Stage Lyme Disease, December 2010. Available: www.hayesinc.com
7. 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.
8. Centers for Disease Control and Prevention (CDC). Lyme disease, diagnosis and treatment, laboratory testing, understanding the immunoblot test. Available: www.cdc.gov
9. 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). http://www.neurology.org/content/69/1/91.short

10. 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
11. Wormser et al. (2006; 43:1089-134). Clinical Infectious Diseases, Volume 45, Issue 7, 1 October 2007, Page 941, https://doi.org/10.1086/521856
12. 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.
13. Treatment of Lyme Disease. Centers for Disease Control and Prevention (CDC). Updated March 1, 2022. Available at: Treatment of Lyme Disease | Lyme Disease | CDC.
14.

Member Product	Medical Management Requirements*
New York Products	
HMO	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
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© 2024 MVP Health Plan, Inc. All rights reserved. Descriptions contained within MVP's Medical Policies are not a guarantee of coverage. Each MVP Group or Subscriber Contract contains specific limitations, exclusions and requirements that may affect a Policy. If there is any discrepancy between your Group or Subscriber Contract and a Policy, your Group or Subscriber Contract shall in all cases govern.	

***Medical Management Requirements**

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

MVP Health Care Medical Policy

Mail Order

Type of Policy:	**Drug Therapy**
Prior Approval Date:	**04/01/2023**
Approval Date:	**02/01/2024**
Effective Date:	**04/01/2024**

Related Policies: **N/A**

Drugs Requiring Prior Authorization

See formulary (drug list)
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:

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:	**03/01/2023**
Approval Date:	**02/01/2024**
Effective Date:	**04/01/2024**

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

Medicare Variation

- Testopel pellets will require prior authorization for quantities greater than 10 pellets
- Aveed will not require failure of Testim and Androgel

Medicaid Variation

- Testopel pellets and Aveed require a trial of self-administered testosterone products and member must meet the diagnostic criteria in the policy below.
- Use in sexual dysfunction and/or erectile dysfunction is excluded from coverage.
- Medications that are a pharmacy benefit are covered and billed to New York State Fee-For-Service (FFS) program. They are defined as medications that go through a retail or specialty pharmacy, including self-administered injectable products. Pharmacy medications are subject to FFS's clinical criteria including (but not limited to) coverage, quantity limit, step therapy, and prior authorization. Pharmacy benefit information can be found here: https://www.emedny.org/info/fullform.pdf

Codes Requiring Prior Authorization (covered under the medical benefit). (See Medicaid and Medicare Variation)

J3145 Aveed (Testosterone undecanoate 750mg/3ml)

Codes Requiring Prior Authorization (covered under the medical benefit) when quantity limits are exceeded. (See Medicaid and Medicare Variation)

J3490 Testopel (Testosterone pellet, 75 mg)

S0189 Testopel (Testosterone pellet, 75 mg non-Medicare)

Drugs Requiring Prior Authorization (covered under the pharmacy benefit)-all products when the quantities below are exceeded. Non-preferred products require prior authorization regardless of quantity. (See Medicaid variation)

Brand Name	**Chemical Name**	**Quantity Limit every 30 days (applies to both brand name and to generic products)**	**Prior Authorization Required (regardless of quantity)**
Androderm Patches *2mg/24 HR* *4mg/24 HR*	testosterone	30 patches	Yes
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

**QL applies when adjudicated through the pharmacy benefit manager*

^Modified testosterone 17a-methyltestosterone, is not recommended as a therapy for treatment of hypogonadism per the Endocrine Society Guidelines due to its hepatoxic side effects[2]

Anabolic Steroids:

Drug Name	chemical name	Quantity per 30 days[#] without PA	Prior authorization required regardless of quantity
Anadrol	oxymetholone	30 tablets	Yes
Oxandrin	oxandrolone	60 tablets	Yes (brand name only)

[#] 90 days supplies are available if the benefit allows.

Overview

Endogenous androgens such as testosterone, are responsible for the normal growth and development of the male sex organs and for maintenance of secondary sex characteristics. Male hypogonadism results from insufficient secretion of testosterone and is characterized by low serum testosterone concentrations (normal range of serum total testosterone is 300-1000 ng/dL). Signs and symptoms associated with male hypogonadism include erectile dysfunction and decreased sexual desire, fatigue and loss of energy, mood depression, regression of secondary sexual characteristics and osteoporosis[7]. Individuals with HIV and on high dose glucocorticoids may experience hypogonadism and may benefit from testosterone therapy. Anabolic steroids are synthetic derivatives of testosterone.

Indications/Criteria

The following criteria must be met for coverage:

- Male; **AND**
- Early morning serum testosterone level below the lower limit of normal range for healthy young men established in the laboratory (200 to 400 ng/dL) prior to start of therapy. The target of therapy should be the mid-normal range of serum total testosterone; **AND**
- Confirmation of early morning serum total testosterone level on a separate occasion OR if the patient is suspected to have alterations in sex hormone-binding globulin (SHBG) measurement below the lower limit of normal established in the laboratory of early morning free testosterone (=50 pg/mL measured by equilibrium dialysis or =65 pg/mL for calculated)[17] or bioavailable testosterone using an accurate and reliable assay. Conditions associated with alterations in SHBG concentration include moderate obesity, nephritic syndrome, hypothyroidism, acromegaly, diabetes mellitus, aging, hepatic cirrhosis and hepatitis, hyperthyroidism, HIV disease, polymorphisms in the SHBG gene, or use of glucocorticoids, progestins, and androgenic steroids, anticonvulsants, and estrogens; **AND**
- Consistent (daily) signs and symptoms of testosterone deficiency**.** Specific symptoms must be provided with each request. (i.e. incomplete or delayed sexual development, eunuchoidism, loss of body (axillary and pubic) hair significant muscle loss or fatigue interfering with activities of daily living, breast discomfort, gynecomastia, very small testes (especially 6mL), low trauma fracture, low bone mineral density); **AND**
- Documentation of:
    - Baseline hematocrit below 48%. For reauthorization of coverage repeat annually.
    - Baseline PSA level prior to initiation of testosterone therapy in men 40 years of age or older. For reauthorization of coverage repeat PSA level at 3-12 months, and then in accordance with prostate cancer screening guidelines; **AND**
- Prior Authorization is required for all non-preferred agents (tier 3) products and documented trial and failure or contraindication to Androgel and Testim is required.
- All agents require prior authorization for quantities exceeding the quantity limit for 30 days stated above.

Initial approval for 6 months. Extension of therapy up to 12 months will be provided if documentation identifies continued benefit including improvement in symptoms and an increase in serum testosterone levels to within normal limits (if used for testosterone deficiency).

Exclusions

- Diagnosis not indicated in FDA approved package labeling or age over 65 years.
- 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

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References

1. AACE Hypogonadism Task Force. American Association of Clinical Endocrinologists medical guidelines for clinical practice for the evaluation and treatment of hypogonadism in adult male patients. Endocrine Practice Vol 8 No. 6 November/December 2002.
2. Bhasin S, Cunningham GR, Hayes FJ, et al. Testosterone therapy in adult men with androgen deficiency syndromes: an endocrine society clinical practice guideline. J Clin Endocrinol Metab. 2010 Jun;95(6):2536-59.
3. Bhasin S, Brito JP, Cunningham GR, et al. Testosterone therapy in men with hypogonadism: An endocrine society clinical practice guideline. J Clin Endocrinol Metab. 2018 May;103(5):1715-1744.

4. Oxandrolone Tablets. Prescribing information. Princeton, NJ: Sandoz, Inc., December 2006.
5. Anadrol® -50 (oxymetholone) 50mg Tablets. Prescribing Information. Marietta, GA: Unimed/Solvay Pharmaceuticals, August 2004.
6. Androgel® (testosterone gel) package insert. North Chicago, IL: AbbVie Inc.; 2019 May.
7. Androgel 1.62% (testosterone gel) package insert. North Chicago, IL: AbbVie Inc.: 2020 Nov.
8. Androderm (testosterone transdermal system) package insert. Madison, NJ: Allergan USA, Inc.; 2020 May.
9. Android (methytestosterone) package insert. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; 2015 Apr.
10. Axiron (testosterone) topical solution, package insert. Indianapolis, IN: Lilly USA, LLC: 2017 Feb.
11. Delatesteryl (testosterone cypionate), Chadds Ford, PA: Endo Pharmaceuticals, Inc.; 2010 Dec.
12. DEPO-TESTOSTERONE (testosterone cypionate) injection, package insert. New York, NY: Pharmacia & Upjohn Co.; 2018 Aug.
13. Fortesta (testosterone) gel, package insert, Malvern, PA: Endo Pharmaceuticals Inc.; 2017 Jul.
14. Striant (testosterone buccal system) package insert. Chesterbrook, PA; Actient Pharmaceuticals LLC; 2015 May.
15. Testim (testosterone gel) package insert. St-Laurent, Quebec; Paladin Labs, Inc. ; 2017 Feb.
16. Testopel (testosterone pellets) package insert. Malvern, PA: Endo Pharmaceuticals Inc.; 2018 Aug.
17. 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.
18. Natesto (testosterone nasal gel) package insert. Bavaria, Germany; Haupt Pharma Amareg GmbH; 2016 Oct.
19. Bhasin S, Brito JP, Cunningham GR, et al. Testosterone therapy in men with hypogonadism: an endocrine society clinical practice guideline. J Clin Endocrinol Metab. 2018 May;103(5):1715-1744.
20. Xyosted (testosterone enanthate) package insert. Ewing, NJ. Antares Pharma, Inc. 2019 November.
21. Vogelxo (testosterone) package insert. Maple Grove, MN. Upsher-Smith Laboratories, LLC.; 2019 May.
22. Androxy (fluoxymesterone) package insert. Maple Grove, MN. Upsher-Smith Laboratories, LLC.; 2017 Sep.
23. Aveed (testosterone undecanoate) package insert. Malvern, PA. Endo Pharmaceuticals Inc.; 2020 Jun.

24. Methyltestosterone Capsules package insert. Bridgewater, NJ. Amneal Pharmaceuticals LLC; 2019 May.
25. Jatenzo package insert. Northbrook, IL. Clarus Therapeutics, Inc.; 2019 Mar.

Member Product	Medical Management Requirements*
New York Products	
HMO	Prior Authorization
PPO in Plan	Prior Authorization
PPO OOP	Prior Authorization
POS in Plan	Prior Authorization
POS OOP	Prior Authorization
Essential Plan	Prior Authorization
MVP Medicaid Managed Care	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Child Health Plus	Prior Authorization
MVP Harmonious Health Care Plan	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Medicare Gold Giveback	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Secure HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare WellSelect PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare WellSelect Plus PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Patriot Plan PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess Complete D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess Plus D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Select PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Secure PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
Healthy NY	Prior Authorization
MVP Premier	Prior Authorization
MVP Premier Plus	Prior Authorization
MVP Premier Plus HDHP	Prior Authorization
MVP Secure	Prior Authorization
MVP EPO	Prior Authorization
MVP EPO HDHP	Prior Authorization
MVP PPO	Prior Authorization
MVP PPO HDHP	Prior Authorization
Student Health Plans	Prior Authorization
ASO	Prior Authorization
Vermont Products	
POS in Plan	Prior Authorization
POS OOP	Prior Authorization
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D
MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part D

UVM Health Advantage Select PPO	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Secure PPO	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D
MVP VT HMO	Prior Authorization
MVP VT Plus HMO	Prior Authorization
MVP VT HDHP HMO	Prior Authorization
MVP VT Plus HDHP HMO	Prior Authorization
MVP Secure	Prior Authorization
ASO	Prior Authorization
♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).	

***Medical Management Requirements**

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

Type of Policy:	**Drug/Medical Therapy**
Prior Approval Date:	**N/A**
Approval Date:	**1/01/2024**
Effective Date:	**01/01/2024**
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 the general limitation on coverage for outpatient drugs under Part B, some self-administered drugs are also 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 therapyA member cannot be required to change drug therapy if currently established 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 an enrollee 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 or LCD. 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 08/03/2023. Available: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf

2. Medicare Claims Processing Manual. Chapter 17- Drugs and Biologicals. Revised 06/02/2023. 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

5.

Medical Drug List

Revised: **09/01/2024**

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 (MMC) 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	
Adcetris (Injection, brentuximab vedotin, 1 mg)	J9042	See Optum List if treatment is being used for a cancer diagnosis
Adstiladrin (inj, nadofaragene firadenovec-vncg)	J9029	See Optum List if treatment is being used for a cancer diagnosis
Adzynma (ADAMTS13, Recombinant)	J7171	Prior Authorization per Orphan Drug(s) and Biologicals Policy
Akynzeo (Injection, fosnetupitant 235 mg and palonosetron 0.25 mg)	J1454	See Optum List if treatment is being used for a cancer diagnosis
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
Altuviiio (antihemophilic factor recombinant Fc-VWF-XTEN fusion protein-ehtl)j	J7214	Subject to Hemophilia Factor policy
Alyglo (injection, immune globulin, IV)	J1599	Subject to 6-month new drug. Prior authorization required.
Alymsys (Injection, bevacizumab)	Q5126	See Optum List if treatment is being used for a cancer diagnosis
Andexxa (Injection, coagulation factor Xa (recombinant), inactivated (andexxa), 10 mg)	J7169	
Anktiva (nogapendekin alfa inbakicept, intravesical))	J9999	Subject to 6-month new drug. Prior authorization required.

Aphexda (motixafortide)	J2277	See Optum List if treatment is being used for a cancer diagnosis
Aponvie (aprepitant,fosaprepitant)	J3490	
Apretude (Injection, cabotegravir)	J0739	
Aralast-NP (Injection, alpha 1-proteinase inhibitor, human, 10 mg, not otherwise specified)	J0256	
Aristada (Injection, aripiprazole lauroxil, (aristada initio), 1 mg)	J1943, J1944	
Avastin (bevacizumab)	C9257, J9035	See Optum List if treatment is being used for a cancer diagnosis; Retrospective Review per VEG-F policy for ocular conditions.
Asparlas (calaspargase pegol-mknl) injection for intravenous use	J9118	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
Benlysta (Injection, belimumab)	J0490	
Beovu (brolucizumab-dbll) injection for intravitreal injection	J0179	
Beqvez (fidanacogene elaparvovec)	J3590	Subject to 6-month new drug. Prior authorization required.
Besponsa (Injection, inotuzumab ozogamicin)	J9229	See Optum List if treatment is being used for a cancer diagnosis

Blenrep (belantamab mafodotin)	J9037	See Optum List if treatment is being used for a cancer diagnosis
Blincyto (Injection, blinatumomab)	J9039	See Optum List if treatment is being used for a cancer diagnosis
Boniva IV (Injection, ibandronate)	J1740	
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
Brixadi (buprenorphine)	J0576, J0577, J0578	
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".
Cimerli (ramibizumab)	Q5128	
Cinvanti (aprepitant)	J0185	See Optum List if treatment is being used for a cancer diagnosis
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
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	
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	
Dsuvia (sufentanil tablets)	J8499	Excluded
Durysta (bimatoprost implant)	J7351	
Dysport (Injection, abobotulinumtoxinA, 5 units)	J0586	Prior authorization is not required for **on label** use and off label compendia supported use. Off label compendia supported use must meet the requirements of the Experimental and Investigational policy. Cosmetic use and formulations are not covered per Cosmetic Drug Agents policy
Elahere (mirvetuximab soravtansine injection)	J9063	See Optum List if treatment is being used for a cancer diagnosis
Elfabrio (pegunigalsidase alfa), solution for injection	J2508	
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

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
Enjaymo (sutimlimab-jome)	J1302	Prior Authorization per the Orphan Drug Policy
Epkinly (epcoritamab) solution for injection	J9321	See Optum List if treatment is being used for a cancer diagnosis
Erwinaze (Injection, asparaginase)	J9019	
Evenity (Injection, romosozumab-aqqg)	J3111	
Evomela (Injection, melphalan hydrochloride)	J9245	See Optum List if treatment is being used for a cancer diagnosis
Exparel (injection, bupivacaine)	J3490	Excluded
Fabrazyme (Injection, agalsidase beta)	J0180	
Feraheme (Injection, ferumoxytol)	Q0138, Q0139	
Fetroja (cefiderocol, IV)	J0693	
Firmagon (Injection, degarelix)	J9155	See Optum List if treatment is being used for a cancer diagnosis
Focinvez (fosasprepitant)	J1434	Subject to 6-month new drug. Prior authorization required. 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	

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 See Biosimilars, Select Medical
Herceptin Hylecta (trastuzumab)	J9356	See Optum List if treatment is being used for a cancer diagnosis See Biosimilars, Select Medical
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 See Biosimilars, Select Medical
Hyaluronic Acid Derivatives	J7318 J7320 J7321 J7322 J7323 J7324 J7325 J7326 J7327 J7328 J7329 J7331 J7332	Not covered for MVP Medicaid Managed Care Products when billed with diagnosis codes for osteoarthritis of the knee as Listed in the Viscosupplementation of the knee: Non-Coverage for Medicaid Managed Care Plans Payment Policy
IDose TR (travoprost implant)	J7355	Subject to 6-month new drug. Prior authorization required.
Iheezo gel (chloroprocaine)	J2403	
Ilumya (Injection, tildrakizumab, 1mg)	J3245	Excluded
Imdelltra (tarlatamab, injection)	J9999	Subject to 6-month new drug. Prior authorization required.
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
Injectafer	J1439	

(Injection, ferric carboxymaltose)		
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
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 See Biosimilars, Select Medical
Keytruda (pembrolizumab)	J9271	See Optum List if treatment is being used for a cancer diagnosis
Kimmtrak (tebentafusp-tebn)	J9274	See Optum List if treatment is being used for a cancer diagnosis
Kimyrsa (oritavancin inj)	J2406	
Kisunla (donanemab, inj)	J3590	Subject to 6-month new drug. Prior authorization required.
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
Lamzede (velmanase alfa, injection)	J0127	Prior Authorization per Orphan Drugs and Biologicals policy

Lartruvo (olaratumab)	J9285	See Optum List if treatment is being used for a cancer diagnosis
Leqvio (injection, inclisiran, 1mg)	J1306	Excluded
Libtayo (cemiplimab-rwlc)	J9119	See Optum List if treatment is being used for a cancer diagnosis
Liletta (Levonorgestrel-releasing intrauterine contraceptive system)	J7297	
Loqtorzi (toripalimab)	J9999	See Optum List if treatment is being used for a cancer diagnosis
Lucentis (ranibizumab)	J2778	
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
Macrilen (macimorelin)	C9399	
Makena (Injection, hydroxyprogesterone caproate)	J1726	
Margenza (margetuximab-cmkb)	J9353	See Optum List if treatment is being used for a cancer diagnosis
Marqibo (Injection, vincristine sulfate liposome)	J9371	
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; Retrospective Review per VEG-F policy for ocular conditions. See Biosimilars, Select Medical

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	
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)	J2796	See Optum List if treatment is being used for a cancer diagnosis
Nulojix (Injection, belatacept)	J0485	
Nuzyra IV (Injection, omadacycline)	J0121	
Ocrevus (Injection, ocrelizumab)	J2350	
Ogivri (Trastuzumab)	Q5114	See Optum List if treatment is being used for a cancer diagnosis See Biosimilars, Select Medical
Olinvyk (oliceridine)	J3490	
Omegaven (10 grams lipids)	B4187	Excluded
Omvoh (mirikizumab, solution for injection, IV)	J2267	Exclude
Onivyde (Injection, irinotecan liposome)	J9205	See Optum List if treatment is being used for a cancer diagnosis

Ontruzant (Injection, trastuzumab-dttb)	Q5112	See Optum List if treatment is being used for a cancer diagnosis See Biosimilars, Select Medical
Opdivo (Injection, nivolumab)	J9299	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
Orbactiv (Injection, oritavancin)	J2407	
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	
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	
Piasky (Crovalimab solution for injection)	J3590	Subject to 6-month new drug. Prior authorization required.
Pombiliti (cipaglucosidase alfa, powder for injection)	J1203	Prior Authorization per Orphan Drug(s) and Biologicals Policy
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)	J3490	
Prevymis IV (letermovir, IV)	J3490	Prior authorization required per Pharmacy Programs Administration Policy
Probuphine (Buprenorphine implant)	J0570	
Prolastin-C (Injection, alpha 1-proteinase inhibitor, human)	J0256	
Prolia (Injection, denosumab)	J0897	See Optum List if treatment is being used for a cancer diagnosis
Propel Implant (Mometasone furoate sinus implant)	S1091	Excluded per UM E/I List
Quzyttir (cetirizine, inj)	J1201	Prior Authorization required as a non-Formulary drug for **Medicaid** only due to CMS rebate labeler requirement
Rapivab (Injection, peramivir)	J2547	
Reclast (Injection, zoledronic acid)	J3489	
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
Rivfloza (nedosiran, vials)	J3490	Subject to 6-month new drug. Prior authorization required
Rolvedon (eflapegrastim)	J1449	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
Rykindo (risperidone, injection)	J2801	
Rylaze (asparaginase erwinia chrysanthemi [recombinant]-rywn)	J9021	See Optum List if treatment is being used for a cancer diagnosis

Rystiggo (rozanolixizumab)	J9333	Prior Authorization per Orphan Drug and Biologicals policy
Rytelo (Imetelstat)	J3490	Subject to 6-month new drug. Prior Authorization required.
Ryzneuta (efbemalenograstim alfa-vuxw)	J9361	Subject to 6-month new drug. Prior authorization required. 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
Saphnelo (anifrolumab)	J0491	
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	
Skyla (Levonorgestrel-releasing intrauterine contraceptive system)	J7301	
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 (Injection, omacetaxine mepesuccinate)	J9262	See Optum List if treatment is being used for a cancer diagnosis
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
Tecelra (afamitresgene autoleucel)	J3590	Subject to 6-month new drug. Prior authorization required.

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
Terlivaz (Injection, terlipressin)	J3490	
Tezspire (Injection, Tezepelumab)	J2356	Excluded
Tivdak (tisotumab vedotin)	J9273	
Tofidence (tocilizumab, inj)	Q5133	Subject to 6-month new drug. Prior authorization required. 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 "Biosimilars, Select Medical policy"; See Optum List if treatment is being used for a cancer diagnosis
Tyenne (tocilizumab)	J3590	Subject to 6-month new drug. Prior authorization required
Uplizna (10mg/ml solution inebilizumab-cdon, 1mg)	J1823	Prior authorization required per Orphan Drug Policy
Uzedy (risperidone) suspension for injection	J2799	Exclude

Vabysmo (faricimab-svoa)	J2777	Prior Authorization per Vascular Endothelial Growth Factor policy for ocular conditions.
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** See Biosimilars, Select Medical
Veopoz (pozelimab, injection)	J9376	Prior Authorization per Orphan Drug and Biologicals policy
Vibativ (Injection, telavancin)	J3095	
Vivitrol (Injection, naltrexone)	J2315	
Voraxaze (Injection, glucarpidase)	J3590	
Vyjuvek (beremagene geperpavec)	J3401	Prior Authorization per the Orphan Drug Policy
Vyvgart (Injection, efgartigimod alfa)	J9332	Prior Authorization per the Orphan Drug Policy
Vyvgart Hytrulo (Injection, efgartigimod alfa; hyaluronidase)	J9334	Prior Authorization per Orphan Drug and Biologicals policy
Vyxeos (Injection, liposomal, 1 mg daunorubicin and 2.27 mg cytarabine)	J9153	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
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	J0122	

(Injection, eravacycline)		
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.
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
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	
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; Retrospective Review per Vascular Endothelial Growth Factor policy for ocular conditions. See Biosimilars, Select Medical Policy

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	
Zynlonta (Loncastuximab tesirine, solution for injection)	J9359	Prior Authorization per the Orphan Drug Policy.
Zynyz (Retifanlimab, solution for injection)	J9345	See Optum List if treatment is being used for a cancer diagnosis
Zyprexa- Relprevv (Injection, olanzapine)	J2358	
Zyvox injection (Injection, linezolid)	J2020	Prior authorization required per Pharmacy Programs Administration Policy

Investigational/Experimental use not covered per member contract.
Unless otherwise specified, does not apply to inpatient use.
Drugs pending committee review may be submitted for consideration on a case-by-case basis.

Optum Cancer Guidance Program Review

Effective 01/01/2024, medical oncology medications will be reviewed by a delegated vendor Optum.

Brand Name	Generic Name	Full HCPC NDC Crosswalk HCPC
Cinvanti	Aprepitant	J0185
Pedmark	sodium thiosulfate	J0208
Busulfex	Busulfan	J0594
Wellcovorin	Leucovorin Calcium	J0640
Fusilev	Levoleucovorin	J0641
Khapzory	Levoleucovorin	J0642
Aranesp	Darbepoetin alfa	J0881
Epogen	Epoetin Alfa	J0885
Decitabine (sun pharma)	Decitabine	J0893
Dacogen	Decitabine	J0894
Reblozyl	Luspatercept-aamt	J0896
Prolia	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
Nplate	Romiplostim	J2796
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
Blenrep	Belantamab mafodont	J9037
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
Bendamustine (Apotex)	Bendamustine	J9058
Bendamustine (Baxter)	Bendamustine	J9059
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

Paclitaxel, protein-bound particles (American Regent)	Paclitaxel, protein-bound particles, not therapeutically equivalent to J9264	J9259
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
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
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
Thioplex	Thiotepa	J9340
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™	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
Paclitaxel protein bound	Paclitaxel protein bound	J9258
Columvi	Glofitamab	J9286
Pemrydi rtu	pemetrexed	J9324
Fylnetra	Pegfilgrastim-pbbk	Q5130

Sodium Thiosulfate (Hope)	Sodium Thiosulfate (Hope)	J0209
Cyclophosphamide	Cyclophosphamide	J9075
Cyclophosphamide	Cyclophosphamide(ingenus)	J9073
Cyclophosphamide	Cyclophosphamide	J9074
Melphalan (apotex)	Melphalan (apotex)	J9249
Focinvez	fosaprepitant	J1434
Elfrexio	elranatamab-bcmm	J1323
Aphexda	motixafortide	J2277
Talvey	talquetamab-tgvs	J3055
Tofidence	tocilizumab-bavi, biosimilar	Q5133
Ryzneuta	efbemalenograstim alfa-vuxw	J9361
Loqtorzi	Toripalimab-tpz	J3263
Palonosetron hcl	Palonosetron hcl (Avyxa)	J2468

MVP Health Care Medical Policy

Medicare Part B vs. Part D Determination

Type of Policy:	**Drug/Medical Therapy**
Prior Approval Date:	**12/01/2023**
Approval Date:	**06/01/2024**
Effective Date:	**08/01/2024**
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 to make the determination[5].

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 with MVP.

Outpatient Drugs-are covered under Part B when furnished incident to a physician service for drugs that are not usually self-administered by the patient. 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) to make determination.

Inhalation Drugs-The following drugs would be covered under Part B when used in the home and administered using a nebulizer:

- Albuterol, arformoterol (Brovana), budesonide, cromolyn, formoterol, ipratropium, levalbuterol, metaproterenol, and revefenacin for the management of obstructive pulmonary disease
- Dornase alpha for the management of cystic fibrosis
- Tobramycin for the management of cystic fibrosis or bronchiectasis
- Pentamidine for the management of HIV, pneumocystosis, or complications of organ transplants.
- Acetylcysteine for the management of persistent thick or tenacious pulmonary secretions
- Treprostinil inhalation solution and iloprost for the treatment of pulmonary arterial hypertension

For a member in a SNF or hospital who does not have Part A coverage, the Part A coverage has run out, or whose stay is non-covered these medications would be covered under Part D as the Part B DME coverage is limited to items that are furnished for use in the patient's home.
Refer to LCD for Nebulizers (L33370) for coverage details

Infusion Pump Medications-The following medications would be covered under Part B if administered in the home using an infusion pump

- Antiviral/antifungal drugs acyclovir, foscarnet, amphotericin B, ganciclovir
- Administration of the anticancer chemotherapy drugs cladribine, fluorouracil, cytarabine, bleomycin, floxuridine, doxorubicin (non-liposomal), vincristine (non-liposomal) or vinblastine by continuous infusion over at least 8 hours when the regimen is proven or generally accepted to have significant advantages over intermittent administration regimens
- Blinatumomab
- Deferoxamine for the treatment of chronic iron overload
- Insulin
- Morphine for the treatment of intractable pain caused by cancer
- Narcotic analgesics (except meperidine) in place of morphine for the treatment of intractable pain caused by cancer that has not responded to an adequate oral/transdermal therapeutic regimen or cannot tolerate oral/transdermal narcotic analgesics
- Administration of parenteral inotropic therapy with dobutamine, milrinone, or dopamine
- Levodopa-Carbidopa enteral suspension for the treatment of motor fluctuations in Parkinson's disease
- Epoprostenol or treprostinil for the treatment pulmonary hypertension
- Gallium nitrate for the treatment of symptomatic cancer-related hypercalcemia
- Subcutaneous immune globulin for the treatment of primary immune deficiency
- Ziconotide (intrathecal) for severe chronic pain

Refer to NCD for Infusion Pumps (280.14) for coverage details and LCD for External Infusion Pumps (L33794)

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
- Patient must have received an organ transplant while enrolled in Medicare Part A and the immunosuppressive therapy is appropriate for the transplant.

Hemophilia clotting factors-are covered under Part B for hemophilia patients competent to use such factors to control bleeding without medical supervision.

Erythropoietin (EPO)-is covered for the treatment of anemia for patients with chronic renal failure who are on dialysis.

- Refer to Chapter 15 Section 50.5.2 of the Medicare Benefit Policy Manual for coverage details

Oral anti-cancer drugs-certain drugs where there is an infusible version of the drug are covered under Part B

- Must be used for the same indication of the infusible version of the drug
- The following oral drugs may be covered under Part B
    - busulfan, capecitabine, cyclophosphamide, etoposide, fludarabine phosphate, melphalan, methotrexate, temozolomide, topotecan
- Refer to LCD for Oral Anticancer Drugs (L33826) and the accompanying Policy Article (A52479) for 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.

Immunizations-covered under Part B

- Hepatitis B vaccine- when administered to patient who is at high or intermediate risk of contracting hepatitis B
    - High risk groups include: individuals with ESRD; individuals with hemophilia who received Factor VIII or IX concentrates; clients of institutions for individuals for the mentally handicapped; persons who live in the same household as a hepatitis B virus (HBV) carrier; homosexual men; illicit injectable drug abusers, persons diagnosed with diabetes mellitus.
    - Intermediate risk groups include staff in institutions for the mentally handicapped and workers in health care professions who have frequent contact with blood or blood-derived body fluids during routine work
- Pneumococcal vaccine
- Tetanus-when administered directly related to the treatment of an injury
- Influenza vaccine

Parenteral nutrition- covered under Part B if meet the following:

- Covered under the prosthetic devices benefit when criteria are met (see Enteral Therapy Policy and the Medicare Local Coverage Determination (LCD) for Enteral Nutrition (LCD L38955**)**)

- Intradialytic Parenteral Nutrition would not be covered under Part B. It is considered a Part D compound because dialysate is not included
- 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
- See Immunoglobulin Therapy policy for coverage criteria

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 8/21/2015. 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 11/6/2015. Available: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf
3. Medicare Part B versus Medicare Part D coverage Issues guidance paper. Revised 7/27/2005. Available: http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/Downloads/PartBandPartDdoc_07.27.05.pdf.
4. Medicare Benefit Policy Manual. Chapter 2. Medicare Marketing Guidelines. Revised 6/7/2012. Available: http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals.html.
5. Department of Health & Human Services (DHHS). Centers for Medicare & Medicaid Services (CMS). Pub 100-04 Medicare Claims Processing. Revisions to the End Stage

Renal Disease (ESRD) Medicare Benefit Policy Manual to Reflect the Implementation of the ESRD Prospective Payment System (PPS). 11/14/2011.
6. NHIC, Corp. LCD (L33370) Nebulizers, Original Article Effective Date 10/1/2015. Available: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?
7. Centers of Medicare & Medicaid Services. National Coverage Determination for Infusion Pumps (280.14). Effective Date 12/17/2004.
8. Medicare Prescription Drug Benefit Manual, Chapter 6. Available at https://cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter6.pdf (Accessed 3/2/16)
9. NHIC, Corp. Article for Intravenous Immune Globulin (A52509)
10. Noridian Healthcare Solutions, LLC. Local Coverage Determination: External Infusion Pumps (L33794).
11. Medicare Local Coverage Determination for Enteral Nutrition (L38955). Effective Date: 01/01/2022.
12. Medicare Local Coverage Determination for Oral Anticancer Drugs (L33826). Revision Effective Date: 01/01/2020.
13. Medicare Local Coverage Article Oral Anticancer Drugs – Policy Article (A52479). Revision Effective Date: 10/01/2022.
14. Medicare Claims Processing Manual. Chapter 17- Drugs and Biologicals. Revised 12/22/2022. Available: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c17.pdf
15. Medicare Benefit Policy Manual. Chapter 15. Covered Medical and Other Health Services. Revised 03/16/2023. Available: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf
16.

MVP Health Care Medical Policy

Medicare Part B Step Therapy

Type of Policy:	**Administrative**
Prior Approval Date:	**11/01/2023**
Approval Date:	**04/01/2024**
Effective Date:	**04/01/2024**

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:

- 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.
- National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable.
- 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	Procrit	Retacrit
Intravitreal Vascular Endothelial Growth Factor (VEGF) Inhibitors	Avastin, Mvasi, Zirabev	Beovu, Byooviz, Cimerli, Eylea, Lucentis, Vabysmo
Multiple Sclerosis Agents	Ocrevus	Lemtrada, Tysabri, Briumvi

*Not an all-inclusive list

Oncology Medical Drug List

Preferred Oncology Product	Non-Preferred Oncology Product
Zirabev Mvasi	Avastin Alymsys Vegzelma
Herceptin Trazimera	Kanjinti Herceptin Hylecta Ogivri Ontruzant Herzuma
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
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; available at

http://www.cms.gov - last checked August 31, 2018 and found under Medicare > Health Plans > Health Plans - General Information > Downloads.
2. Centers for Medicare and Medicaid Services, Medicare Benefit Policy Manual, CMS Pub. 100-02, Chapter 15, Sec. 50 (Rev. 241, Feb. 2, 2018); available at http://www.cms.gov - last checked August 31, 2018 and found under Medicare > Regulations and Guidance > Manuals > Internet-Only Manuals (IOMs).
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 May 23, 2019. Available at: eCFR :: 42 CFR 422.136 -- Medicare Advantage (MA) and step therapy for Part B drugs.

MVP Health Care Medical Policy

Metformin ER

Type of Policy: **Drug Therapy**
Prior Approval Date: **03/01/2023**
Approval Date: **02/01/2024**
Effective Date: **04/01/2024**
Related Policies: N/A

Drugs Requiring Prior Authorization under the pharmacy benefit
Glumetza (Metformin SR 24hr modified release, 500 mg and 1000 mg extended release tablets)

Metformin SR 24hr modified release, 500mg and 1000mg extended release tablets

Metformin SR 24hr osmotic, 500mg and 1000mg extend release tablets (generic Fortamet)

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

Overview
Glumetza is a brand name version, for which generics are available, of metformin, a biguanide used to help control hyperglycemia in patients with type 2 diabetes mellitus. Clinical data suggests that patients receiving extended release formulations of metformin experience less gastrointestinal upset than those receiving immediate release formulations. Through increased glucose control, patients may experience an improvement in hemoglobin A1c, as well as modest weight loss.

Indications/Criteria

Generic Fortamet and Glumetza are indicated as an adjunct to diet and exercise to improve glycemic control to improve control in adults with type 2 diabetes mellitus

All requests require the following:

- Current HbA1c must be provided with request
- Member has a diagnosis of type 2 diabetes mellitus

Generic Fortamet will be considered for coverage when all of the following criteria are met:

- Chart notes documenting contraindication or intolerable adverse reaction causing discontinuation of therapy after appropriate dose titration and administration to **ALL** of the following products, with immediate-release (IR) trialed prior to extended-release (ER) formulations:
    1. Metformin IR (generic Glucophage IR)
    2. 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)
    3. Metformin IR (generic Glucophage IR)
    4. Metformin ER (generic Glucophage XR)
    5. Metformin SR 24hr osmotic release (generic Fortamet)
- If approved generic Glumetza must be used and failed prior to approval for brand Glumetza

If approved, coverage will be for a period of up to one year. Requests for continuation of therapy must be 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

- Any non-FDA approved indications
- Doses above the FDA package label
- Doses and administration not consistent with 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 Authorization
PPO in Plan	Prior Authorization
PPO OOP	Prior Authorization
POS in Plan	Prior Authorization
POS OOP	Prior Authorization
Essential Plan	Prior Authorization
MVP Medicaid Managed Care	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Child Health Plus	Prior Authorization
MVP Harmonious Health Care Plan	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Medicare Gold Giveback	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Secure HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare WellSelect PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare WellSelect Plus PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Patriot Plan PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess Complete D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess Plus D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Select PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Secure PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
Healthy NY	Prior Authorization
MVP Premier	Prior Authorization
MVP Premier Plus	Prior Authorization
MVP Premier Plus HDHP	Prior Authorization
MVP Secure	Prior Authorization
MVP EPO	Prior Authorization

MVP EPO HDHP	Prior Authorization
MVP PPO	Prior Authorization
MVP PPO HDHP	Prior Authorization
Student Health Plans	Prior Authorization
ASO	Prior Authorization
Vermont Products	
POS in Plan	Prior Authorization
POS OOP	Prior Authorization
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D
MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Select PPO	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Secure PPO	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D
MVP VT HMO	Prior Authorization
MVP VT Plus HMO	Prior Authorization
MVP VT HDHP HMO	Prior Authorization
MVP VT Plus HDHP HMO	Prior Authorization
MVP Secure	Prior Authorization
ASO	Prior Authorization
♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).	

***Medical Management Requirements**

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

MVP Health Care Medical Policy

Methotrexate autoinjector

Type of Policy:	**Drug Therapy**
Prior Approval Date:	**08/01/2023**
Approval Date:	**08/01/2024**
Effective Date:	**10/01/2024**
Related Policies:	**Rheumatoid Arthritis Drug Therapy**
	Inflammatory Biologic Drug Therapy
	Experimental or Investigational Policy

Drug Requiring Prior Authorization

Otrexup® (methotrexate autoinjector) 10, 12.5, 15,17.5, 20, 22.5, 25 mg for subcutaneous injection

Rasuvo® (methotrexate autoinjector) 7.5, 10, 12.5, 15, 17.5, 20, 22.5, 25, 30mg for subcutaneous injection

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

Overview

Otrexup and Rasuvo, the subcutaneous autoinjector formulations of methotrexate, are indicated for severe, active Rheumatoid Arthritis (RA), Polyarticular Juvenile Idiopathic Arthritis (pJIA), and severe, recalcitrant, disabling psoriasis.[3,6] These autoinjector formulations are not FDA approved for psoriatic arthritis. Otrexup and Rasuvo are both for once weekly, subcutaneous use only; other methotrexate formulations allow for intramuscular, intravenous, intra-arterial, and intrathecal dosing. Each injector is one-time use, and the pre-filled dose to be administered cannot be changed on the device.

Indications/Criteria

Otrexup® and Rasuvo® (methotrexate for subcutaneous auto injection) may be considered medically necessary when the following criteria are met:

For Rheumatoid Arthritis (RA):

- Prescriber must be a rheumatologist/immunologist
- Failure/intolerance of oral methotrexate
- Failure/intolerance of generically available injectable methotrexate ('vial & syringe')

For Polyarticular Juvenile Idiopathic Arthritis (pJIA):

- Prescriber must be a rheumatologist
- Failure of oral methotrexate
- Failure/intolerance of generically available injectable methotrexate ('vial & syringe')

For Psoriasis:

- Prescriber must be a dermatologist
- Failure of oral methotrexate
- Failure/intolerance of generically available injectable methotrexate ('vial & syringe')

Initial authorizations and continuations, if approved, will be for a period of one year.

Exclusions

- Hypersensitivity reaction to methotrexate
- Pregnancy
- Nursing mothers
- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling Creatinine clearance ≤ 30 mL/min[5]
- Active alcoholism
- Liver disease
- Immunodeficiency syndromes
- Active infection
- Blood dyscrasias like bone marrow hypoplasia, leukopenia, thrombocytopenia, or significant anemia
- Concomitant cytotoxic drugs

- Concomitant radiation therapy

References

1. Lehman, TJ. Polyarticular onset juvenile idiopathic arthritis: Management. In: UpToDate, Klein-Gitelman, M (Ed), UpToDate, Waltham, MA; Feb 2013 [cited July 7 2014].
2. Foell D, Wulffraat N, Wedderburn LR, et al. Methotrexate withdrawal at 6 vs 12 months in juvenile idiopathic arthritis in remission: a randomized clinical trial. JAMA. 2010;303(13):1266-73.
3. Otrexup® (Methotrexate) injection, for subcutaneous use. Prescribing Information. Ewing, NJ: Antares Pharma; April 2014. Revised December 2019.
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Member Product	Medical Management Requirements*
New York Products	
HMO	Prior Auth
PPO in Plan	Prior Auth
PPO OOP	Prior Auth
POS in Plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Child Health Plus	Prior Auth
MVP Harmonious Health Care Plan	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Medicare Gold Giveback	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Secure HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare WellSelect PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare WellSelect Plus PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Patriot Plan PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.

MVP DualAccess Complete D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess Plus D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Select PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Secure PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	
POS in Plan	Prior Auth
POS OOP	Prior Auth
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D
MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Select PPO	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Secure PPO	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D
MVP VT HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD
♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).	

***Medical Management Requirements**

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

MVP Health Care Medical Policy

Migraine Agents

Type of Policy: **Drug Therapy**
Prior Approval Date:
Approval Date: **08/01/2024**
Effective Date: **10/01/2024**
Related Policies: **Calcitonin Gene-Related Peptide (CGRP) Antagonists**

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

Overview

Generic triptan agents (i.e. naratriptan, rizatriptan, and sumatriptan), are formulary/select agents.

Triptans, diclofenac potassium for oral solution, dihydroergotamine, and ditans are only indicated for treatment of acute migraine attacks and are not indicated for prophylactic therapy for migraines or for use in the management of hemiplegic or basilar migraine. Butorphanol tartrate nasal spray is indicated for the management of pain when the use of an opioid analgesic is appropriate. Sumatriptan injection is the only triptan approved for cluster headaches.

Butorphanol nasal spray is an opioid agonist-antagonist analgesic. Dihydroergotamine nasal spray is an ergotamine derivative. Diclofenac potassium is a non-steroidal anti-inflammatory drug (NSAID). The mechanism of action, like that of other NSAIDs, is not completely understood but may be related to prostaglandin synthetase inhibition. Lasmiditan is an oral serotonin receptor 5-HT_{1F} agonist also known as a "ditan" The remaining medications identified in this policy are serotonin 5-HT_1 receptor agonists also known as "triptans". Triptans are available as oral tablets/capsules, disintegrating tablets, nasal sprays, and subcutaneous injections.

The management of migraines involves avoiding known triggers where possible and using medications that either prevent an attack (prophylaxis) or shorten the attack. Although the cause of migraine is not understood, triptans are thought to shorten a

migraine attack by constricting blood vessels and preventing the release of pro-inflammatory neuropeptides.[1]

Drugs Requiring Prior Authorization and/or Quantity Limits Brand name medications require prior authorization. Generic medications require prior authorization when quantity limits are exceeded unless otherwise noted.

Name	**Quantity Limit every 30 days unless indicated otherwise**	**Notes**
Amerge® 1mg/**Naratriptan**	18 tablets	
Amerge® 2.5mg /**Naratriptan**	9 tablets	
Almotriptan 6.25mg	12 tablets	
Almotriptan 12.5mg	8 tablets	
butorphanol nasal spray	10 mls (4 canisters)	
Cambia™ 50mg /**Diclofenac**	9 packets/45 days	Brand requires prior authorization when quantity limits exceeded.
D.H.E. 45 inj. /**Dihydroergotamine mesylate**	20 ampules	Both brand and generic require prior authorization
Ergotamine-Caffeine tablets	40 tablets	
Elyxyb Solution	1 box (6 bottles) per 45 days	Brand requires prior authorization when quantity limits exceeded.
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	Both brand and generic require prior authorization
Migranal® Nasal Spray /**dihydroergotamine mesylate**	8 units	Both brand and generic require prior authorization
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	Both brand and generic require prior authorization
Sumatriptan 6mg/0.5ml injection	4 kits (8 injections)	
Treximet™	9 tablets	Both brand and generic require prior authorization
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	

Indications/Criteria

In addition to generic triptans, see above table for migraine agents that do not require a prior authorization unless the quantities identified in this policy are exceeded.

1. **Tier 3 triptans (see Treximet variation)** that require prior authorization may be considered for coverage when all the following criteria are met:
    - Diagnosis of a Food and Drug Administration approved indication.
    - Member has a documented failure, contraindication, intolerance, or allergy to all generic formulary triptans.

    Initial approval will be for a period of one year.

    Extension requests will be up to one year based upon clinical response and must include current chart notes identifying continued benefit.

2. **Treximet and Sumatriptan-Naproxen**
    - Diagnosis of a Food and Drug Administration approved indication
    - Member has a documented failure, contraindication, intolerance, or allergy to all generic formulary triptans AND naproxen

    Initial approval will be for a period of one year.

Extension requests will be up to one year based upon clinical response and must include current chart notes identifying continued benefit.

3. **Quantity Limit Exceptions**

Quantities that exceed the quantity limits listed in the preceding chart will be considered when ALL the following are met:

- Headache diary identifies more than 4 headaches per month.
- Chart notes identifying consult with a neurologist.
- Preventative treatment has been initiated or rationale provided why all preventative therapies are contraindicated (e.g. antiepileptics, antidepressants, beta-blockers).
- The quantity limit amount has been tried and does not provide adequate coverage for the number of headaches identified in the headache diary.
- If the preventative therapy has not decreased the number of headaches per week, a 2-month trial of a different preventative drug is required until all preventative drug classes have been exhausted.
- **For Reyvow requests only**: Documentation identifies that a second dose for the same migraine attack is not being used

Initial approval for quantity limit exceptions, will be for a maximum of 3 months.

Extension requests for quantity limit exceptions will be for a maximum of 3 months and must include the following:

- Current chart notes identifying the number of headaches per week that have occurred since the preventative therapy was initiated. A trial of preventative treatment should last at least 2 months[3,6].
- If the number of headaches has not decreased, documentation must be provided identifying treatment plan with a different preventative therapy trial.

4. **Dihydroergotamine Nasal/Injection and Migergot Suppositories**

Dihydroergotamine nasal/injection and Migergot suppositories may be considered for **cluster headaches** when the following criteria is met:

- Member has a documented failure of sumatriptan injection.
    - If the member has a significant intolerance to sumatriptan injection, the member must have a documented failure of sumatriptan nasal spray.
- For chronic cluster headaches, member is receiving preventative therapy with verapamil

Dihydroergotamine nasal/injection and Migergot suppositories may be considered for **migraine headaches** when the following criteria is met:

- Documentation of a trial and failure of naproxen or diclofenac
- If migraines are not associated with nausea and vomiting must have failure of all oral generic triptans
- Documentation of a trial and failure of injectable sumatriptan.

If the member has a significant intolerance to sumatriptan injection, the member must have a documented failure of sumatriptan nasal spray. **Initial approval** will be for a period of one year.

Extension requests will be up to 12 months if the member has current chart notes documenting a continued benefit to therapy. Extension requests where Dihydroergotamine nasal/injection and Migergot suppositories did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

5. **Reyvow**

Reyvow may be considered for migraine headaches when the following criteria is met:

- The strength and dose are indicated, and the dose is within the FDA approved package label (dose increases require a new prior authorization request and are subject to quantity limits or quantity limit exception criteria)
- Chart notes have documented a contraindication to the use of triptans **OR**
- Chart notes have documented a failure or intolerance to at least 2 oral triptans, as determined by either health care provider attestation or a validated acute treatment patient-reported outcome questionnaire (e.g., Migraine Treatment Optimization Questionnaire [mTOQ], Migraine Assessment of Current Therapy [Migraine-ACT], Patient Perception of Migraine Questionnaire-Revised [PPMQ-R], Functional Impairment Scale [FIS], Patient Global Impression of Change [PGIC])

Initial approval will be for 6 months

Extension requests will be up to 12 months if the member has current chart notes documenting a continued benefit to therapy.

Initial extension request should include documentation assessing the efficacy and tolerability of at least 2 treated migraine attacks.

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

Exclusions

- Combination use (more than one triptan per month).
- Off-label diagnosis.
- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling

References

1. Dean, L. (2010) National Center of Biotechnology Information (NCBI). Comparing triptans. Available from http://www.ncbi.nlm.nih.gov/bookshelf/br.fcgi?book=ebm&part=triptans#bottom. Accessed on December 31, 2012.
2. Package labels.
3. Ramadan NM, Silberstein SD, Freitag, Gilbert TT, Frishberg BM, for the US Headache Consortium. Evidence-based guidelines for migraine headache in the primary care setting: pharmacological management for prevention of migraine. Available at: http://www.aan.com/professionals/practice/pdfs/gl0090.pdf. Accessed on January 2, 2013.
4. Silberstein SD, for the US Headache Consortium Practice parameter: evidence-based guidelines for migraine headache (an evidence-based review): report of the Quality Standards Subcommittee of the American Academy of Neurology. Neurology. 2000; 55:754-762.
5. Campbell JK, Penzien D, Wall EM. Evidenced-based guidelines for migraine headache: behavioral and physical treatments. Available at: http://www.aan.com/professionals/practice/pdfs/gl0089.pdf. Accessed on January 2, 2013.
6. Silbersetin SD, Holland S, Freitag F, et al. Evidence-based guideline update: Pharmacologic treatment for episodic migraine prevention in adults: Report of the Quality Standards Subcommittee of the American Academy of Neurology and the American Headache Society. Neurology 2012; 78:1337-1345.
7. Ailani Jessica, Burch Rebecca et al. The American Headache Society Consensus Statement : Update on integrating new migraine treatments into clinical practice. Headache The Journal of Head and Face Pain. The American Headache Society Consensus Statement: Update on integrating new migraine treatments into

clinical practice - Ailani - 2021 - Headache: The Journal of Head and Face Pain - Wiley Online Library

Member Product	Medical Management Requirements*
New York Products	
HMO	Prior Auth
PPO in Plan	Prior Auth
PPO OOP	Prior Auth
POS in Plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Child Health Plus	Prior Auth
MVP Harmonious Health Care Plan	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Medicare Gold Giveback	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Secure HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare WellSelect PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare WellSelect Plus PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Patriot Plan PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess Complete D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess Plus D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Select PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Secure PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	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).

***Medical Management Requirements**

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

MVP Health Care Medical Policy

Migraine Agents

Type of Policy: Drug Therapy
Prior Approval Date: 03/01/2023
Approval Date: 08/01/2023
Effective Date: 10/01/2023
Related Policies: Calcitonin Gene-Related Peptide (CGRP) Antagonists

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

Overview

Generic triptan agents (i.e. naratriptan, rizatriptan, and sumatriptan), are formulary/select agents.

Triptans, diclofenac potassium for oral solution, dihydroergotamine, and ditans are only indicated for treatment of acute migraine attacks and are not indicated for prophylactic therapy for migraines or for use in the management of hemiplegic or basilar migraine. Butorphanol tartrate nasal spray is indicated for the management of pain when the use of an opioid analgesic is appropriate. Sumatriptan injection is the only triptan approved for cluster headaches.

Butorphanol nasal spray is an opioid agonist-antagonist analgesic. Dihydroergotamine nasal spray is an ergotamine derivative. Diclofenac potassium is a non-steroidal anti-inflammatory drug (NSAID). The mechanism of action, like that of other NSAIDs, is not completely understood but may be related to prostaglandin synthetase inhibition. Lasmiditan is an oral serotonin receptor 5-HT_{1F} agonist also known as a “ditan” The remaining medications identified in this policy are serotonin 5-HT_1 receptor agonists also known as “triptans”. Triptans are available as oral tablets/capsules, disintegrating tablets, nasal sprays, and subcutaneous injections.

The management of migraines involves avoiding known triggers where possible and using medications that either prevent an attack (prophylaxis) or shorten the attack.

Although the cause of migraine is not understood, triptans are thought to shorten a migraine attack by constricting blood vessels and preventing the release of pro-inflammatory neuropeptides.[1]

Drugs Requiring Prior Authorization and/or Quantity Limits Brand name medications require prior authorization. Generic medications require prior authorization when quantity limits are exceeded unless otherwise noted.

Name	Quantity Limit every 30 days unless indicated otherwise	Notes
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	Brand requires prior authorization when quantity limits exceeded.
D.H.E. 45 inj. /**Dihydroergotamine mesylate**	20 ampules	Both brand and generic require prior authorization
Ergotamine-Caffeine tablets	40 tablets	
Elyxyb Solution	1 box (6 bottles) per 45 days	Brand requires prior authorization when quantity limits exceeded.
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	Both brand and generic require prior authorization
Migranal® Nasal Spray /**dihydroergotamine mesylate**	8 units	Both brand and generic require prior authorization
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	Both brand and generic require prior authorization
Treximet™	9 tablets	Both brand and generic require prior authorization
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	

Indications/Criteria

In addition to generic triptans, see above table for migraine agents that do not require a prior authorization unless the quantities identified in this policy are exceeded.

1. **Tier 3 triptans (see Treximet variation)** that require prior authorization may be considered for coverage when all the following criteria are met:
    - Diagnosis of a Food and Drug Administration approved indication.
    - Member has documented failure, contraindication, intolerance, or allergy to all generic formulary triptans.

    Initial approval will be for a period of one year.

    Extension requests will be up to one year based upon clinical response and must include current chart notes identifying continued benefit.

2. **Treximet and Sumatriptan-Naproxen**
    - Diagnosis of a Food and Drug Administration approved indication
    - Member has documented failure, contraindication, intolerance, or allergy to all generic formulary triptans AND naproxen

    Initial approval will be for a period of one year.

    Extension requests will be up to one year based upon clinical response and must include current chart notes identifying continued benefit.

3. **Quantity Limit Exceptions**

    Quantities that exceed the quantity limits listed in the preceding chart will be considered when ALL the following are met:
    - Headache diary identifies more than 4 headaches per month.
    - Chart notes identifying consult with a neurologist.
    - Preventative treatment has been initiated or rationale provided why all preventative therapies are contraindicated (e.g. antiepileptics, antidepressants, beta-blockers).
    - The quantity limit amount has been tried and does not provide adequate coverage for the number of headaches identified in the headache diary.
    - If the preventative therapy has not decreased the number of headaches per week, a 2-month trial of a different preventative drug will be expected until all preventative drug classes have been exhausted.
    - Documentation identifies that a second dose for the same migraine attack is not being used (applies to Reyvow requests only)

Initial approval for quantity limit exceptions, will be for a maximum of 3 months.

Extension requests for quantity limit exceptions will be for a maximum of 3 months and must include the following:

- Current chart notes identifying the number of headaches per week that have occurred since the preventative therapy was initiated. A trial of preventative treatment should last at least 2 months[3,6].
- If the number of headaches has not decreased, documentation must be provided identifying treatment plan with a different preventative therapy trial.

4. Dihydroergotamine Nasal/Injection and Migergot Suppositories

For cluster headaches, the following criteria must be met:

- Must have documented failure of sumatriptan injection. If unable to tolerate injection must have failure of sumatriptan nasal spray
- Must be receiving preventative therapy with verapamil if member has chronic cluster headaches

For migraine headaches, all the following agents must be tried and failed:

- Naproxen or diclofenac
- If migraines are not associated with nausea and vomiting must have failure of all oral generic triptans
- Injectable sumatriptan. If unable to tolerate injection must have failure of sumatriptan and Zomig nasal spray

Initial approval will be for a period of one year.

Extension requests will be up to one year based upon clinical response and must include current chart notes identifying continued benefit.

5. Reyvow

Request will be considered for coverage when:

- The strength and dose are indicated, and the dose is within the FDA approved package label (dose increases require a new prior authorization request and are subject to quantity limits or quantity limit exception criteria)
- Within an FDA approved age range
- Chart notes have documented contraindication to the use of triptans OR
- Chart notes have documented a failure to respond to or tolerate at least 2 oral triptans, as determined by either health care provider attestation or a validated acute treatment patient-reported outcome questionnaire (e.g., Migraine Treatment Optimization Questionnaire [mTOQ], Migraine Assessment of Current Therapy [Migraine-ACT], Patient Perception of Migraine Questionnaire-Revised [PPMQ-R], Functional Impairment Scale [FIS], Patient Global Impression of Change [PGIC])

Initial approval will be for 6 months

Extension requests will be up to one year based upon clinical response and current chart notes identifying continued benefit. Initial extension request should include documentation assessing the efficacy and tolerability of at least 2 treated migraine attacks.

Exclusions

- Combination use (more than one triptan per month).
- Off-label diagnosis.

References

1. Dean, L. (2010) National Center of Biotechnology Information (NCBI). Comparing triptans. Available from http://www.ncbi.nlm.nih.gov/bookshelf/br.fcgi?book=ebm&part=triptans#bottom. Accessed on December 31, 2012.
2. Package labels.
3. Ramadan NM, Silberstein SD, Freitag, Gilbert TT, Frishberg BM, for the US Headache Consortium. Evidence-based guidelines for migraine headache in the primary care setting: pharmacological management for prevention of migraine. Available at: http://www.aan.com/professionals/practice/pdfs/gl0090.pdf. Accessed on January 2, 2013.
4. Silberstein SD, for the US Headache Consortium Practice parameter: evidence-based guidelines for migraine headache (an evidence-based review): report of the Quality Standards Subcommittee of the American Academy of Neurology. Neurology. 2000; 55:754-762.
5. Campbell JK, Penzien D, Wall EM. Evidenced-based guidelines for migraine headache: behavioral and physical treatments. Available at: http://www.aan.com/professionals/practice/pdfs/gl0089.pdf. Accessed on January 2, 2013.
6. Silbersetin SD, Holland S, Freitag F, et al. Evidence-based guideline update: Pharmacologic treatment for episodic migraine prevention in adults: Report of the Quality Standards Subcommittee of the American Academy of Neurology and the American Headache Society. Neurology 2012; 78:1337-1345.

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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
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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).	

***Medical Management Requirements**

Prior Auth	Prior Authorization Required
Potential for Retrospective Review	No Prior Authorization Required. May be subject to Retrospective Review.
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: 08/01/2023
Approval Date: 11/01/2023
Effective Date: 11/01/2023

Related Policies: N/A

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

Drugs Requiring Prior Authorization (covered under the medical benefit)

J0172 Aduhelm (aducanumab-avwa)

J0174 Leqembi (lecanemab-irmb)

Overview

Aduhelm 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.

Both Leqembi and Aduhelm 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 abnormalitieshemosiderin deposition (ARIA-H), which includes microhemorrhage and superficial siderosis.

Clinical Criteria

Medicaid Variation

Before initiating aducanumab-avwa (Aduhelm®), prescribers must attest that the patient has been diagnosed with mild cognitive impairment due to Alzheimer's disease or mild Alzheimer's dementia by meeting one of the following scores:

- Clinical Dementia Rating (CDR)-Global Score of 0.5 to 1
- Mini-Mental Status Exam (MMSE) score between 24 and 30
- Montreal Cognitive Assessment (MoCA) score of at least 18

Before initiating aducanumab-avwa (Aduhelm®), prescribers must provide medical records for the following pre-treatment testing:

- genetic testing to assess apolipoprotein E ε4 carrier status, **and**
- positron emission tomography (PET) scan or cerebrospinal fluid (CSF) analysis to confirm the presence of amyloid beta deposits.

Before initiating aducanumab-avwa (Aduhelm®), prescribers must attest that the patient does not have evidence of any medical or neurological condition other than Alzheimer's disease that could be contributing to the patient's cognitive impairment.

Before initiating aducanumab-avwa (Aduhelm®), prescribers must attest that the patient does not have a history of a clotting disorder and is not taking any form of antiplatelet or anticoagulant medications other than aspirin ≤325 mg/day.

Requests for Leqembi must meet the criteria above

Initial authorization for 6 months

For continuation of therapy, providers must attest that the patient's score remained stable or improved, utilizing the same baseline assessment tool as outlined for initiation of therapy.

<u>Commercial (NY & VT), Exchange (NY & VT), ASO, CHP, Essential Plan Variation</u>

Aduhelm and Leqembi may be considered for coverage when ALL the following criteria is met:

1. Documented clinical diagnosis of mild cognitive impairment (MCI) due to Alzheimer's Disease (AD) or mild AD dementia consistent with Stage 3 and Stage 4 Alzheimer's disease
2. Confirmed presence of amyloid beta pathology
3. Documentation of one of the following scores:
    a. Clinical Dementia Rating (CDR)-Global Score of 0.5 to 1

   b. Mini-Mental Status Exam (MMSE) score between 19 to 24
   c. Montreal Cognitive Assessment (MoCA) score of at least 18
4. Documentation of the following pre-treatment testing:
   a. Genetic testing to assess apolipoprotein E ε4 carrier status, **AND**
   b. Positron emission tomography (PET) scan or cerebrospinal fluid (CSF) analysis to confirm the presence of amyloid beta deposits.

Initial authorization for 6 months

For continuation of therapy, providers must attest that the patient'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
- Coadministration of Aduhelm and Leqembi

References

1. FDA News Release: https://www.fda.gov/news-events/press-announcements/fda-grantsaccelerated-approval-alzheimers-drug.
2. Biogen Press Release (FDA Approval): https://investors.biogen.com/news-releases/news-releasedetails/fda-grants-accelerated-approval-aduhelmtm-first-and-only.
3. ICER Press Release: https://icer.org/news-insights/press-releases/icer-issues-statement-on-thefdas-approval-of-aducanumab-for-alzheimers-disease/.
4. Aduhelm Label: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761178s000lbl.pdf.
5. Medicare Coverage Policy for Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease. April 7, 2022. Medicare Coverage Policy for Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease | CMS. Accessed April 21, 2022.
6. Medicare National Coverage Analysis Decision Memo for Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease (CAG-00460N). Effective Date: 04/07/2022.
7. Updates to Medicaid Fee-For-Service Practitioner Administered Drug Policies and Billing Guidance: Aducanumab-avwa (Aduhelm). New York State Medicaid Update November 2022 Volume 38 Number 13 (ny.gov)

8. Medicare National Coverage Determination for Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease (AD) (NCD 200.3). Effective Date: 04/07/2022; Implementation Date: 12/12/2022. Available at: https://www.cms.gov.
9. Medicare Learning Network Article National Coverage Determination 200.3: Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease. MLN Matters: MM12950. Related Request (CR) Number: 12950. Initial article release date: 12/08/2022.CMS announces new details of plan to cover Alzheimer's drugs Fact Sheet. June 22, 2023. Available at: www.cms.gov/newsroom/fact-sheets/cms-announces-new-details-plan-cover-alzheimers-drugs.
10. Clinical Dementia Rating - an overview | ScienceDirect Topics
11. Prescribing-Information.pdf (leqembi.com). Revised 07/20263.

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	Prior Auth
MVP Medicare Secure HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP Medicare WellSelect PPO	Prior Auth
MVP Medicare WellSelect Plus PPO	Prior Auth
MVP Medicare Patriot Plan PPO	Prior Auth
MVP DualAccess D-SNP HMO	Prior Auth
MVP DualAccess Complete D-SNP HMO	Prior Auth
MVP DualAccess Plus D-SNP HMO	Prior Auth
UVM Health Advantage Select PPO	Prior Auth
UVM Health Advantage Secure PPO	Prior Auth
UVM Health Advantage Preferred 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
UVM Health Advantage Select PPO	Prior Auth
UVM Health Advantage Secure PPO	Prior Auth
UVM Health Advantage Preferred PPO	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: Monoclonal Antibodies for Alzheimer's Disease

Type of Policy: **Drug Therapy**

Prior Approval Date: **N/A**

Approval Date: **11/01/2023**

Effective Date: **01/01/2024**

Related Policies: **N/A**

Drugs Requiring Prior Authorization (covered under the medical benefit)

J0172 Aduhelm (aducanumab-avwa)

J0174 Leqembi (lecanemab-irmb)

Overview

Aduhelm and Leqembi areamyloid 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 patients. Continued approval for this indication may be contingent upon verification of clinical benefit in confirmatory trials.

Aduhelm can cause amyloid related imaging abnormalities-edema (ARIA-E), which canbe observed on MRI as brain edema or sulcal effusions, and amyloid related imaging abnormalitieshemosiderin 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 patients 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.

Exclusions

- 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

MVP Health Care Medical Policy

Movement Disorders

Type of Policy:	**Drug Therapy**
Prior Approval Date:	**11/01/2022**
Approval Date:	**11/01/2023**
Effective Date:	**01/01/2024**
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 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.

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

Huntington's disease

All of the following must be met for coverage of Xenazine (brand and generic),Austedo/XR, and Ingrezza:

- Diagnosis of Huntington's disease including family history, clinical features (i.e., chorea, abnormal eye movement) and genetic testing
- Baseline Total Chorea Score from the Unified Huntington's Disease Rating Scale must be provided
- Approval for brand Xenazine will require contraindication or therapeutic failure of Austedo **and** tetrabenazine (generic Xenazine).

Initial approval will be for 12 weeks. Extension requests will require a decrease in the Total Chorea Score of 2.5 units from baseline. Approval will be for 12 months.

Tardive Dyskinesia

All of the following must be met for coverage of Austedo/XR and Ingrezza:

- Diagnosis of moderate to severe tardive dyskinesia
- If clinically appropriate the offending dopamine receptor blocking agent must be discontinued. If offending agent cannot be discontinued documentation must be provided identifying that the lowest effective dose is being used
- If patient is on a first-generation antipsychotic a switch to a second-generation antipsychotic should be attempted unless clinically inappropriate.
- Baseline Abnormal involuntary Movement Scale (AIMS)-items 1 to 8 scores must be provided

Initial approval will be for 12 weeks.

Extension request will require a decrease in the AIMS score of 3 points from baseline. Approval will be for 12 months

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Exclusions

- Dosing and/or frequency exceeding the FDA approved package labeling
- Patients with untreated or inadequately treated depression or who are suicidal

- Patients with long QT syndrome or arrhythmias associated with a prolong QT interval

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References

1. Bhidayasiri R, Fahn S, Weiner W, et al. Evidence-based guideline: Treatment of tardive syndromes. Report of the Guidelines Development Subcommittee of the American Academy of Neurology. Neurology, Jul 2013, 81(5) 463-469
2. Tarsy, Daniel MD. Tardive dyskinesia: Prevention and treatment. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com (Accessed on 1/3/2018)
3. Suchowersky, Oksana MD. Huntington disease: Management. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com (Accessed on 1/3/2018)
4. Nance M, Paulsen J, Rosenblatt A. A Physician's Guide to the Management of Huntington's Disease. Third Edition. Huntington's Disease Society of America. http://hdsas.org (Accessed on 1/3/2018)
5. Austedo (deutetrabenazine) tablets. Prescribing Information. North Wales, PA. Teva Pharmaceuticals. August 2017. Revised February 2023.
6. Ingrezza (valbenazine) capsules. Prescribing Information. San Diego, CA. Neurocrine Biosciences, Inc. October 2017. Revised August 2023.
7. Xenazine (tetrabenazine) tablets. Prescribing Information. Deerfield, IL. Valeant Pharmaceuticals North America LLC.
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

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

Mulpleta/Doptelet

Type of Policy: Drug Therapy
Prior Approval Date: 10/01/2022
Approval Date: 10/01/2023
Effective Date: 12/01/2023
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 patients with chronic liver disease who are scheduled to undergo a procedure. Doptelet is also indicated for the treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenia who have had an insufficient response to a previous treatment.

Policy Criteria

Treatment of thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure:

Mulpleta will be considered medically necessary in adults who meet the following criteria:

- Documentation of thrombocytopenia with current platelet count provided.
- Patient has a diagnosis of chronic liver disease
- Patient 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 will be considered medically necessary in adults who meet the following criteria:

- 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 patients with chronic liver disease to normalize platelet counts.
- Doptelet dosing exceeding 40mg per day when treating thrombocytopenia in adult patients with chronic immune thrombocytopenia who have had an insufficient response to a previous treatment.

References

1. Mulpleta [package insert]. Florham Park, NJ: Shionogi Pharmaceuticals, Inc; April 2020.
2. Doptelet [package insert]. Durham, NC: AkaRx, Inc.; June 2021.
3. Doptelet [package insert]. Durham, NC: AkaRx, Inc.; Revised July 2021.
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 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

Multiple Sclerosis Agents

Type of Policy: **Drug and Medical Therapy**
Prior Approval Date: **03/01/2023**
Approval Date: **11/01/2023**
Effective Date: **01/01/2024**
Related Policies: **Acthar**

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

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

Codes Requiring Prior Authorization (covered under the medical benefit)

J0202 Lemtrada (alemtuzmab injection, 1mg)

J2323 Tysabri (natalizumab injection, 1 mg)

J2329 Briumvi (ublituximab, 150mg/6mL solution for infusion)

Codes Not Requiring Prior Authorization (covered under the medical benefit)

J2350 Ocrevus (ocrelizumab injection, 1mg)

Drugs Requiring Prior Authorization (covered under the pharmacy benefit)

Extavia (Interferon Beta 1 B)
Zinbryta (daclizumab)
Mavenclad (cladribine)
Zeposia (ozanimod)
Kesimpta (ofatumumab)
Ponvory (ponesimod)

Drugs Not Requiring Prior Authorization (covered under the pharmacy benefit)

Aubagio (Teriflunomide)

Avonex (Interferon Beta 1A)
Betaseron (Interferon Beta 1B)
Copaxone (Glatiramer Acetate)
Gilenya (fingolimod)
Dimethyl Fumarate
Plegridy (peginterferon beta-1a)
Rebif (interferon Beta-1a)
Mayzent (Siponimod)
Bafiertam (monomethyl fumarate)
Vumerity (diroximel fumarate)

Overview

Multiple sclerosis (MS) is a chronic central nervous system disease that is an autoimmune disease. The body's own defense system attacks the myelin sheath which protects the nerve fibers in the central nervous system (CNS). Damage to the myelin sheath and nerve fibers may cause disruption to nerve impulses between the brain and spinal cord which can cause a variety of symptoms. The severity of symptoms and progression of disease is variable between individuals. FDA-approved drugs approved for multiple sclerosis included in this policy are indicated for functional improvement or disease modification.

FDA Approved Indications for MS:

Ampyra:

- A potassium channel blocker indicated to improve walking in patients with multiple sclerosis (MS).

Aubagio:

- Is a pyrimidine synthesis inhibitor indicated for the treatment of patients with relapsing forms of multiple sclerosis.

Avonex:

- Indicated in relapsing forms of MS to slow the accumulation of physical disability and decrease the frequency of clinical exacerbations. Patients with multiple sclerosis in whom efficacy has been demonstrated include patients who have experienced a first clinical episode and have MRI features consistent with multiple sclerosis. Efficacy in chronic progressive MS has not been established. Indicated for adult and pediatric patients. (*Intramuscular)*

Bafiertam

- Indicated for the treatment of relapsing forms of multiple sclerosis, including clinically isolated syndrome, relapsing-remitting disease and active secondary progressive disease.

Betaseron:

- Is indicated for the treatment of relapsing forms of multiple sclerosis to reduce the frequency of clinical exacerbations. Patients with multiple sclerosis in whom efficacy has been demonstrated include patients who have experienced a first clinical episode and have MRI features consistent with multiple sclerosis.

Briumvi:

- Briumvi is a CD20-directed cytolytic antibody indicated for the treatment of relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

Copaxone:

- Reduction of the frequency of relapses in patients with Relapsing-Remitting Multiple Sclerosis (RRMS), including patients who have experienced a first clinical episode and have MRI features consistent with multiple sclerosis. *(Subcutaneous)*

Extavia:

- Extavia is an interferon beta indicated for the treatment of relapsing forms of multiple sclerosis to reduce the frequency of clinical exacerbations, Patients with multiple sclerosis in whom efficacy has been demonstrated include patients who have experienced a first clinical episode and have MRI features consistent with multiple sclerosis.

Gilenya:

- is a sphingosine 1-phosphate receptor modulator indicated for the treatment of patients with relapsing forms of multiple sclerosis to reduce the frequency of clinical exacerbations and to delay the accumulation of physical disability.

Kesimpta

- Kesimpta is a human monoclonal antibody that binds specifically to the CD20 molecule expressed on normal B lymphocytes. Kesimpta is approved for the treatment of relapsing forms of multiple sclerosis, including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease.

Lemtrada:

- is a CD52-directed cytolytic monoclonal antibody indicated for the treatment of patients with relapsing forms of multiple sclerosis. Because of its safety profile,

the use of Lemtrada should generally be reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of MS.

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 patients with clinically isolated syndrome.

Mayzent

- is an oral sphingosine 1-phosphate receptor modulator indicated for relapsing forms of multiple sclerosis (including clinical isolated syndrome, relapsing-remitting disease and active secondary progressive disease. Due to heart rate decrease or atrioventricular conduction delays, a baseline electrocardiogram is recommended prior to the start of treatment and first dose monitoring is recommended for patients with preexisting cardiac conditions. Patients also must be tested for CYP2C9 variants to determine their CYP2C9 genotype prior to the start of therapy.

Ocrevus:

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

Plegridy:

- is an interferon beta indicated for the treatment of patients with relapsing forms of multiple sclerosis

Ponvory:

- is a oral sphingosine 1-phosphate receptor modulator indicated for the treatment of relapsing forms of multiple sclerosis in adults, to include clinically isolated syndrome, relapsing-remitting disease and active secondary progressive disease.

Rebif:

- For the treatment of relapsing forms of Multiple Sclerosis to decrease the frequency of clinical exacerbations and delay the accumulation of physical disability. Efficacy in chronic progressive MS has not been established.
  The results of multicenter, randomized trials demonstrate that initiation of an interferon (IFN)-b1-a delays the development of clinically defined MS (CDMS) in patients at high risk for this outcome. These studies do not, however, provide

evidence that the ultimate development of CDMS is prevented by such treatment nor that early treatment affects long term disability outcome.

Tecfidera:

- is indicated for the treatment of patients with relapsing forms of multiple sclerosis.

Tysabri:

- As monotherapy for the treatment of patients with relapsing forms of multiple sclerosis to delay the accumulation of physical disability and reduce the frequency of clinical exacerbations. TYSABRI is generally recommended for patients who have had an inadequate response to, or are unable to tolerate, an alternate MS therapy.

Vumerity

- Vumerity is an oral fumarate (like dimethyl fumarate) and it is indicated for the treatment of relapsing forms of multiple sclerosis, including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease.

Zeposia

- Is and oral sphingosine 1-phosphate receptor modulator which is indicated for the treatment of relapsing forms of multiple sclerosis in adults, including clinically isolated syndrome, relapsing- remitting disease and active secondary progressive disease.

Zinbryta:

- Is an interleukin-2 receptor blocking antibody indicated for the treatment of relapsing forms of MS in patients that have had inadequate response to two or more drugs indicated for the treatment of MS.

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:

Aubagio (Teriflunomide), Avonex (Interferon Beta 1A), Betaseron (Interferon Beta 1B), Copaxone (Glatiramer Acetate), Gilenya (fingolimod), Ocrevus (ocrelizumab), Plegridy (peginterferon beta-1a), Rebif (interferon beta 1-a) Dimethyl Fumarate, Mayzent (siponimod), Vumerity (Diroximal fumarate) and Bafiertam (Monomethyl Fumarate).

- Do not require prior authorization however must meet criteria below on retro review.

Non-Preferred Agents (prior authorization required):

Tysabri (natalizumab), Briumvi (ublituximab), Extavia (Interferon Beta 1 B), Mavenclad (cladribine), Zeposia (ozanimod), Kesimpta (ofatumumab), Ponvory (ponesimod) and Zinbryta (daclizumab)

- See Medicaid Variation for Tysabri and Lemtrada coverage

Non-Preferred Agents will be considered for coverage for the treatment of FDA approved indications for multiple sclerosis when all of the following are met:

- Prescribed by a neurologist.
- Greater than or equal to 18 years old.
- Monitoring and REMS requirements per the prescribing information are met.
- Neurology chart notes for the past 2 years, including all radiologic reports substantiate MS diagnosis consistent with prescribing information and detail previous treatment, if any.
- Documented failure or significant adverse effects to all preferred agents
    - Documented failure defined as:
        - At least 2 relapses within the past 12 months, AND
        - MRI identifying lesion progression.
- **Tysabri** (natalizumab) coverage will be limited to monotherapy for those patients meeting all the above criteria and have had an inadequate response to, or are unable to tolerate, both preferred and non-preferred MS therapies described above AND
    1. A baseline MRI scan must be obtained prior to natalizumab
    2. Patients must be evaluated at 3 and 6 months after the first infusion and every 6 months thereafter.
    3. Alternative treatment criteria for members currently with high disease activity, as defined by a high number of relapses while on treatment and

the progression of gadolinium-positive lesions on MRI, will be reviewed on a case-by-case basis

- **Lemtrada** (alemtuzumab)-Must have inadequate response to all preferred MS therapies AND not have Human Immunodeficiency Virus (HIV)
- **Briumvi** (ublituximab) coverage will be considered for those patients meeting all the above criteria for non-preferred agents and have had an inadequate response to, or are unable to tolerate ALL preferred MS therapies described above AND
    - Hepatitis B virus screening and quantitative serum immunoglobulin screening required prior to first dose
    - Patient must be assessed for active infection prior to every infusion; if patient has active infection, infusion must be delayed until infection is resolved.
    - Pregnancy test results prior to each infusion for females of reproductive potential
    - Patient must not have received live vaccines within 4 weeks and non-live vaccines within 2 weeks of treatment with Briumvi.

- Initial approval for up to 6 months for self-administered agents and up to 3 infusions in 3 months for Tysabri. For continuation of therapy for up to 6 months:
    - Continued benefit – decrease in number of relapses.
- Lemtrada (alemtuzumab)
    - Initial approval will be for 12mg/day on 5 consecutive days.
    - Second approval will be 12 months after initial approval for 12mg/day on three consecutive days if documentation identifies benefit from initial treatment and no adverse reactions
- Briumvi
    - Initial approval for Briumvi will be 2 infusions within one month (150mg initially, followed by 450mg infusion 2 weeks later)
    - Continuation of therapy will be 1 infusion every 24 weeks for subsequent infusions if documentation identifies benefit from initial treatment and no adverse reactions

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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

- For Medical drugs requiring prior authorization (Lemtrada 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/fullform.pdf and 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

Agents for Disease Modification exclusions:
- Combination use of disease modifying agents
- Doses exceeding prescribing information
- Patients 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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27. Mavenclad (cladribine) tablet. Prescribing Information. Rockland, MA. April 2019.
28. Mayzent (siponimod) tablet. Prescribing Information. East Hanover, NJ. March 2019.
29. Kesimpta (ofatumumab). Prescribing Information. East Hanover, NJ. Novartis Pharmaceuticals corporation. August 2020.
30. Vumerity (diroximel fumarate). Prescribing Information. Cambridge, MA. Biogen, INC. January 2021.
31. Zeposia (ozanimod). Prescribing Information. Summit, NJ. Celgene Corporation. March 2020.
32. Briumvi (ublituximab). Prescribing Information. Morrisville, NC. TG Therapeutics. Revised: December 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	
MVP Harmonious Health Care Plan	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP Medicare WellSelect PPO	Prior Auth
MVP Medicare WellSelect Plus PPO	Prior Auth
MVP Medicare Patriot Plan PPO	Prior Auth
MVP DualAccess D-SNP HMO	Prior Auth
MVP DualAccess Complete D-SNP HMO	Prior Auth
MVP DualAccess Plus D-SNP HMO	Prior Auth
UVM Health Advantage Select PPO	Prior Auth
UVM Health Advantage Secure PPO	Prior Auth
UVM Health Advantage Preferred 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
UVM Health Advantage Select PPO	Prior Auth
UVM Health Advantage Secure PPO	Prior Auth
UVM Health Advantage Preferred PPO	Prior Auth
MVP VT HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD
♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).	

***Medical Management Requirements**

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

MVP Health Care Medical Policy

Medicare Part B: Multiple Sclerosis Agents

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

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

Codes Requiring Prior Authorization (covered under the medical benefit)

J0202 Lemtrada (alemtuzmab injection, 1mg)

J2323 Tysabri (natalizumab injection, 1 mg)

J2329 Briumvi (ublituximab, 150mg/6mL solution for infusion)

Codes Not Requiring Prior Authorization (covered under the medical benefit)

J2350 Ocrevus (ocrelizumab injection, 1mg)

Overview

Multiple sclerosis (MS) is a chronic central nervous system disease that is an autoimmune disease. The body's own defense system attacks the myelin sheath which protects the nerve fibers in the central nervous system (CNS). Damage to the myelin sheath and nerve fibers may cause disruption to nerve impulses between the brain and spinal cord which can cause a variety of symptoms. The severity of symptoms and progression of disease is variable between individuals. FDA-approved drugs approved for multiple sclerosis included in this policy are indicated for functional improvement or disease modification.

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- A potassium channel blocker indicated to improve walking in patients with multiple sclerosis (MS).

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- Is a pyrimidine synthesis inhibitor indicated for the treatment of patients with relapsing forms of multiple sclerosis.

Avonex:

- Indicated in relapsing forms of MS to slow the accumulation of physical disability and decrease the frequency of clinical exacerbations. Patients with multiple sclerosis in whom efficacy has been demonstrated include patients who have experienced a first clinical episode and have MRI features consistent with multiple sclerosis. Efficacy in chronic progressive MS has not been established. Indicated for adult and pediatric patients. (*Intramuscular)*

Bafiertam

- Indicated for the treatment of relapsing forms of multiple sclerosis, including clinically isolated syndrome, relapsing-remitting disease and active secondary progressive disease.

Betaseron:

- Is indicated for the treatment of relapsing forms of multiple sclerosis to reduce the frequency of clinical exacerbations. Patients with multiple sclerosis in whom efficacy has been demonstrated include patients who have experienced a first clinical episode and have MRI features consistent with multiple sclerosis.

Briumvi:

- Briumvi is a CD20-directed cytolytic antibody indicated for the treatment of relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

Copaxone:

- Reduction of the frequency of relapses in patients with Relapsing-Remitting Multiple Sclerosis (RRMS), including patients who have experienced a first clinical episode and have MRI features consistent with multiple sclerosis. *(Subcutaneous)*

Extavia:

- Extavia is an interferon beta indicated for the treatment of relapsing forms of multiple sclerosis to reduce the frequency of clinical exacerbations, Patients with multiple sclerosis in whom efficacy has been demonstrated include patients who have experienced a first clinical episode and have MRI features consistent with multiple sclerosis.

Gilenya:

- is a sphingosine 1-phosphate receptor modulator indicated for the treatment of patients with relapsing forms of multiple sclerosis to reduce the frequency of clinical exacerbations and to delay the accumulation of physical disability.

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Lemtrada:

- is a CD52-directed cytolytic monoclonal antibody indicated for the treatment of patients with relapsing forms of multiple sclerosis. Because of its safety profile, the use of Lemtrada should generally be reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of MS.

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 patients with clinically isolated syndrome.

Mayzent

- is an oral sphingosine 1-phosphate receptor modulator indicated for relapsing forms of multiple sclerosis (including clinical isolated syndrome, relapsing-remitting disease and active secondary progressive disease. Due to heart rate decrease or atrioventricular conduction delays, a baseline electrocardiogram is recommended prior to the start of treatment and first dose monitoring is recommended for patients with preexisting cardiac conditions. Patients also must be tested for CYP2C9 variants to determine their CYP2C9 genotype prior to the start of therapy.

Ocrevus:

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

Plegridy:

- is an interferon beta indicated for the treatment of patients with relapsing forms of multiple sclerosis

Ponvory:

- is a oral sphingosine 1-phosphate receptor modulator indicated for the treatment of relapsing forms of multiple sclerosis in adults, to include clinically isolated syndrome, relapsing-remitting disease and active secondary progressive disease.

Rebif:

- For the treatment of relapsing forms of Multiple Sclerosis to decrease the frequency of clinical exacerbations and delay the accumulation of physical disability. Efficacy in chronic progressive MS has not been established.
  The results of multicenter, randomized trials demonstrate that initiation of an interferon (IFN)-b1-a delays the development of clinically defined MS (CDMS) in patients at high risk for this outcome. These studies do not, however, provide evidence that the ultimate development of CDMS is prevented by such treatment nor that early treatment affects long term disability outcome.

Tecfidera:

- is indicated for the treatment of patients with relapsing forms of multiple sclerosis.

Tysabri:

- As monotherapy for the treatment of patients with relapsing forms of multiple sclerosis to delay the accumulation of physical disability and reduce the frequency of clinical exacerbations. TYSABRI is generally recommended for patients who have had an inadequate response to, or are unable to tolerate, an alternate MS therapy.

Vumerity

- Vumerity is an oral fumarate (like dimethyl fumarate) and it is indicated for the treatment of relapsing forms of multiple sclerosis, including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease.

Zeposia

- Is and oral sphingosine 1-phosphate receptor modulator which is indicated for the treatment of relapsing forms of multiple sclerosis in adults, including clinically isolated syndrome, relapsing- remitting disease and active secondary progressive disease.

Zinbryta:

- Is an interleukin-2 receptor blocking antibody indicated for the treatment of relapsing forms of MS in patients that have had inadequate response to two or more drugs indicated for the treatment of MS.

Indications/Criteria

Agents for Disease Modification

Treatment will be considered for coverage for the treatment of the FDA approved indications for multiple sclerosis:

Preferred Agents:
Ocrevus (ocrelizumab)

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

Non-Preferred Agents (prior authorization required):
Tysabri (natalizumab), Lemtrada (alemtuzumab), Briumvi (ublituximab),

Non-Preferred Agents will be considered for coverage for the treatment of FDA approved indications for multiple sclerosis when all of the following are met:

- Prescribed by a neurologist.
- Greater than or equal to 18 years old.
- Monitoring and REMS requirements per the prescribing information are met.
- Neurology chart notes for the past 2 years, including all radiologic reports substantiate MS diagnosis consistent with prescribing information and detail previous treatment, if any.
- Documented failure or significant adverse effects to all preferred agents
    - Documented failure defined as:
        - At least 2 relapses within the past 12 months, AND
        - MRI identifying lesion progression.
- **Tysabri** (natalizumab) coverage will be limited to monotherapy for those patients meeting all the above criteria and have had an inadequate response to, or are

unable to tolerate, both preferred and non-preferred MS therapies described above AND

1. A baseline MRI scan must be obtained prior to natalizumab
2. Patients must be evaluated at 3 and 6 months after the first infusion and every 6 months thereafter.
3. Alternative treatment criteria for members currently with high disease activity, as defined by a high number of relapses while on treatment and the progression of gadolinium-positive lesions on MRI, will be reviewed on a case-by-case basis

- **Lemtrada** (alemtuzumab)-Must have inadequate response to all preferred MS therapies AND not have Human Immunodeficiency Virus (HIV)
- **Briumvi** (ublituximab) coverage will be considered for those patients meeting all the above criteria for non-preferred agents and have had an inadequate response to, or are unable to tolerate ALL preferred MS therapies described above AND
    - Hepatitis B virus screening and quantitative serum immunoglobulin screening required prior to first dose
    - Patient must be assessed for active infection prior to every infusion; if patient has active infection, infusion must be delayed until infection is resolved.
    - Pregnancy test results prior to each infusion for females of reproductive potential
    - Patient must not have received live vaccines within 4 weeks and non-live vaccines within 2 weeks of treatment with Briumvi.

Initial approval for up to 6 months for self-administered agents and up to 3 infusions in 3 months for Tysabri.

- For continuation of therapy for up to 6 months:
    - Continued benefit – decrease in number of relapses.
- Lemtrada (alemtuzumab)
    - Initial approval will be for 12mg/day on 5 consecutive days.
    - Second approval will be 12 months after initial approval for 12mg/day on three consecutive days if documentation identifies benefit from initial treatment and no adverse reactions
- Briumvi
    - Initial approval for Briumvi will be 2 infusions within one month (150mg initially, followed by 450mg infusion 2 weeks later)

- Continuation of therapy will be 1 infusion every 24 weeks for subsequent infusions if documentation identifies benefit from initial treatment and no adverse reactions

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Exclusions

Lemtrada
- Use beyond two years

Briumvi
- Active hepatitis B virus infection
- History of life-threatening infusion reaction to Briumvi

Agents for Disease Modification exclusions:
- Combination use of disease modifying agents
- Doses exceeding prescribing information
- Patients 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.

References

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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: **N/A**
Approval Date: **11/01/2023**
Effective Date: **1/1/2024**

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	Kanjinti Herceptin Hylecta Ogivri Ontruzant Herzuma
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
Aloxi Emend Fosaprepitant	Akynzeo Cinvanti Sustol

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

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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

Cancer Guidance Program-Oncology Medication Coverage and Review

Type of Policy:	**Drug/Medical Therapy**
Prior Approval Date:	
Approval Date:	**11/01/2023**
Effective Date:	**1/1/2024**
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*:

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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	Kanjinti Herceptin Hylecta Ogivri Ontruzant Herzuma
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
Aloxi Emend Fosaprepitant	Akynzeo Cinvanti Sustol

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).

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- 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

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.

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	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
UVM Health Advantage Secure PPO	Prior Auth
UVM Health Advantage Preferred 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
UVM Health Advantage Select PPO	Prior Auth
UVM Health Advantage Secure PPO	Prior Auth
UVM Health Advantage Preferred PPO	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	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).	

***Medical Management Requirements**

Prior Auth	Prior Authorization Required
Potential for Retrospective Review	No Prior Authorization Required. May be subject to Retrospective Review.
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: Densoumab (Prolia and Xgeva)

Type of Policy:	**Drug/Medical Therapy**
Prior Approval Date:	**N/A**
Approval Date:	**11/01/2023**
Effective Date:	**1/01/2024**

Related Policies:

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

Considerations

Coverage guidelines for participants in the Cancer Guidance Program (CGP) where some Certificates of Coverage allow for coverage of experimental/investigational/unproven treatments for life-threatening illnesses when certain conditions are met. The member specific benefit plan document must be consulted to make coverage decisions for this service. Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances when certain conditions are met. Where such mandates apply, they supersede language in the benefit document or in the medical or drug policy. Benefit coverage for an otherwise unproven service for the treatment of serious rare diseases may occur when certain conditions are met. Refer to the Policy and Procedure addressing the treatment of serious rare diseases.

Background

Osteoporosis is characterized by low bone mass, microarchitectural disruption, and increased skeletal fragility. The Word Health Organization (WHO) established diagnostic thresholds for bone mineral density (BMD) by dual-energy x-ray absorptiometry (DXA) according to the standard deviation (SD) difference between a patient's BMD and that of a young adult reference population (T-score). A T-score of -2.5 SD or below is defined as osteoporosis, provided that other causes of low BMD have been ruled out, and a T-score between -1 and -2.5 SD is defined as osteopenia. Additionally, guidelines state that osteoporosis can be diagnosed by one of the following: (1) Presence of fragility fractures in the absence of other metabolic bone disorders; (2) T-score ≤ −2.5 SD in the lumbar spine (antero-posterior), femoral neck, total hip, or one-third radius; or (3) T-score between −1.0 and −2.5 and increased fracture risk using the FRAX® (fracture risk assessment tool) country-specific thresholds. The FRAX tool is designed to assist clinicians in predicting the ten-year probability of hip fracture and 10-year probability of a major osteoporotic fracture (spine, forearm, hip or shoulder fracture) with or without the addition of femoral neck BMD. In the United States, a clinical diagnosis of osteoporosis may be made when the FRAX 10-year probability of major osteoporotic fracture (hip, clinical spine, proximal humerus, or forearm) is greater than or equal to 20 percent or the FRAX 10- year probability of hip fracture is greater than or equal to 3 percent. Denosumab binds to RANKL, a transmembrane or soluble protein essential for the formation, function, and survival of osteoclasts, the cells responsible for bone resorption, thereby modulating calcium release from bone. Denosumab prevents RANKL from activating its receptor, RANK, on the surface of osteoclasts, their precursors, and osteoclast-like giant cells. Prevention of the RANKL/RANK interaction inhibits osteoclast formation, function, and survival, thereby decreasing bone resorption and increasing bone mass and strength in both cortical and trabecular bone. Increased osteoclast activity, stimulated by RANKL, is a mediator of bone pathology in solid tumors with osseous metastases. Similarly, giant cell tumors of bone consist of stromal cells expressing RANKL and osteoclast-like giant cells expressing RANK receptor and signaling through the RANK receptor contributes to osteolysis and tumor growth. (Amgen, 2022; Amgen 2020)

Instructions for Use

This medical guideline aids in interpreting National Comprehensive Cancer Network (NCCN)® cancer guidelines. Before using this guideline, please check the member specific benefit plan documents and any applicable federal or state mandates. Optum

reserves the right to modify its Guidelines as necessary. This Guideline is provided for informational purposes and does not constitute medical advice.

This Guideline may also be applied to Medicare Advantage plans in some instances. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence. (Medicare IOM Pub. No. 100-16, Chapter 4, Section 90.5)

Optum Medical Benefit Guidelines are intended to be used in connection with the independent professional medical judgement of a qualified health care provider and do not constitute the practice of medicine or medical advice.

Recommendation

Prolia (densoumab)

Prolia® is proven to increase bone mass in patients at high risk for fracture receiving androgen deprivation therapy for non-metastatic prostate cancer when all the following criteria are met:

- Initial Therapy
    - Diagnosis of non-metastatic prostate cancer; and
    - Patient is receiving androgen deprivation therapy; and
    - Prolia dosing is in accordance with the United States Food and Drug Administration approved labeling;
    - History of failure, contraindications, or intolerance to other available osteoporosis therapy (e.g., oral bisphosphonates, intravenous bisphosphonates); and
    - Authorization is for no more than 12 months.

- Reauthorization/Continuation of Care Criteria

- For patients currently on Prolia® to increase bone mass in patients at high risk for fracture receiving androgen deprivation therapy for non-metastatic prostate cancer, continued use will be approved based on the following criteria:
- Patient is receiving androgen deprivation therapy; and
- Provider attests to a positive clinical response; and
- Prolia® dosing is in accordance with the United States Food and Drug Administration approved labeling; and
- Authorization is for no more than 12 months.

Prolia® is proven to treat patients at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer when all the following criteria are met:

- Initial Therapy
  - Diagnosis of breast cancer; and
  - Patient is receiving aromatase inhibitor therapy; and
  - Prolia dosing is in accordance with the United States Food and Drug Administration approved labeling;
  - History of failure, contraindications, or intolerance to other available osteoporosis therapy (e.g., oral bisphosphonates, intravenous bisphosphonates); and
  - Authorization is for no more than 12 months.

- Reauthorization/Continuation of Care Criteria
  - For patients currently on Prolia® to treat patients at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer, continued use will be approved based on the following criteria:
    - Patient is receiving aromatase inhibitor; and

        - Provider attests to a positive clinical response; and
        - Prolia® dosing is in accordance with the United States Food and Drug Administration approved labeling; and
    - Authorization is for no more than 12 months.

Xgeva (densoumab)

Xgeva is proven for the prevention of skeletal-related events in patients with multiple myeloma and with bone metastases from solid tumors when all of the following criteria are met:

- Initial Therapy
    - One of the following:
        - Diagnosis of multiple myeloma
        - Presences of metastatic disease secondary to a solid tumor (e.g., bladder, breast, kidney, lung, ovaria, thyroid, etc.)

And

    - Xgeva® dosing is in accordance with the United States Food and Drug Administration approved labeling;
    - History of failure, contraindications, or intolerance to other available osteoporosis therapy (e.g., oral bisphosphonates, intravenous bisphosphonates); and
    - Authorization is for no more than 12 months.

- Reauthorization/Continuation of Care Criteria
    - For patients currently on Xgeva® for the prevention of skeletal-related events in patients with multiple myeloma and with bone metastases from solid tumors, continued use will be approved based on the following criteria:
        - Provider attests to a positive clinical response; and

- Xgeva® dosing is in accordance with the United States Food and Drug Administration approved labeling; and
- Authorization is for no more than 12 months.

Xgeva® is proven for the treatment of giant cell tumor of the bone when all the following criteria are met:

- Initial Therapy
  - Patient is one of the following:
    - Patient is ≥ 18 years of age
    - Patient is a skeletally mature adolescent as defined by having at least 1 mature long bone (e.g., closed epiphyseal growth plat of the humerus)

And

  - Diagnosis of localized, recurrent or metastatic giant cell tumor of the bone; and
  - Disease is one of the following:
    - Unresectable
    - Surgical resection is likely to result in severe morbidity

And

  - Xgeva® dosing is in accordance with the United States Food and Drug Administration approved labeling;
  - Authorization is for no more than 12 months.

- Reauthorization/Continuation of Care Criteria
  - For patients currently on Xgeva for the treatment of giant cell tumor of the bone, continued use will be approved based on the following criteria:

- Provider attests to the positive clinical response; and
- Xgeva® dosing is in accordance with the United States Food and Drug Administration approved labeling; and
- Authorization is for no more than 12 months.

Xgeva® is proven for the treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy when all of the following criteria are met:

- Initial Therapy
    - Diagnosis of hypercalcemia of malignancy as defined as: albumin-corrected serum calcium level greater than 12.5 mg/dL (3.1 mmol/L); and
    - Refractory (within the last 30 days), contraindication (including renal insufficiency), or intolerance to treatment with intravenous bisphosphonates therapy (e.g., pamidronate, zoledronic acid); and
    - Xgeva® dosing is in accordance with the United States Food and Drug Administration approved labeling; and
    - Authorization is for no more than 12 months.

- Reauthorization/Continuation of Care Criteria
    - For patients currently on Xgeva® for the treatment of hypercalcemia of malignancy, continued use will be approved based on the following criteria:
        - Provider attests to a positive clinical response; and
        - Xgeva® dosing is in accordance with the treatment of hypercalcemia of malignancy, continued use will be approved based on the following criteria:
        - Authorization is for no more than 12 months.

Xgeva® is proven for treatment of osteopenia/osteoporosis in patients with systemic mastocytosis with bone pain not responding to bisphosphonates when all the following criteria are met:

- Initial Therapy
    - Diagnosis of systemic mastocytosis; and
    - Patient has bone pain; and
    - Diagnosis of osteoporosis or osteopenia based on one of the following:
        - BMD T-score ≤ -1 based on BMD measurements from lumbar spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site); or
        - History of one of the following resulting from minimal trauma:
            - Vertebral compression fracture
            - Fracture of the hip
            - Fracture of the distal radius
            - Fracture of the pelvis
            - Fracture of the proximal humerus

And

- Refractory (within the past 30 days), contraindication (including renal insufficiency), or intolerance to treatment with intravenous bisphosphonate therapy (e.g., pamidronate, zoledronic acid) (for Medicare reviews, refer to the CMS section*); and
- Xgeva® dosing is in accordance with the United States Food and Drug Administration approved labeling; and
- Authorization for no more than 12 months.

- Reauthorization/Continuation of Care Criteria

- For patients currently on Xgeva for the treatment of osteopenia/osteoporosis in patients with systemic mastocytosis with bone pain not responding to bisphosphonates, continued use will be approved based on the following criteria:
    - Provider attests to a positive clinical response; and
    - Xgeva® dosing is in accordance with the United States Food and Drug Administration approved labeling; and
    - Authorization is for no more than 12 months.

Unproven/Not Medically Necessary

Denosumab is unproven and not medically necessary for the following indications:

- Combination therapy of denosumab and intravenous bisphosphonates
- Bone loss associated with hormone-ablation therapy (other than aromatase inhibitors) in breast/prostate cancer
- Cancer pain
- Central giant cell granuloma
- Hyper-parathyroidism
- Immobilization hypercalcemia
- Osteogenesis Imperfecta
- Osteopenia

Clinical Evidence

Prolia

Patients at High Risk for Fracture Receiving Androgen Deprivation Therapy for Non-Metastatic Prostate Cancer

Smith ME et al investigated the effects of denosumab in a double-blind, multicenter study, on bone mineral density and fractures in patients with non-metastatic prostate cancer who are receiving androgen-deprivation therapy.8 Patients were randomly assigned to receive denosumab at a dose of 60 mg subcutaneously every 6 months or

placebo (n = 734 per group). The primary end point was percent change in bone mineral density at the lumbar spine at 24 months. Secondary end points included percent change in bone mineral densities at the femoral neck and total hip at 24 months and at all three sites at 36 months, as well as frequency of new vertebral fractures. At 24 months, patients receiving denosumab experienced an increase in bone mineral density of the lumbar spine by 5.6% as compared with a loss of 1.0% in the placebo group ($p < 0.001$). Significant differences between the placebo and denosumab groups were seen at 1 month and continued through 36 months. Treatment was also associated with significant increases in bone mineral density at the total hip, femoral neck, and distal third of the radius. Patients who received denosumab had a decreased incidence of new vertebral fractures at 36 months (1.5%, vs. 3.9% with placebo) (relative risk, 0.38; 95% confidence interval, 0.19 to 0.78; $p = 0.006$). Similar rates of adverse events were reported in the two groups. (Smith, 2009) The authors conclude that denosumab is associated with increased bone mineral density at all sites and a reduction in the incidence of new vertebral fractures among patients receiving androgen-deprivation therapy for non-metastatic prostate cancer. (ClinicalTrials.gov number, NCT00089674)

Professional Societies

National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology (NCCN Guidelines®)

Several National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology (NCCN Guidelines®) include denosumab as a treatment for several conditions related to malignant disease. The following NCCN Guidelines® state (NCCN, 2023):

- For invasive and inflammatory breast cancer, the NCCN recommends (Category 2A) denosumab to be considered in postmenopausal (natural or induced) patients receiving adjuvant endocrine therapy along with calcium and vitamin D supplementation to maintain or improve bone mineral density and reduce risk of fractures.
- For prostate cancer, the NCCN recommends (Category 2A) denosumab for the prevention or treatment of osteoporosis during androgen deprivation therapy (ADT) for patients with high fracture risk.

Xgeva

In an ad hoc analysis of the phase 3 clinical trial of 1,776 patients with metastases from solid tumors or multiple myeloma, where it was shown that denosumab was non-inferior to zoledronic acid (ZA) in delaying or preventing SREs, Henry et al reports outcomes in the subgroup of 1,597 patients with solid tumors, excluding multiple myeloma.17 In the ad hoc analysis, denosumab significantly delayed time to first on-study SRE compared to ZA (HR, 0.81; 95% CI, 0.68–0.96) and time to first-and

subsequent SREs (RR, 0.85; 95% CI, 0.72–1.00). Denosumab also significantly delayed time to development of moderate or severe pain (HR, 0.81; 95% CI, 0.66–1.00), pain worsening (HR, 0.83; 95% CI, 0.71–0.97), and worsening pain interference in patients with no/mild baseline pain (HR, 0.77; 95% CI, 0.61–0.96). Overall survival was similar in both groups. The median KM estimate was 10.7 months for denosumab-treated patients and 10.0 months for ZA-treated patients (HR, 0.92; 95% CI, 0.81– 1.05: p = 0.215). Similarly, there was no difference between groups in time to disease progression. The median KM estimate was 5.3 (4.9, 5.7) months for denosumab-treated and 5.4 (4.8, 5.7) months for ZA-treated patients (HR, 0.96; 95% CI, 0.85–1.08: p = 0.497). The authors concluded that denosumab was more effective in delaying the incidence of SREs, however did not significantly affect the overall incidence or disease progression or overall survival.

In a double-blind, double-dummy, phase III clinical trial, Henry et al compared denosumab with zoledronic acid (ZA) for delaying or preventing skeletal-related events (SRE) in patients with advanced cancer and bone metastases (excluding breast and prostate) or myeloma (Henry, 2011). Patients were randomly assigned to receive either monthly subcutaneous denosumab 120mg (n = 886) or intravenous ZA 4mg (dose adjustment for renal impairment; n = 890). The primary end point was time to first on-study SRE (pathologic fracture, radiation or surgery to bone, or spinal cord compression). The trial demonstrated that denosumab was noninferior to ZA in delaying time to first on-study SRE (hazard ratio, 0.84; 95% CI, 0.71 to 0.98; p = 0.0007). Denosumab was not statistically superior to ZA in delaying time to first on-study SRE (p = 0.03 unadjusted; p = 0.06 adjusted for multiplicity) or time to first-and-subsequent (multiple) SRE (rate ratio, 0.90; 95% CI, 0.77 to 1.04; p = 0.14). Overall survival and disease progression were similar between groups. Hypocalcemia occurred more frequently with denosumab. Osteonecrosis of the jaw occurred at similarly low rates in both groups. Acute-phase reactions after the first dose occurred more frequently with ZA, as did renal adverse events and elevations in serum creatinine. The authors concluded that denosumab was noninferior to ZA in preventing or delaying first on-study SRE in patients with advanced cancer metastatic to bone or myeloma.

Fizazi et al evaluated the comparison of denosumab with zoledronic acid (ZA) for the prevention of skeletal-related events in men with bone metastases from castration-resistant prostate cancer (Fizazi, 2011). In a phase 3 clinical study, 1904 men with castration-resistant prostate cancer had no previous exposure to IV bisphosphonate were randomized 1:1 to either receive 120mg subcutaneous denosumab plus IV placebo (n = 950), or 4mg IV ZA plus subcutaneous placebo (n = 951) every 4 weeks. The primary endpoint was time to first on-study skeletal related event (pathological fracture, radiation therapy, surgery to bone, or spinal cord compression), and was assessed for non-inferiority. The same outcome was further assessed for superiority as a secondary endpoint. Efficacy analysis was by intention to treat. Median time to first on-study

skeletal-related event was 20.7 months (95% CI 18.8–24.9) with denosumab compared with 17.1 months (15.0–19.4) with zoledronic acid (hazard ratio 0.82, 95% CI 0.71–0.95; p = 0.0002 for non-inferiority; p = 0.008 for superiority). While there was a three-month increase in the time to first skeletal-related events observed with denosumab in men with prostate cancer, there was no clinically meaningful difference in skeletal-related events for denosumab as compared with zoledronic acid: Overall confirmed events (ZA vs. denosumab) 41% vs. 36%; radiation to bone (21% vs. 19%); pathological fracture (15% vs. 14%); spinal cord compression (4% vs. 3%); surgery to bone (< 1% vs. < 1%). The authors concluded that denosumab was better than ZA for delaying the time to first SRE, however, was not significantly better at preventing the overall incidence of SREs versus zoledronic acid.

Professional Societies

National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology (NCCN Guidelines®)

Several National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology (NCCN Guidelines®) include denosumab as a treatment for several conditions related to malignant disease. The following NCCN Guidelines® state (NCCN, 2023)

For giant cell tumor of the bone, the NCCN recommends (Category 2A) denosumab as a single agent or combined with serial embolization (preferred), and/or radiation therapy for resectable disease with unacceptable morbidity and/or unresectable axial lesions for patients with localized disease, metastases at presentation, or recurrence. Denosumab is also recommended as a single agent for unresectable metastatic disease, unresectable metastatic recurrence or considered prior to surgery for resectable local recurrence.

- For invasive or inflammatory breast cancer, the NCCN recommends (Category 1) denosumab to be used with calcium and vitamin D supplementation in addition to chemotherapy or endocrine therapy for bone metastasis in patients with expected survival ≥ 3 months with adequate renal function.
- For kidney cancer, the NCCN recommends (Category 2A) denosumab to be used as a component of best supportive care for bony metastases.
- For multiple myeloma, the NCCN recommends (Category 2A) denosumab to be used in combination with primary myeloma therapy and is the preferred agent in patients with renal insufficiency.

- For non-small cell lung cancer, the NCCN recommends (Category 2A) denosumab to be considered for supportive therapy in patients with bone metastases.
- For prostate cancer, the NCCN recommends (Category 1) denosumab as the preferred agent for the prevention of skeletal-related events in patients with castration-resistant prostate cancer who have documented bone metastases and creatinine clearance greater than 30 ml/min.
- For systemic mastocytosis, the NCCN recommends (Category 2A) denosumab as second-line therapy for osteopenia/osteoporosis in patients with bone pain not responding to bisphosphonates or for patients who are not candidates for bisphosphonates because of renal insufficiency.
- For thyroid carcinoma (anaplastic, follicular, Hürthle cell, medullary, papillary), the NCCN recommends (Category 2A) denosumab to be considered for bone metastases or palliative care for bone metastases (anaplastic).

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Prolia (denosumab) is a RANK ligand inhibitor indicated for the following uses:

- Treatment of postmenopausal women with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy. In postmenopausal women with osteoporosis, Prolia reduces the incidence of vertebral, nonvertebral, and hip fractures.
- Treatment to increase bone mass in men with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.
- Treatment of glucocorticoid-induced osteoporosis in men and women at high risk of fracture who are either initiating or continuing systemic glucocorticoids in a daily dosage equivalent to 7.5 mg or greater of prednisone and expected to remain on glucocorticoids for at least 6 months. High risk of fracture is defined as

a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy.
- Treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer. In these patients Prolia also reduced the incidence of vertebral fractures.
- Treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer.

Xgeva (denosumab) is a RANK ligand inhibitor indicated for the prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors, the treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity, and for the treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy. (Amgen, 2020)

Medicare does not have a National Coverage Determination (NCD) specifically for denosumab (Xgeva® and Prolia®). Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist; refer to the LCDs/LCAs for Bisphosphonates (Intravenous [IV] and Monoclonal Antibodies in the Treatment of Osteoporosis and their Other Indications and Drugs and Biologicals, Coverage of, for Label and Off-Label Uses.

In general, Medicare may cover outpatient (Part B) drugs that are furnished "incident to" a physician's service provided that the drugs are not usually self-administered by the patients who take them. Refer to the Medicare Benefit Policy Manual, Chapter 15, Section 50 – Drugs and Biologicals. (Accessed March 6, 2023)

Applicable Codes

HCPCS Code	Description
J0897	Injection, denosumab, 1 mg

Diagnosis Code	Description
Prolia®	
M81.8	Other osteoporosis without current pathological fracture
M80.811A	Other osteoporosis with current pathological fracture, right shoulder, initial encounter for fracture
M80.811D	Other osteoporosis with current pathological fracture, right shoulder, subsequent encounter for fracture with routine healing

M80.811G	Other osteoporosis with current pathological fracture, right shoulder, subsequent encounter for fracture with delayed healing
M80.811K	Other osteoporosis with current pathological fracture, right shoulder, subsequent encounter for fracture with nonunion
M80.811P	Other osteoporosis with current pathological fracture, right shoulder, subsequent encounter for fracture with malunion
M80.811S	Other osteoporosis with current pathological fracture, right shoulder, sequela
M80.8AXA	Other osteoporosis with current pathological fracture, other site, initial encounter for fracture
M80.8AXD	Other osteoporosis with current pathological fracture, other site, subsequent encounter for fracture with routine healing
M80.8AXG	Other osteoporosis with current pathological fracture, other site, subsequent encounter for fracture with delayed healing
M80.8AXK	Other osteoporosis with current pathological fracture, other site, subsequent encounter for fracture with nonunion
M80.8AXP	Other osteoporosis with current pathological fracture, other site, subsequent encounter for fracture with malunion
M80.8AXS	Other osteoporosis with current pathological fracture, other site, sequela
M80.812A	Other osteoporosis with current pathological fracture, left shoulder, initial encounter for fracture
M80.812D	Other osteoporosis with current pathological fracture, left shoulder, subsequent encounter for fracture with routine healing
M80.812G	Other osteoporosis with current pathological fracture, left shoulder, subsequent encounter for fracture with delayed healing
M80.812K	Other osteoporosis with current pathological fracture, left shoulder, subsequent encounter for fracture with nonunion
M80.812P	Other osteoporosis with current pathological fracture, left shoulder, subsequent encounter for fracture with malunion
M80.812S	Other osteoporosis with current pathological fracture, left shoulder, sequela
M80.819A	Other osteoporosis with current pathological fracture, unspecified shoulder, initial encounter for fracture
M80.819D	Other osteoporosis with current pathological fracture, unspecified shoulder, subsequent encounter for fracture with routine healing
M80.819G	Other osteoporosis with current pathological fracture, unspecified shoulder, subsequent encounter for fracture with delayed healing
M80.819K	Other osteoporosis with current pathological fracture, unspecified shoulder, subsequent encounter for fracture with nonunion
M80.819P	Other osteoporosis with current pathological fracture, unspecified shoulder, subsequent encounter for fracture with malunion
M80.819S	Other osteoporosis with current pathological fracture, unspecified shoulder,

	sequela
M80.821A	Other osteoporosis with current pathological fracture, right humerus, initial encounter for fracture
M80.821D	Other osteoporosis with current pathological fracture, right humerus, subsequent encounter for fracture with routine healing
M80.821G	Other osteoporosis with current pathological fracture, right humerus, subsequent encounter for fracture with delayed healing
M80.821K	Other osteoporosis with current pathological fracture, right humerus, subsequent encounter for fracture with nonunion
M80.821P	Other osteoporosis with current pathological fracture, right humerus, subsequent encounter for fracture with malunion
M80.821S	Other osteoporosis with current pathological fracture, right humerus, sequela
M80.822A	Other osteoporosis with current pathological fracture, left humerus, initial encounter for fracture
M80.822D	Other osteoporosis with current pathological fracture, left humerus, subsequent encounter for fracture with routine healing
M80.822G	Other osteoporosis with current pathological fracture, left humerus, subsequent encounter for fracture with delayed healing
M80.822K	Other osteoporosis with current pathological fracture, left humerus, subsequent encounter for fracture with nonunion
M80.822P	Other osteoporosis with current pathological fracture, left humerus, subsequent encounter for fracture with malunion
M80.822S	Other osteoporosis with current pathological fracture, left humerus, sequela
M80.829A	Other osteoporosis with current pathological fracture, unspecified humerus, initial encounter for fracture
M80.829D	Other osteoporosis with current pathological fracture, unspecified humerus, subsequent encounter for fracture with routine healing
M80.829G	Other osteoporosis with current pathological fracture, unspecified humerus, subsequent encounter for fracture with delayed healing
M80.829K	Other osteoporosis with current pathological fracture, unspecified humerus, subsequent encounter for fracture with nonunion
M80.829P	Other osteoporosis with current pathological fracture, unspecified humerus, subsequent encounter for fracture with malunion
M80.829S	Other osteoporosis with current pathological fracture, unspecified humerus, sequela
M80.831A	Other osteoporosis with current pathological fracture, right forearm, initial encounter for fracture
M80.831D	Other osteoporosis with current pathological fracture, right forearm, subsequent encounter for fracture with routine healing
M80.831G	Other osteoporosis with current pathological fracture, right forearm, subsequent

	encounter for fracture with delayed healing
M80.831K	Other osteoporosis with current pathological fracture, right forearm, subsequent encounter for fracture with nonunion
M80.831P	Other osteoporosis with current pathological fracture, right forearm, subsequent encounter for fracture with malunion
M80.831S	Other osteoporosis with current pathological fracture, right forearm, sequela
M80.832A	Other osteoporosis with current pathological fracture, left forearm, initial encounter for fracture
M80.832D	Other osteoporosis with current pathological fracture, left forearm, subsequent encounter for fracture with routine healing
M80.832G	Other osteoporosis with current pathological fracture, left forearm, subsequent encounter for fracture with routine healing
M80.832K	Other osteoporosis with current pathological fracture, left forearm, subsequent encounter for fracture with nonunion
M80.832P	Other osteoporosis with current pathological fracture, left forearm, subsequent encounter for fracture with malunion
M80.832S	Other osteoporosis with current pathological fracture, left forearm, sequela
M80.839A	Other osteoporosis with current pathological fracture, unspecified forearm, initial encounter for fracture
M80.839D	Other osteoporosis with current pathological fracture, unspecified forearm, subsequent encounter for fracture with routine healing
M80.839G	Other osteoporosis with current pathological fracture, unspecified forearm, subsequent encounter for fracture with delayed healing
M80.839K	Other osteoporosis with current pathological fracture, unspecified forearm, subsequent encounter for fracture with nonunion
M80.839P	Other osteoporosis with current pathological fracture, unspecified forearm, subsequent encounter for fracture with malunion
M80.839S	Other osteoporosis with current pathological fracture, unspecified forearm, sequela
M80.841A	Other osteoporosis with current pathological fracture, right hand, initial encounter for fracture
M80.841D	Other osteoporosis with current pathological fracture, right hand, subsequent encounter for fracture with routine healing
M80.841G	Other osteoporosis with current pathological fracture, right hand, subsequent encounter for fracture with delayed healing
M80.841K	Other osteoporosis with current pathological fracture, right hand, subsequent encounter for fracture with nonunion
M80.841P	Other osteoporosis with current pathological fracture, right hand, subsequent encounter for fracture with malunion
M80.841S	Other osteoporosis with current pathological fracture, right hand, sequela

M80.842A	Other osteoporosis with current pathological fracture, left hand, initial encounter for fracture
M80.842D	Other osteoporosis with current pathological fracture, left hand, subsequent encounter for fracture with routine healing
M80.842G	Other osteoporosis with current pathological fracture, left hand, subsequent encounter for fracture with delayed healing
M80.842K	Other osteoporosis with current pathological fracture, left hand, subsequent encounter for fracture with nonunion
M80.842P	Other osteoporosis with current pathological fracture, left hand, subsequent encounter for fracture with malunion
M80.842S	Other osteoporosis with current pathological fracture, left hand, sequela
M80.849A	Other osteoporosis with current pathological fracture, unspecified hand, initial encounter for fracture
M80.849D	Other osteoporosis with current pathological fracture, unspecified hand, subsequent encounter for fracture with routine healing
M80.849G	Other osteoporosis with current pathological fracture, unspecified hand, subsequent encounter for fracture with delayed healing
M80.849K	Other osteoporosis with current pathological fracture, unspecified hand, subsequent encounter for fracture with nonunion
M80.849P	Other osteoporosis with current pathological fracture, unspecified hand, subsequent encounter for fracture with malunion
M80.849S	Other osteoporosis with current pathological fracture, unspecified hand, sequela
M80.851A	Other osteoporosis with current pathological fracture, right femur, initial encounter for fracture
M80.851D	Other osteoporosis with current pathological fracture, right femur, subsequent encounter for fracture with routine healing
M80.851G	Other osteoporosis with current pathological fracture, right femur, subsequent encounter for fracture with delayed healing
M80.851K	Other osteoporosis with current pathological fracture, right femur, subsequent encounter for fracture with nonunion
M80.851P	Other osteoporosis with current pathological fracture, right femur, subsequent encounter for fracture with malunion
M80.851S	Other osteoporosis with current pathological fracture, right femur, sequela
M80.852A	Other osteoporosis with current pathological fracture, left femur, initial encounter for fracture
M80.852D	Other osteoporosis with current pathological fracture, left femur, subsequent encounter for fracture with routine healing
M80.852G	Other osteoporosis with current pathological fracture, left femur, subsequent encounter for fracture with delayed healing
M80.852K	Other osteoporosis with current pathological fracture, left femur, subsequent

	encounter for fracture with nonunion
M80.852P	Other osteoporosis with current pathological fracture, left femur, subsequent encounter for fracture with malunion
M80.852S	Other osteoporosis with current pathological fracture, left femur, sequela
M80.859A	Other osteoporosis with current pathological fracture, unspecified femur, initial encounter for fracture
M80.859D	Other osteoporosis with current pathological fracture, unspecified femur, subsequent encounter for fracture with routine healing
M80.859G	Other osteoporosis with current pathological fracture, unspecified femur, subsequent encounter for fracture with delayed healing
M80.859K	Other osteoporosis with current pathological fracture, unspecified femur, subsequent encounter for fracture with nonunion
M80.859P	Other osteoporosis with current pathological fracture, unspecified femur, subsequent encounter for fracture with malunion
M80.859S	Other osteoporosis with current pathological fracture, unspecified femur, sequela
M80.861A	Other osteoporosis with current pathological fracture, right lower leg, initial encounter for fracture
M80.861D	Other osteoporosis with current pathological fracture, right lower leg, subsequent encounter for fracture with routine healing
M80.861G	Other osteoporosis with current pathological fracture, right lower leg, subsequent encounter for fracture with delayed healing
M80.861K	Other osteoporosis with current pathological fracture, right lower leg, subsequent encounter for fracture with nonunion
M80.861P	Other osteoporosis with current pathological fracture, right lower leg, subsequent encounter for fracture with malunion
M80.861S	Other osteoporosis with current pathological fracture, right lower leg, sequela
M80.862A	Other osteoporosis with current pathological fracture, left lower leg, initial encounter for fracture
M80.862D	Other osteoporosis with current pathological fracture, left lower leg, subsequent encounter for fracture with routine healing
M80.862G	Other osteoporosis with current pathological fracture, left lower leg, subsequent encounter for fracture with delayed healing
M80.862K	Other osteoporosis with current pathological fracture, left lower leg, subsequent encounter for fracture with nonunion
M80.862P	Other osteoporosis with current pathological fracture, left lower leg, subsequent encounter for fracture with malunion
M80.862S	Other osteoporosis with current pathological fracture, left lower leg, sequela
M80.869A	Other osteoporosis with current pathological fracture, unspecified lower leg, initial encounter for fracture
M80.869D	Other osteoporosis with current pathological fracture, unspecified lower leg,

	subsequent encounter for fracture with routine healing
M80.869G	Other osteoporosis with current pathological fracture, unspecified lower leg, subsequent encounter for fracture with delayed healing
M80.869K	Other osteoporosis with current pathological fracture, unspecified lower leg, subsequent encounter for fracture with nonunion
M80.869P	Other osteoporosis with current pathological fracture, unspecified lower leg, subsequent encounter for fracture with malunion
M80.869S	Other osteoporosis with current pathological fracture, unspecified lower leg, sequela
M80.871A	Other osteoporosis with current pathological fracture, right ankle and foot, initial encounter for fracture
M80.871D	Other osteoporosis with current pathological fracture, right ankle and foot, subsequent encounter for fracture with routine healing
M80.871G	Other osteoporosis with current pathological fracture, right ankle and foot, subsequent encounter for fracture with delayed healing
M80.871K	Other osteoporosis with current pathological fracture, right ankle and foot, subsequent encounter for fracture with nonunion
M80.871P	Other osteoporosis with current pathological fracture, right ankle and foot, subsequent encounter for fracture with malunion
M80.871S	Other osteoporosis with current pathological fracture, right ankle and foot, sequela
M80.872A	Other osteoporosis with current pathological fracture, left ankle and foot, initial encounter for fracture
M80.872D	Other osteoporosis with current pathological fracture, left ankle and foot, subsequent encounter for fracture with routine healing
M80.872G	Other osteoporosis with current pathological fracture, left ankle and foot, subsequent encounter for fracture with delayed healing
M80.872K	Other osteoporosis with current pathological fracture, left ankle and foot, subsequent encounter for fracture with nonunion
M80.872P	Other osteoporosis with current pathological fracture, left ankle and foot, subsequent encounter for fracture with malunion
M80.872S	Other osteoporosis with current pathological fracture, left ankle and foot, sequela
M80.879A	Other osteoporosis with current pathological fracture, unspecified ankle and foot, initial encounter for fracture
M80.879D	Other osteoporosis with current pathological fracture, unspecified ankle and foot, subsequent encounter for fracture with routine healing
M80.879G	Other osteoporosis with current pathological fracture, unspecified ankle and foot, subsequent encounter for fracture with delayed healing
M80.879K	Other osteoporosis with current pathological fracture, unspecified ankle and foot, subsequent encounter for fracture with nonunion

M80.879P	Other osteoporosis with current pathological fracture, unspecified ankle and foot, subsequent encounter for fracture with malunion
M80.879S	Other osteoporosis with current pathological fracture, unspecified ankle and foot, sequela
M80.88XA	Other osteoporosis with current pathological fracture, vertebra(e), initial encounter for fracture
M80.88XD	Other osteoporosis with current pathological fracture, vertebra(e), subsequent encounter for fracture with routine healing
M80.88XG	Other osteoporosis with current pathological fracture, vertebra(e), subsequent encounter for fracture with delayed healing
M80.88XK	Other osteoporosis with current pathological fracture, vertebra(e), subsequent encounter for fracture with nonunion
M80.88XP	Other osteoporosis with current pathological fracture, vertebra(e), subsequent encounter for fracture with malunion
M80.88XS	Other osteoporosis with current pathological fracture, vertebra(e), sequela
Z78.310	Personal history of (healed) osteoporosis fracture

Diagnosis Code	Description
Xgeva®	
C61	Malignant neoplasm of prostrate
C79.00	Secondary malignant neoplasm of unspecified kidney and renal pelvis
C79.01	Secondary malignant neoplasm of right kidney and renal pelvis
C79.02	Secondary malignant neoplasm of left kidney and renal pelvis
C79.10	Secondary malignant neoplasm of unspecified urinary organs
C79.11	Secondary malignant neoplasm of bladder
C79.19	Secondary malignant neoplasm of other urinary organs
C79.2	Secondary malignant neoplasm of skin
C79.31	Secondary malignant neoplasm of brain
C79.32	Secondary malignant neoplasm of cerebral meninges
C79.40	Secondary malignant neoplasm of unspecified part of nervous system
C79.49	Secondary malignant neoplasm of other parts of nervous system
C79.51	Secondary malignant neoplasm of bone
C79.52	Secondary malignant neoplasm of bone marrow
C79.60	Secondary malignant neoplasm of unspecified ovary
C79.61	Secondary malignant neoplasm of right ovary

C79.62	Secondary malignant neoplasm of left ovary
C79.63	Secondary malignant neoplasm of bilateral ovaries
C79.70	Secondary malignant neoplasm of unspecified adrenal gland
C79.71	Secondary malignant neoplasm of right adrenal gland
C79.72	Secondary malignant neoplasm of left adrenal gland
C79.81	Secondary malignant neoplasm of breast
C79.82	Secondary malignant neoplasm of genital organs
C79.89	Secondary malignant neoplasm of other specified sites
C79.9	Secondary malignant neoplasm of unspecified site
C90.00	Multiple myeloma not having achieved remission
C90.02	Multiple myeloma in relapse
D47.02	Systemic mastocytosis
D48.0	Neoplasm of uncertain behavior of bone and articular cartilage
E83.52	Hypercalcemia

Exclusions

The use of <Drug> will not be covered for the following situations:

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References

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4. Reid IR et al. Effects of denosumab on bone histomorphometry: the FREEDOM and STAND studies. J Bone Miner Res. 2010 Oct;25(10):2256-65.

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9. Henry D, Vadhan-Raj S, Hirsh V, et al. Delaying skeletal-related events in a randomized phase 3 study of denosumab versus zoledronic acid in patients with advanced cancer: an analysis of data from patients with solid tumors. Support Care Cancer. 2014 Mar;22(3):679-87.
10. Fizazi K, Carducci M, Smith M et al. Denosumab versus zoledronic acid for treatment of bone metastases in men with castration-resistant prostate cancer: a randomised, double-blind study. Lancet 2011; 377:813.
11. Kendler DL, Chines A, Brandi ML, et al. The risk of subsequent osteoporotic fractures is decreased in subjects experiencing fracture while on denosumab: results from the FREEDOM and FREEDOM Extension studies. Osteoporos Int. 2019 Jan;30(1):71-78.

MVP Health Care Medical Policy

Densoumab (Prolia and Xgeva)

Type of Policy:	**Drug/Medical Therapy**
Prior Approval Date:	
Approval Date:	**11/01/2023**
Effective Date:	**1/01/2024**

Related Policies:

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

Overview

Considerations

Coverage guidelines for participants in the Cancer Guidance Program (CGP) where some Certificates of Coverage allow for coverage of experimental/investigational/unproven treatments for life-threatening illnesses when certain conditions are met. The member specific benefit plan document must be consulted to make coverage decisions for this service. Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances when certain conditions are met. Where such mandates apply, they supersede language in the benefit document or in the medical or drug policy. Benefit coverage for an otherwise unproven service for the treatment of serious rare diseases may occur when certain conditions are met. Refer to the Policy and Procedure addressing the treatment of serious rare diseases.

Background

Osteoporosis is characterized by low bone mass, microarchitectural disruption, and increased skeletal fragility. The Word Health Organization (WHO) established diagnostic thresholds for bone mineral density (BMD) by dual-energy x-ray absorptiometry (DXA)

according to the standard deviation (SD) difference between a patient's BMD and that of a young adult reference population (T-score). A T-score of -2.5 SD or below is defined as osteoporosis, provided that other causes of low BMD have been ruled out, and a T-score between -1 and -2.5 SD is defined as osteopenia. Additionally, guidelines state that osteoporosis can be diagnosed by one of the following: (1) Presence of fragility fractures in the absence of other metabolic bone disorders; (2) T-score ≤ −2.5 SD in the lumbar spine (antero-posterior), femoral neck, total hip, or one-third radius; or (3) T-score between −1.0 and −2.5 and increased fracture risk using the FRAX® (fracture risk assessment tool) country-specific thresholds. The FRAX tool is designed to assist clinicians in predicting the ten-year probability of hip fracture and 10-year probability of a major osteoporotic fracture (spine, forearm, hip or shoulder fracture) with or without the addition of femoral neck BMD. In the United States, a clinical diagnosis of osteoporosis may be made when the FRAX 10-year probability of major osteoporotic fracture (hip, clinical spine, proximal humerus, or forearm) is greater than or equal to 20 percent or the FRAX 10- year probability of hip fracture is greater than or equal to 3 percent. Denosumab binds to RANKL, a transmembrane or soluble protein essential for the formation, function, and survival of osteoclasts, the cells responsible for bone resorption, thereby modulating calcium release from bone. Denosumab prevents RANKL from activating its receptor, RANK, on the surface of osteoclasts, their precursors, and osteoclast-like giant cells. Prevention of the RANKL/RANK interaction inhibits osteoclast formation, function, and survival, thereby decreasing bone resorption and increasing bone mass and strength in both cortical and trabecular bone. Increased osteoclast activity, stimulated by RANKL, is a mediator of bone pathology in solid tumors with osseous metastases. Similarly, giant cell tumors of bone consist of stromal cells expressing RANKL and osteoclast-like giant cells expressing RANK receptor and signaling through the RANK receptor contributes to osteolysis and tumor growth. (Amgen, 2022; Amgen 2020)

Instructions for Use

This medical guideline aids in interpreting National Comprehensive Cancer Network (NCCN)® cancer guidelines. Before using this guideline, please check the member specific benefit plan documents and any applicable federal or state mandates. Optum reserves the right to modify its Guidelines as necessary. This Guideline is provided for informational purposes and does not constitute medical advice.

This Guideline may also be applied to Medicare Advantage plans in some instances. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence. (Medicare IOM Pub. No. 100-16, Chapter 4, Section 90.5)

Optum Medical Benefit Guidelines are intended to be used in connection with the independent professional medical judgement of a qualified health care provider and do not constitute the practice of medicine or medical advice.

Recommendation

Prolia (densoumab)

Prolia® is proven to increase bone mass in patients at high risk for fracture receiving androgen deprivation therapy for non-metastatic prostate cancer when all the following criteria are met:

- Initial Therapy
    - Diagnosis of non-metastatic prostate cancer; and
    - Patient is receiving androgen deprivation therapy; and
    - Prolia dosing is in accordance with the United States Food and Drug Administration approved labeling;
    - History of failure, contraindications, or intolerance to other available osteoporosis therapy (e.g., oral bisphosphonates, intravenous bisphosphonates); and
    - Authorization is for no more than 12 months.

- Reauthorization/Continuation of Care Criteria
    - For patients currently on Prolia® to increase bone mass in patients at high risk for fracture receiving androgen deprivation therapy for non-metastatic prostate cancer, continued use will be approved based on the following criteria:

- Patient is receiving androgen deprivation therapy; and
- Provider attests to a positive clinical response; and
- Prolia® dosing is in accordance with the United States Food and Drug Administration approved labeling; and
- Authorization is for no more than 12 months.

Prolia® is proven to treat patients at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer when all the following criteria are met:

- Initial Therapy
  - Diagnosis of breast cancer; and
  - Patient is receiving aromatase inhibitor therapy; and
  - Prolia dosing is in accordance with the United States Food and Drug Administration approved labeling;
  - History of failure, contraindications, or intolerance to other available osteoporosis therapy (e.g., oral bisphosphonates, intravenous bisphosphonates); and
  - Authorization is for no more than 12 months.

- Reauthorization/Continuation of Care Criteria
  - For patients currently on Prolia® to treat patients at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer, continued use will be approved based on the following criteria:
    - Patient is receiving aromatase inhibitor; and
    - Provider attests to a positive clinical response; and
    - Prolia® dosing is in accordance with the United States Food and Drug Administration approved labeling; and
  - Authorization is for no more than 12 months.

Xgeva (densoumab)

Xgeva is proven for the prevention of skeletal-related events in patients with multiple myeloma and with bone metastases from solid tumors when all of the following criteria are met:

- Initial Therapy
    - One of the following:
        - Diagnosis of multiple myeloma
        - Presences of metastatic disease secondary to a solid tumor (e.g., bladder, breast, kidney, lung, ovaria, thyroid, etc.)

And

    - Xgeva® dosing is in accordance with the United States Food and Drug Administration approved labeling;
    - History of failure, contraindications, or intolerance to other available osteoporosis therapy (e.g., oral bisphosphonates, intravenous bisphosphonates); and
    - Authorization is for no more than 12 months.

- Reauthorization/Continuation of Care Criteria
    - For patients currently on Xgeva® for the prevention of skeletal-related events in patients with multiple myeloma and with bone metastases from solid tumors, continued use will be approved based on the following criteria:
        - Provider attests to a positive clinical response; and
        - Xgeva® dosing is in accordance with the United States Food and Drug Administration approved labeling; and
        - Authorization is for no more than 12 months.

Xgeva® is proven for the treatment of giant cell tumor of the bone when all the following criteria are met:

- Initial Therapy
    - Patient is one of the following:
        - Patient is ≥ 18 years of age
        - Patient is a skeletally mature adolescent as defined by having at least 1 mature long bone (e.g., closed epiphyseal growth plat of the humerus)

And

    - Diagnosis of localized, recurrent or metastatic giant cell tumor of the bone; and
    - Disease is one of the following:
        - Unresectable
        - Surgical resection is likely to result in severe morbidity

And

    - Xgeva® dosing is in accordance with the United States Food and Drug Administration approved labeling;
    - Authorization is for no more than 12 months.

- Reauthorization/Continuation of Care Criteria
    - For patients currently on Xgeva for the treatment of giant cell tumor of the bone, continued use will be approved based on the following criteria:
        - Provider attests to the positive clinical response; and
        - Xgeva® dosing is in accordance with the United States Food and Drug Administration approved labeling; and
        - Authorization is for no more than 12 months.

Xgeva® is proven for the treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy when all of the following criteria are met:

- Initial Therapy
    - Diagnosis of hypercalcemia of malignancy as defined as: albumin-corrected serum calcium level greater than 12.5 mg/dL (3.1 mmol/L); and
    - Refractory (within the last 30 days), contraindication (including renal insufficiency), or intolerance to treatment with intravenous bisphosphonates therapy (e.g., pamidronate, zoledronic acid); and
    - Xgeva® dosing is in accordance with the United States Food and Drug Administration approved labeling; and
    - Authorization is for no more than 12 months.

- Reauthorization/Continuation of Care Criteria
    - For patients currently on Xgeva® for the treatment of hypercalcemia of malignancy, continued use will be approved based on the following criteria:
        - Provider attests to a positive clinical response; and
        - Xgeva® dosing is in accordance with the treatment of hypercalcemia of malignancy, continued use will be approved based on the following criteria:
        - Authorization is for no more than 12 months.

Xgeva® is proven for treatment of osteopenia/osteoporosis in patients with systemic mastocytosis with bone pain not responding to bisphosphonates when all the following criteria are met:

- Initial Therapy
    - Diagnosis of systemic mastocytosis; and

- Patient has bone pain; and
- Diagnosis of osteoporosis or osteopenia based on one of the following:
    - BMD T-score ≤ -1 based on BMD measurements from lumbar spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site); or
    - History of one of the following resulting from minimal trauma:
        - Vertebral compression fracture
        - Fracture of the hip
        - Fracture of the distal radius
        - Fracture of the pelvis
        - Fracture of the proximal humerus

And

- Refractory (within the past 30 days), contraindication (including renal insufficiency), or intolerance to treatment with intravenous bisphosphonate therapy (e.g., pamidronate, zoledronic acid) (for Medicare reviews, refer to the CMS section*); and
- Xgeva® dosing is in accordance with the United States Food and Drug Administration approved labeling; and
- Authorization for no more than 12 months.

- Reauthorization/Continuation of Care Criteria
    - For patients currently on Xgeva for the treatment of osteopenia/osteoporosis in patients with systemic mastocytosis with bone pain not responding to bisphosphonates, continued use will be approved based on the following criteria:
        - Provider attests to a positive clinical response; and

- Xgeva® dosing is in accordance with the United States Food and Drug Administration approved labeling; and
- Authorization is for no more than 12 months.

Unproven/Not Medically Necessary

Denosumab is unproven and not medically necessary for the following indications:

- Combination therapy of denosumab and intravenous bisphosphonates
- Bone loss associated with hormone-ablation therapy (other than aromatase inhibitors) in breast/prostate cancer
- Cancer pain
- Central giant cell granuloma
- Hyper-parathyroidism
- Immobilization hypercalcemia
- Osteogenesis Imperfecta
- Osteopenia

Clinical Evidence

Prolia

Patients at High Risk for Fracture Receiving Androgen Deprivation Therapy for Non-Metastatic Prostate Cancer

Smith ME et al investigated the effects of denosumab in a double-blind, multicenter study, on bone mineral density and fractures in patients with non-metastatic prostate cancer who are receiving androgen-deprivation therapy.8 Patients were randomly assigned to receive denosumab at a dose of 60 mg subcutaneously every 6 months or placebo (n = 734 per group). The primary end point was percent change in bone mineral density at the lumbar spine at 24 months. Secondary end points included percent change in bone mineral densities at the femoral neck and total hip at 24 months and at all three sites at 36 months, as well as frequency of new vertebral fractures. At 24 months, patients receiving denosumab experienced an increase in bone mineral density of the lumbar spine by 5.6% as compared with a loss of 1.0% in the placebo group ($p < 0.001$). Significant differences between the placebo and denosumab groups were seen

at 1 month and continued through 36 months. Treatment was also associated with significant increases in bone mineral density at the total hip, femoral neck, and distal third of the radius. Patients who received denosumab had a decreased incidence of new vertebral fractures at 36 months (1.5%, vs. 3.9% with placebo) (relative risk, 0.38; 95% confidence interval, 0.19 to 0.78; p = 0.006). Similar rates of adverse events were reported in the two groups. (Smith, 2009) The authors conclude that denosumab is associated with increased bone mineral density at all sites and a reduction in the incidence of new vertebral fractures among patients receiving androgen-deprivation therapy for non-metastatic prostate cancer. (ClinicalTrials.gov number, NCT00089674)

Professional Societies

National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology (NCCN Guidelines®)

Several National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology (NCCN Guidelines®) include denosumab as a treatment for several conditions related to malignant disease. The following NCCN Guidelines® state (NCCN, 2023):

- For invasive and inflammatory breast cancer, the NCCN recommends (Category 2A) denosumab to be considered in postmenopausal (natural or induced) patients receiving adjuvant endocrine therapy along with calcium and vitamin D supplementation to maintain or improve bone mineral density and reduce risk of fractures.
- For prostate cancer, the NCCN recommends (Category 2A) denosumab for the prevention or treatment of osteoporosis during androgen deprivation therapy (ADT) for patients with high fracture risk.

Xgeva

In an ad hoc analysis of the phase 3 clinical trial of 1,776 patients with metastases from solid tumors or multiple myeloma, where it was shown that denosumab was non-inferior to zoledronic acid (ZA) in delaying or preventing SREs, Henry et al reports outcomes in the subgroup of 1,597 patients with solid tumors, excluding multiple myeloma.17 In the ad hoc analysis, denosumab significantly delayed time to first on-study SRE compared to ZA (HR, 0.81; 95% CI, 0.68–0.96) and time to first-and subsequent SREs (RR, 0.85; 95% CI, 0.72–1.00). Denosumab also significantly delayed time to development of moderate or severe pain (HR, 0.81; 95% CI, 0.66–1.00), pain worsening (HR, 0.83; 95% CI, 0.71–0.97), and worsening pain interference in patients with no/mild baseline pain (HR, 0.77; 95% CI, 0.61–0.96). Overall survival was similar in both groups. The median KM estimate was 10.7 months for denosumab-treated patients and 10.0 months for ZA-treated patients (HR, 0.92; 95% CI, 0.81– 1.05: p = 0.215). Similarly, there was no difference between groups in time to disease progression. The

median KM estimate was 5.3 (4.9, 5.7) months for denosumab-treated and 5.4 (4.8, 5.7) months for ZA-treated patients (HR, 0.96; 95% CI, 0.85–1.08: p = 0.497). The authors concluded that denosumab was more effective in delaying the incidence of SREs, however did not significantly affect the overall incidence or disease progression or overall survival.

In a double-blind, double-dummy, phase III clinical trial, Henry et al compared denosumab with zoledronic acid (ZA) for delaying or preventing skeletal-related events (SRE) in patients with advanced cancer and bone metastases (excluding breast and prostate) or myeloma (Henry, 2011). Patients were randomly assigned to receive either monthly subcutaneous denosumab 120mg (n = 886) or intravenous ZA 4mg (dose adjustment for renal impairment; n = 890). The primary end point was time to first on-study SRE (pathologic fracture, radiation or surgery to bone, or spinal cord compression). The trial demonstrated that denosumab was noninferior to ZA in delaying time to first on-study SRE (hazard ratio, 0.84; 95% CI, 0.71 to 0.98; p = 0.0007). Denosumab was not statistically superior to ZA in delaying time to first on-study SRE (p = 0.03 unadjusted; p = 0.06 adjusted for multiplicity) or time to first-and-subsequent (multiple) SRE (rate ratio, 0.90; 95% CI, 0.77 to 1.04; p = 0.14). Overall survival and disease progression were similar between groups. Hypocalcemia occurred more frequently with denosumab. Osteonecrosis of the jaw occurred at similarly low rates in both groups. Acute-phase reactions after the first dose occurred more frequently with ZA, as did renal adverse events and elevations in serum creatinine. The authors concluded that denosumab was noninferior to ZA in preventing or delaying first on-study SRE in patients with advanced cancer metastatic to bone or myeloma.

Fizazi et al evaluated the comparison of denosumab with zoledronic acid (ZA) for the prevention of skeletal-related events in men with bone metastases from castration-resistant prostate cancer (Fizazi, 2011). In a phase 3 clinical study, 1904 men with castration-resistant prostate cancer had no previous exposure to IV bisphosphonate were randomized 1:1 to either receive 120mg subcutaneous denosumab plus IV placebo (n = 950), or 4mg IV ZA plus subcutaneous placebo (n = 951) every 4 weeks. The primary endpoint was time to first on-study skeletal related event (pathological fracture, radiation therapy, surgery to bone, or spinal cord compression), and was assessed for non-inferiority. The same outcome was further assessed for superiority as a secondary endpoint. Efficacy analysis was by intention to treat. Median time to first on-study skeletal-related event was 20.7 months (95% CI 18.8–24.9) with denosumab compared with 17.1 months (15.0–19.4) with zoledronic acid (hazard ratio 0.82, 95% CI 0.71–0.95; p = 0.0002 for non-inferiority; p = 0.008 for superiority). While there was a three-month increase in the time to first skeletal-related events observed with denosumab in men with prostate cancer, there was no clinically meaningful difference in skeletal-related events for denosumab as compared with zoledronic acid: Overall confirmed events (ZA vs. denosumab) 41% vs. 36%; radiation to bone (21% vs. 19%); pathological fracture

(15% vs. 14%); spinal cord compression (4% vs. 3%); surgery to bone (< 1% vs. < 1%). The authors concluded that denosumab was better than ZA for delaying the time to first SRE, however, was not significantly better at preventing the overall incidence of SREs versus zoledronic acid.

Professional Societies

National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology (NCCN Guidelines®)

Several National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology (NCCN Guidelines®) include denosumab as a treatment for several conditions related to malignant disease. The following NCCN Guidelines® state (NCCN, 2023)

For giant cell tumor of the bone, the NCCN recommends (Category 2A) denosumab as a single agent or combined with serial embolization (preferred), and/or radiation therapy for resectable disease with unacceptable morbidity and/or unresectable axial lesions for patients with localized disease, metastases at presentation, or recurrence. Denosumab is also recommended as a single agent for unresectable metastatic disease, unresectable metastatic recurrence or considered prior to surgery for resectable local recurrence.

- For invasive or inflammatory breast cancer, the NCCN recommends (Category 1) denosumab to be used with calcium and vitamin D supplementation in addition to chemotherapy or endocrine therapy for bone metastasis in patients with expected survival ≥ 3 months with adequate renal function.
- For kidney cancer, the NCCN recommends (Category 2A) denosumab to be used as a component of best supportive care for bony metastases.
- For multiple myeloma, the NCCN recommends (Category 2A) denosumab to be used in combination with primary myeloma therapy and is the preferred agent in patients with renal insufficiency.
- For non-small cell lung cancer, the NCCN recommends (Category 2A) denosumab to be considered for supportive therapy in patients with bone metastases.
- For prostate cancer, the NCCN recommends (Category 1) denosumab as the preferred agent for the prevention of skeletal-related events in patients with castration-resistant prostate cancer who have documented bone metastases and creatinine clearance greater than 30 ml/min.

- For systemic mastocytosis, the NCCN recommends (Category 2A) denosumab as second-line therapy for osteopenia/osteoporosis in patients with bone pain not responding to bisphosphonates or for patients who are not candidates for bisphosphonates because of renal insufficiency.
- For thyroid carcinoma (anaplastic, follicular, Hürthle cell, medullary, papillary), the NCCN recommends (Category 2A) denosumab to be considered for bone metastases or palliative care for bone metastases (anaplastic).

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Prolia (denosumab) is a RANK ligand inhibitor indicated for the following uses:

- Treatment of postmenopausal women with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy. In postmenopausal women with osteoporosis, Prolia reduces the incidence of vertebral, nonvertebral, and hip fractures.
- Treatment to increase bone mass in men with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.
- Treatment of glucocorticoid-induced osteoporosis in men and women at high risk of fracture who are either initiating or continuing systemic glucocorticoids in a daily dosage equivalent to 7.5 mg or greater of prednisone and expected to remain on glucocorticoids for at least 6 months. High risk of fracture is defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy.
- Treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer. In these patients Prolia also reduced the incidence of vertebral fractures.
- Treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer.

Xgeva (denosumab) is a RANK ligand inhibitor indicated for the prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors, the treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity, and for the treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy. (Amgen, 2020)

Medicare does not have a National Coverage Determination (NCD) specifically for denosumab (Xgeva® and Prolia®). Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist; refer to the LCDs/LCAs for Bisphosphonates (Intravenous [IV] and Monoclonal Antibodies in the Treatment of Osteoporosis and their Other Indications and Drugs and Biologicals, Coverage of, for Label and Off-Label Uses.

In general, Medicare may cover outpatient (Part B) drugs that are furnished "incident to" a physician's service provided that the drugs are not usually self-administered by the patients who take them. Refer to the Medicare Benefit Policy Manual, Chapter 15, Section 50 – Drugs and Biologicals. (Accessed March 6, 2023)

Applicable Codes

HCPCS Code	Description
J0897	Injection, denosumab, 1 mg

Diagnosis Code	Description
Prolia®	
M81.8	Other osteoporosis without current pathological fracture
M80.811A	Other osteoporosis with current pathological fracture, right shoulder, initial encounter for fracture
M80.811D	Other osteoporosis with current pathological fracture, right shoulder, subsequent encounter for fracture with routine healing
M80.811G	Other osteoporosis with current pathological fracture, right shoulder, subsequent encounter for fracture with delayed healing
M80.811K	Other osteoporosis with current pathological fracture, right shoulder, subsequent encounter for fracture with nonunion
M80.811P	Other osteoporosis with current pathological fracture, right shoulder, subsequent encounter for fracture with malunion
M80.811S	Other osteoporosis with current pathological fracture, right shoulder, sequela
M80.8AXA	Other osteoporosis with current pathological fracture, other site, initial encounter for fracture

M80.8AXD	Other osteoporosis with current pathological fracture, other site, subsequent encounter for fracture with routine healing
M80.8AXG	Other osteoporosis with current pathological fracture, other site, subsequent encounter for fracture with delayed healing
M80.8AXK	Other osteoporosis with current pathological fracture, other site, subsequent encounter for fracture with nonunion
M80.8AXP	Other osteoporosis with current pathological fracture, other site, subsequent encounter for fracture with malunion
M80.8AXS	Other osteoporosis with current pathological fracture, other site, sequela
M80.812A	Other osteoporosis with current pathological fracture, left shoulder, initial encounter for fracture
M80.812D	Other osteoporosis with current pathological fracture, left shoulder, subsequent encounter for fracture with routine healing
M80.812G	Other osteoporosis with current pathological fracture, left shoulder, subsequent encounter for fracture with delayed healing
M80.812K	Other osteoporosis with current pathological fracture, left shoulder, subsequent encounter for fracture with nonunion
M80.812P	Other osteoporosis with current pathological fracture, left shoulder, subsequent encounter for fracture with malunion
M80.812S	Other osteoporosis with current pathological fracture, left shoulder, sequela
M80.819A	Other osteoporosis with current pathological fracture, unspecified shoulder, initial encounter for fracture
M80.819D	Other osteoporosis with current pathological fracture, unspecified shoulder, subsequent encounter for fracture with routine healing
M80.819G	Other osteoporosis with current pathological fracture, unspecified shoulder, subsequent encounter for fracture with delayed healing
M80.819K	Other osteoporosis with current pathological fracture, unspecified shoulder, subsequent encounter for fracture with nonunion
M80.819P	Other osteoporosis with current pathological fracture, unspecified shoulder, subsequent encounter for fracture with malunion
M80.819S	Other osteoporosis with current pathological fracture, unspecified shoulder, sequela
M80.821A	Other osteoporosis with current pathological fracture, right humerus, initial encounter for fracture
M80.821D	Other osteoporosis with current pathological fracture, right humerus, subsequent encounter for fracture with routine healing
M80.821G	Other osteoporosis with current pathological fracture, right humerus, subsequent encounter for fracture with delayed healing
M80.821K	Other osteoporosis with current pathological fracture, right humerus, subsequent encounter for fracture with nonunion

M80.821P	Other osteoporosis with current pathological fracture, right humerus, subsequent encounter for fracture with malunion
M80.821S	Other osteoporosis with current pathological fracture, right humerus, sequela
M80.822A	Other osteoporosis with current pathological fracture, left humerus, initial encounter for fracture
M80.822D	Other osteoporosis with current pathological fracture, left humerus, subsequent encounter for fracture with routine healing
M80.822G	Other osteoporosis with current pathological fracture, left humerus, subsequent encounter for fracture with delayed healing
M80.822K	Other osteoporosis with current pathological fracture, left humerus, subsequent encounter for fracture with nonunion
M80.822P	Other osteoporosis with current pathological fracture, left humerus, subsequent encounter for fracture with malunion
M80.822S	Other osteoporosis with current pathological fracture, left humerus, sequela
M80.829A	Other osteoporosis with current pathological fracture, unspecified humerus, initial encounter for fracture
M80.829D	Other osteoporosis with current pathological fracture, unspecified humerus, subsequent encounter for fracture with routine healing
M80.829G	Other osteoporosis with current pathological fracture, unspecified humerus, subsequent encounter for fracture with delayed healing
M80.829K	Other osteoporosis with current pathological fracture, unspecified humerus, subsequent encounter for fracture with nonunion
M80.829P	Other osteoporosis with current pathological fracture, unspecified humerus, subsequent encounter for fracture with malunion
M80.829S	Other osteoporosis with current pathological fracture, unspecified humerus, sequela
M80.831A	Other osteoporosis with current pathological fracture, right forearm, initial encounter for fracture
M80.831D	Other osteoporosis with current pathological fracture, right forearm, subsequent encounter for fracture with routine healing
M80.831G	Other osteoporosis with current pathological fracture, right forearm, subsequent encounter for fracture with delayed healing
M80.831K	Other osteoporosis with current pathological fracture, right forearm, subsequent encounter for fracture with nonunion
M80.831P	Other osteoporosis with current pathological fracture, right forearm, subsequent encounter for fracture with malunion
M80.831S	Other osteoporosis with current pathological fracture, right forearm, sequela
M80.832A	Other osteoporosis with current pathological fracture, left forearm, initial encounter for fracture
M80.832D	Other osteoporosis with current pathological fracture, left forearm, subsequent

	encounter for fracture with routine healing
M80.832G	Other osteoporosis with current pathological fracture, left forearm, subsequent encounter for fracture with routine healing
M80.832K	Other osteoporosis with current pathological fracture, left forearm, subsequent encounter for fracture with nonunion
M80.832P	Other osteoporosis with current pathological fracture, left forearm, subsequent encounter for fracture with malunion
M80.832S	Other osteoporosis with current pathological fracture, left forearm, sequela
M80.839A	Other osteoporosis with current pathological fracture, unspecified forearm, initial encounter for fracture
M80.839D	Other osteoporosis with current pathological fracture, unspecified forearm, subsequent encounter for fracture with routine healing
M80.839G	Other osteoporosis with current pathological fracture, unspecified forearm, subsequent encounter for fracture with delayed healing
M80.839K	Other osteoporosis with current pathological fracture, unspecified forearm, subsequent encounter for fracture with nonunion
M80.839P	Other osteoporosis with current pathological fracture, unspecified forearm, subsequent encounter for fracture with malunion
M80.839S	Other osteoporosis with current pathological fracture, unspecified forearm, sequela
M80.841A	Other osteoporosis with current pathological fracture, right hand, initial encounter for fracture
M80.841D	Other osteoporosis with current pathological fracture, right hand, subsequent encounter for fracture with routine healing
M80.841G	Other osteoporosis with current pathological fracture, right hand, subsequent encounter for fracture with delayed healing
M80.841K	Other osteoporosis with current pathological fracture, right hand, subsequent encounter for fracture with nonunion
M80.841P	Other osteoporosis with current pathological fracture, right hand, subsequent encounter for fracture with malunion
M80.841S	Other osteoporosis with current pathological fracture, right hand, sequela
M80.842A	Other osteoporosis with current pathological fracture, left hand, initial encounter for fracture
M80.842D	Other osteoporosis with current pathological fracture, left hand, subsequent encounter for fracture with routine healing
M80.842G	Other osteoporosis with current pathological fracture, left hand, subsequent encounter for fracture with delayed healing
M80.842K	Other osteoporosis with current pathological fracture, left hand, subsequent encounter for fracture with nonunion
M80.842P	Other osteoporosis with current pathological fracture, left hand, subsequent

	encounter for fracture with malunion
M80.842S	Other osteoporosis with current pathological fracture, left hand, sequela
M80.849A	Other osteoporosis with current pathological fracture, unspecified hand, initial encounter for fracture
M80.849D	Other osteoporosis with current pathological fracture, unspecified hand, subsequent encounter for fracture with routine healing
M80.849G	Other osteoporosis with current pathological fracture, unspecified hand, subsequent encounter for fracture with delayed healing
M80.849K	Other osteoporosis with current pathological fracture, unspecified hand, subsequent encounter for fracture with nonunion
M80.849P	Other osteoporosis with current pathological fracture, unspecified hand, subsequent encounter for fracture with malunion
M80.849S	Other osteoporosis with current pathological fracture, unspecified hand, sequela
M80.851A	Other osteoporosis with current pathological fracture, right femur, initial encounter for fracture
M80.851D	Other osteoporosis with current pathological fracture, right femur, subsequent encounter for fracture with routine healing
M80.851G	Other osteoporosis with current pathological fracture, right femur, subsequent encounter for fracture with delayed healing
M80.851K	Other osteoporosis with current pathological fracture, right femur, subsequent encounter for fracture with nonunion
M80.851P	Other osteoporosis with current pathological fracture, right femur, subsequent encounter for fracture with malunion
M80.851S	Other osteoporosis with current pathological fracture, right femur, sequela
M80.852A	Other osteoporosis with current pathological fracture, left femur, initial encounter for fracture
M80.852D	Other osteoporosis with current pathological fracture, left femur, subsequent encounter for fracture with routine healing
M80.852G	Other osteoporosis with current pathological fracture, left femur, subsequent encounter for fracture with delayed healing
M80.852K	Other osteoporosis with current pathological fracture, left femur, subsequent encounter for fracture with nonunion
M80.852P	Other osteoporosis with current pathological fracture, left femur, subsequent encounter for fracture with malunion
M80.852S	Other osteoporosis with current pathological fracture, left femur, sequela
M80.859A	Other osteoporosis with current pathological fracture, unspecified femur, initial encounter for fracture
M80.859D	Other osteoporosis with current pathological fracture, unspecified femur, subsequent encounter for fracture with routine healing
M80.859G	Other osteoporosis with current pathological fracture, unspecified femur,

	subsequent encounter for fracture with delayed healing
M80.859K	Other osteoporosis with current pathological fracture, unspecified femur, subsequent encounter for fracture with nonunion
M80.859P	Other osteoporosis with current pathological fracture, unspecified femur, subsequent encounter for fracture with malunion
M80.859S	Other osteoporosis with current pathological fracture, unspecified femur, sequela
M80.861A	Other osteoporosis with current pathological fracture, right lower leg, initial encounter for fracture
M80.861D	Other osteoporosis with current pathological fracture, right lower leg, subsequent encounter for fracture with routine healing
M80.861G	Other osteoporosis with current pathological fracture, right lower leg, subsequent encounter for fracture with delayed healing
M80.861K	Other osteoporosis with current pathological fracture, right lower leg, subsequent encounter for fracture with nonunion
M80.861P	Other osteoporosis with current pathological fracture, right lower leg, subsequent encounter for fracture with malunion
M80.861S	Other osteoporosis with current pathological fracture, right lower leg, sequela
M80.862A	Other osteoporosis with current pathological fracture, left lower leg, initial encounter for fracture
M80.862D	Other osteoporosis with current pathological fracture, left lower leg, subsequent encounter for fracture with routine healing
M80.862G	Other osteoporosis with current pathological fracture, left lower leg, subsequent encounter for fracture with delayed healing
M80.862K	Other osteoporosis with current pathological fracture, left lower leg, subsequent encounter for fracture with nonunion
M80.862P	Other osteoporosis with current pathological fracture, left lower leg, subsequent encounter for fracture with malunion
M80.862S	Other osteoporosis with current pathological fracture, left lower leg, sequela
M80.869A	Other osteoporosis with current pathological fracture, unspecified lower leg, initial encounter for fracture
M80.869D	Other osteoporosis with current pathological fracture, unspecified lower leg, subsequent encounter for fracture with routine healing
M80.869G	Other osteoporosis with current pathological fracture, unspecified lower leg, subsequent encounter for fracture with delayed healing
M80.869K	Other osteoporosis with current pathological fracture, unspecified lower leg, subsequent encounter for fracture with nonunion
M80.869P	Other osteoporosis with current pathological fracture, unspecified lower leg, subsequent encounter for fracture with malunion
M80.869S	Other osteoporosis with current pathological fracture, unspecified lower leg, sequela

M80.871A	Other osteoporosis with current pathological fracture, right ankle and foot, initial encounter for fracture
M80.871D	Other osteoporosis with current pathological fracture, right ankle and foot, subsequent encounter for fracture with routine healing
M80.871G	Other osteoporosis with current pathological fracture, right ankle and foot, subsequent encounter for fracture with delayed healing
M80.871K	Other osteoporosis with current pathological fracture, right ankle and foot, subsequent encounter for fracture with nonunion
M80.871P	Other osteoporosis with current pathological fracture, right ankle and foot, subsequent encounter for fracture with malunion
M80.871S	Other osteoporosis with current pathological fracture, right ankle and foot, sequela
M80.872A	Other osteoporosis with current pathological fracture, left ankle and foot, initial encounter for fracture
M80.872D	Other osteoporosis with current pathological fracture, left ankle and foot, subsequent encounter for fracture with routine healing
M80.872G	Other osteoporosis with current pathological fracture, left ankle and foot, subsequent encounter for fracture with delayed healing
M80.872K	Other osteoporosis with current pathological fracture, left ankle and foot, subsequent encounter for fracture with nonunion
M80.872P	Other osteoporosis with current pathological fracture, left ankle and foot, subsequent encounter for fracture with malunion
M80.872S	Other osteoporosis with current pathological fracture, left ankle and foot, sequela
M80.879A	Other osteoporosis with current pathological fracture, unspecified ankle and foot, initial encounter for fracture
M80.879D	Other osteoporosis with current pathological fracture, unspecified ankle and foot, subsequent encounter for fracture with routine healing
M80.879G	Other osteoporosis with current pathological fracture, unspecified ankle and foot, subsequent encounter for fracture with delayed healing
M80.879K	Other osteoporosis with current pathological fracture, unspecified ankle and foot, subsequent encounter for fracture with nonunion
M80.879P	Other osteoporosis with current pathological fracture, unspecified ankle and foot, subsequent encounter for fracture with malunion
M80.879S	Other osteoporosis with current pathological fracture, unspecified ankle and foot, sequela
M80.88XA	Other osteoporosis with current pathological fracture, vertebra(e), initial encounter for fracture
M80.88XD	Other osteoporosis with current pathological fracture, vertebra(e), subsequent encounter for fracture with routine healing
M80.88XG	Other osteoporosis with current pathological fracture, vertebra(e), subsequent encounter for fracture with delayed healing

M80.88XK	Other osteoporosis with current pathological fracture, vertebra(e), subsequent encounter for fracture with nonunion
M80.88XP	Other osteoporosis with current pathological fracture, vertebra(e), subsequent encounter for fracture with malunion
M80.88XS	Other osteoporosis with current pathological fracture, vertebra(e), sequela
Z78.310	Personal history of (healed) osteoporosis fracture

Diagnosis Code	Description
Xgeva®	
C61	Malignant neoplasm of prostrate
C79.00	Secondary malignant neoplasm of unspecified kidney and renal pelvis
C79.01	Secondary malignant neoplasm of right kidney and renal pelvis
C79.02	Secondary malignant neoplasm of left kidney and renal pelvis
C79.10	Secondary malignant neoplasm of unspecified urinary organs
C79.11	Secondary malignant neoplasm of bladder
C79.19	Secondary malignant neoplasm of other urinary organs
C79.2	Secondary malignant neoplasm of skin
C79.31	Secondary malignant neoplasm of brain
C79.32	Secondary malignant neoplasm of cerebral meninges
C79.40	Secondary malignant neoplasm of unspecified part of nervous system
C79.49	Secondary malignant neoplasm of other parts of nervous system
C79.51	Secondary malignant neoplasm of bone
C79.52	Secondary malignant neoplasm of bone marrow
C79.60	Secondary malignant neoplasm of unspecified ovary
C79.61	Secondary malignant neoplasm of right ovary
C79.62	Secondary malignant neoplasm of left ovary
C79.63	Secondary malignant neoplasm of bilateral ovaries
C79.70	Secondary malignant neoplasm of unspecified adrenal gland
C79.71	Secondary malignant neoplasm of right adrenal gland
C79.72	Secondary malignant neoplasm of left adrenal gland
C79.81	Secondary malignant neoplasm of breast
C79.82	Secondary malignant neoplasm of genital organs
C79.89	Secondary malignant neoplasm of other specified sites

C79.9	Secondary malignant neoplasm of unspecified site
C90.00	Multiple myeloma not having achieved remission
C90.02	Multiple myeloma in relapse
D47.02	Systemic mastocytosis
D48.0	Neoplasm of uncertain behavior of bone and articular cartilage
E83.52	Hypercalcemia

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advanced cancer: an analysis of data from patients with solid tumors. Support Care Cancer. 2014 Mar;22(3):679-87.

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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 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
UVM Health Advantage Secure PPO	Prior Auth
UVM Health Advantage Preferred 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
UVM Health Advantage Select PPO	Prior Auth
UVM Health Advantage Secure PPO	Prior Auth
UVM Health Advantage Preferred PPO	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	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

Dose Rounding for Systemic Therapy

Type of Policy:	**Drug/Medical Therapy**
Prior Approval Date:	
Approval Date:	**11/01/2023**
Effective Date:	**1/01/2024**
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 patient'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 patient'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 patient's care or treatment. Care decisions are between the physician and patient.

Drug table for Dose Rounding

HCPCS Code	Drug
J0893	Decitabine(sun pharma)
J0894	Decitabine (Dacogen®)
J9000	Doxorubicin (Adriamycin®)
J9025	Azacitidine (Vidaza®)
J9033	Bendamustine (Treanda®)
J9034	Bendamustine (Bendeka®)
J9035	Bevacizumab (Avastin®)
J9036	Bendamustine HCl (Belrapzo®)

J9041	Bortezomib (Velcade®)
J9042	Brentuximab (Adcetris®)
J9043	Cabazitaxel (Jevtana®)
J9046	Bortezomib(dr. reddy's)
J9047	Carfilzomib (Kyprolis®)
J9048	Bortezomib(Fresenius kabi)
J9049	Bortezomib(Hospira)
J9055	Cetuximab (Erbitux®)
J9056	Bendamustine(Vivimusta)
J9058	Bendamustine(Apotex)
J9059	Bendamustine(Baxter)
J9145	Daratumumab (Darzalex®)
J9176	Elotuzumab (Empliciti®)
J9179	Eribulin Mesylate (Halaven®)
J9207	Ixabepoline (Ixempra®)
J9228	Ipilimumab (Yervoy®)
J9271	Pembrolizumab (Keytruda®)
J9294	Pemetrexed(Hospira)
J9296	Pemetrexed(Accord)
J9297	Pemetrexed(Sandoz)
J9299	Nivolumab (Opdivo®)
J9303	Panitumumab (Vectibix®)
J9304	Pemetrexed (Pemfexy®)
J9305	Pemetrexed (Alimta®)
J9312	Rituximab (Rituxan®)
J9314	Pemetrexed(teva)
J9322	Pemetrexed(Bluepoint)
J9323	Pemetrexed ditromethamine
J9352	Trabectedin (Yondelis®)
J9354	Ado-trastuzumab emtansine (Kadcyla®)
Q2050	Doxorubicin, Liposomal (Doxil®)
Q5107	Bevacizumab-awwb, biosimilar (Mvasi™)
Q5115	Rituximab-abbs, biosimilar (Truxima®)
Q5118	Bevacizumab-bvzr, biosimilar (Zirabev®)
Q5119	Rituximab-pvvr, biosimilar (Ruxience®)
Q5123	Rituximab-arrx, biosimilar (Riabni®)
Q5126	Bevacizumab-maly, biosimilar (Alymsys®)
Q5129	Bevacizumab-adcd, biosimilar (Vegzelma®)

References

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

Member Product	Medical Management Requirements*
New York Products	
HMO	Prior Auth
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PPO OOP	Prior Auth
POS in Plan	Prior Auth
POS OOP	Prior Auth
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MVP Medicare WellSelect Plus PPO	Prior Auth
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UVM Health Advantage Preferred 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
UVM Health Advantage Select PPO	Prior Auth
UVM Health Advantage Secure PPO	Prior Auth
UVM Health Advantage Preferred PPO	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	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).	

***Medical Management Requirements**

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

MVP Health Care ***2023 Medicare Part D Internal Transition Supply Policy***

For Contracts: H3305, H9615, S0586

Overview

To ensure that new or existing members to the MVP Medicare Part D program have continued access to medications that are non-formulary or are subject to utilization management tools (prior authorization, step therapy, quantity limits) during their initial enrollment period, during their stay in a long-term care facility, upon a level of care change or after a calendar year formulary change. This transition supply of medications will allow sufficient time for members to work with their provider to switch to an alternative formulary agent, to request a formulary exception, or to request a coverage determination. For a complete definition of a Coverage Determination, please refer to the CMS Prescription Drug Manual, Chapter 6, Section 30.4. This policy documents the process and procedure to effectuate a transition supply of medication. MVP Health Care delegates select transition fill activities to its Pharmacy Benefit Manager (PBM), CVS Caremark Part D Services, L.L.C. This program has been reviewed and approved by the MVP Pharmacy & Therapeutics and the Quality Improvement Committees.

POLICY

1. MVP Health Care allows a meaningful transition for the following groups of Beneficiaries whose current drug therapy may not be covered by the plan (a.) new Beneficiaries enrolled into the plan following the annual coordinated election period; (b.) newly eligible Medicare Beneficiaries from other coverage; (c.) the transition of Beneficiaries who switch from one plan to another after the start of a contract year; (d.) current Beneficiaries affected by negative formulary changes across contract years; (e.) Beneficiaries residing in long-term care (LTC) facilities, including Beneficiaries being admitted to or discharged from an LTC facility
2. MVP Health Care will submit a copy of its transition policy process as required to CMS.
3. The transition policy will apply to Non-formulary Drugs, meaning: (a.) Part D drugs that are not on the formulary; (b.) Part D drugs previously approved for coverage under an exception once the exception expires unless the exception timeframe is identified in the approval notification and (c.) Part D drugs that are on a the formulary but require prior authorization or step therapy or approved quantity limits lower than the Beneficiary's current dose under the utilization management rules. The transition process allows for medical review of Non-formulary Drug requests, and when appropriate, a process for switching new Part D Plan Beneficiaries to therapeutically appropriate formulary alternatives failing an affirmative medical necessity determination. Delegated PBM will handle Biosimilars as non-interchangeable brand products for it programs and processes involving transition fill. MVP Health Care's P&T committee will meet on a regular basis, but no less than quarterly and review procedures for coverage determination and exceptions, and, if appropriate, a process for switching new Beneficiaries to therapeutically appropriate formulary alternatives failing an affirmative medical necessity determination.
4. A temporary supply of non-formulary Part D drugs will be provided in order to accommodate the immediate needs of a Beneficiary, as well as, to allow MVP Health

Care and/or the Beneficiary sufficient time to work with the prescriber to make an appropriate switch to a therapeutically equivalent medication or the completion of an exception request to maintain coverage of an existing drug based on medical necessity reasons. Delegated PBM Transition Fill (TF) processing and coding applies point-of-sale (POS) messaging to pharmacies.

5. The transition process will apply in the non-LTC setting such that the transition policy provides for a one-time temporary fill, of at least the applicable month's supply of medication, up to 30 days, (unless the Beneficiary presents a prescription written for less than a month's supply in which case the Sponsor must allow multiple fills to provide up to a total of the applicable month's supply of medication) anytime during the first 90 days of a Beneficiary's enrollment in a plan, beginning on the Beneficiary's effective date of coverage.
6. The cost-sharing tier for a temporary supply of drugs provided under the transition process will not exceed the statutory maximum co-payment amounts for low-income subsidy (LIS) eligible Beneficiaries.
   For non-LIS eligible Beneficiaries:
   a. Non-formulary Part D drugs transition supply will receive the same cost sharing that would apply for non-formulary drugs approved through a formulary exception in accordance with §423.578(b).
   b. Formulary transition supply will receive the same cost sharing for a formulary drug subject to utilization management edits provided during the transition that would apply if the utilization management criteria are met.
7. The transition process in the LTC setting will include the following attributes: (a.) the transition policy will provide for a one time temporary fill of at least an applicable month's supply, up to 31 days, (unless the Beneficiary presents with a prescription written for less) consistent with the applicable dispensing increment in the LTC setting with multiple fills allowed to provide up to a total of a month's supply of medication if needed during the first 90 days of a Beneficiary's enrollment in a plan, beginning on the Beneficiary's effective date of coverage; (b.) after the transition period has expired or the days supply is exhausted, the transition policy will provide for at least a 31-day emergency supply of non-formulary Part D drugs per rolling 30 days, (unless the Beneficiary presents with a prescription written for less than the 31 days supply) while an exception or Prior Authorization determination is pending; and (c.) for Beneficiaries being admitted to or discharged from an LTC facility, early refill edits will not be used to limit appropriate and necessary access to their Part D benefit, and such Beneficiaries will be allowed to access a refill upon admission or discharge.
8. Only the following utilization management edits will apply during transition at POS: edits to determine Part A or B versus Part D coverage, edits to prevent coverage of non-Part D drugs, and edits to promote safe utilization of a Part D drug. Step therapy and prior authorization edits will be coded to be resolved at POS.
9. Transition process will allow refills for transition prescriptions dispensed for less than the written amount due to quantity limit safety edits or drug utilization edits that are based on approved product labeling.

10. The transition processes will be applied to a brand-new prescription for a Non-formulary Drug if it cannot make the distinction between a brand-new prescription for a Non-formulary Drug and an ongoing prescription for a Non-formulary Drug at POS.
11. MVP Health Care will send written notice via U.S. first class mail to Beneficiary within three business days of adjudication of a temporary transition fill. The notice will include (a.) an explanation of the temporary nature of the transition supply a Beneficiary has received; (b.) instructions for working with MVP Health Careand the Beneficiary's prescriber to satisfy utilization management requirements or to identify appropriate therapeutic alternatives that are on the MVP formulary; (c.) an explanation of the Beneficiary's right to request a formulary exception; and (d.) a description of the procedures for requesting a formulary exception. For LTC residents dispensed multiple supplies of a Part D drug in increments of 14-days-or-less, the written notice will be provided within 3 business days after adjudication of the first temporary fill. MVP Health Care will use the CMS model Transition Notice via the file-and-use process. Reasonable efforts to provide notice to prescribers of affected enrollees who have received a TF will be made via mail.. The delegated PBM provides a daily extract file to MVP Health Care containing Part D TF paid transactions requiring a transition notice.
12. MVP Health Care is responsible for review of coverage determination requests. Prior authorization or exception request forms will be available upon request to both Beneficiaries and prescribing physicians via mail, fax, email and the MVP Medicare or provider website.
13. The transition policy will be extended across contract years should a Beneficiary enroll in a plan with an effective enrollment date of either November 1 or December 1 and need access to a transition supply.
14. The transition policy will be available to Beneficiaries via the Medicare Prescription Drug Plan Finder link to Sponsor's web site as well as in Beneficiary formulary and pre- and post-enrollment materials as directed by CMS.
15. MVP Health Care will provide Beneficiaries with a process to receive necessary Part D drugs via an extension of the transition period, on a case-by-case basis, to the extent that their exception requests or appeals have not been processed by the end of the minimum transaction period and until such time as a transition has been made (either through a switch to an appropriate formulary drug or a decision on an exception request). MVP Health Care will allow a 30 days supply for transition extension.
16. The transition process will be effectuated for renewing beneficiaries whose drugs will be affected by negative formulary changes in the upcoming contract year. MVP Health Care's plan set up for Renewing Beneficiary history review is at a GPI 10 level with a look back of 180 days.

Procedures

1. The Transition Fill (TF) program is implemented by CVS Caremark according to MVP Health Care's requested benefit design.
    a. Transition supplies are provided at point of sale (POS) to eligible Beneficiaries which are coded as the following:
        i. New Beneficiaries in the plan following the annual coordinated election period
        ii. Newly eligible Medicare Beneficiaries from other coverage
        iii. Beneficiaries who switch from another Part D plan after the start of a Contract Year
        iv. Current Beneficiaries affected by negative formulary changes (including new utilization management requirements)
        v. Beneficiaries residing in LTC facilities
    b. Transition supply limits are defined as cumulative days supplies calculated on Generic Product Identifier (GPI) 14 and are note based on number of fills. See Implementation Statement 16.a for additional information
    c. Transition-eligible claims submitted for LICS III Beneficiaries are processed according to the Beneficiary's LICS Level and pharmacy submitted codes to determine if the claim received will be processed as non-LTC, LICS III, or LTC.
2. MVP Health Care will maintain a Med D TF policy and procedure and review the document at least annually and as needed when process changes occur.
3. Non-formulary Drugs
    a. Procedures to apply the transition policy to Non-formulary Drugs are to obtain the P&T Committee approved formulary and UM edits, and code into the adjudication system to identify the TF eligible claim at POS so that it can be paid.
    b. Notwithstanding any references in this document to expiring formulary exceptions, since CMS has issued guidance stating that it does not expect Part D sponsors to include expiring formulary exception in their transition policies CVS Caremark Part D Services, L.L.C. will not apply its transition policy to expiring formulary exception unless CMS issues guidance requiring otherwise.
    c. Procedures for medical review and identifying Formulary Alternatives are as follows:
        i. Coverage determination and medical review processes for Non-formulary drug requests are documented in the MVP Health Care Pharmacy Programs Administration Policy.
        ii. Information regarding therapeutically appropriate formulary alternatives is made available to Beneficiaries and prescribers failing an affirmative medical necessity determination.
        iii. Beneficiaries who contact Customer Care and Pharmacies that contact the Pharmacy Help Desk are provided with information regarding available formulary alternatives when requested. .

4. POS transition fill processing is available and there are procedures in place for transition extensions and overrides, if needed, through the Pharmacy Help Desk and Customer Care. Transition fill POS messaging to pharmacies applies as follows:
    a. The CVS Caremark PBM adjudication system automatically processes and pays transition fill-eligible claims and transmits POS messaging that the claims are paid under transition fill rules.
    b. Transition fill messaging to pharmacies is consistent with current National Council of Prescription Drug Programs (NCPDP) Telecommunication claim standards (at the time of this publication, the current standard is D.0 and hereafter referred to as "Current NCPDP Telecommunication Claim Standards"). Pharmacies are not required to either submit, or resubmit, a Prior Authorization/Medical Certification Code (PAMC), or other transition fill-specific code for transition fill-eligible claims to pay.
    c. Transition fill processing applies to both new and ongoing prescriptions at POS
    d. Communication and educational outreach to network pharmacies is ongoing throughout the year to provide information and instructions regarding transition fill policies and claim processing. At least annually, and more often as needed, transition fill pharmacy communications are distributed through the CVS Caremark pharmacy network department.
5. Transition Fill for New or Renewing Beneficiaries in the Non-LTC setting
    a. In a Non-LTC setting, the CVS Caremark PBM adjudication system automatically processes and pays transition fill-eligible claims and transmits POS messaging that the claims are paid under Transition Fill rules for up to a cumulative applicable month's supply.
    b. Pharmacies are not required to either submit, or resubmit a PAMC, or other transition fill-specific code for transition fill-eligible claims to adjudicate and pay.
    c. Transition fills are available at POS through this functionality within the first 90 days of enrollment, beginning on the enrollment effective date.
    d. The new and renewing Beneficiaries in a Non-LTC setting may have greater quantity and time plan limits based on the benefit design and will be limited by the amount prescribed.
    e. Non-LTC Level of Care Change: For non-LTC residents, an early refill edit will not be used to limit appropriate and necessary access to a transition fill. A transition fill may be provided automatically at POS, if the adjudication process indicates a Level of Care change from LTC to non-LTC with an early refill edit. Otherwise, the pharmacy will call the CVS Caremark Help Desk in order to obtain an override to submit a Level of Care transition fill request.
6. CVS Caremark will stablish cost-sharing per the MVP Health Care plan design.
    a. Cost-sharing for drugs supplies as a transition fill is set by statute for low-income subsidy (LIS) Beneficiaries.
    b. For non-LIS Beneficiaries:
        i. Non-formulary transition supply will receive the same cost share as would apply if a non-formulary exception was applied

ii. Transition supply for formulary drugs with a utilization management edit will receive the same cost share as would apply if the utilization management criteria is met.

7. Long-Term Care Processing
   For LTC transition fills, the CVS Caremark PBM adjudication system automatically processes and pays transition fill-eligible LTC claims and transmits POS messaging that these are paid under Transition Fill. LTC transition fills are allowed a cumulative applicable month's supply, except for oral brand solids which are limited to 14 day fills with exceptions as required by CMS guidance, unless submitted with a submission clarification code (SCC) of 21-36. SCC codes 21-36 indicate LTC dispensing of varying days supply. Multiple fills to provide up to a total of the applicable month's supply of medication are allowed, consistent with the applicable dispensing increment in the LTC setting. These quantity and time plan limits may be greater based on the benefit design. Pharmacies are not required to either submit, or resubmit a PAMC, or other transition fill-specific code for transition fill-eligible claims to adjudicate and pay.
   a. LTC Transition Fill Emergency Supplies (ES)
      i. To accommodate emergency fills for LTC residents after the new or renewing TF supply has been exhausted or the transition window expired, and while an exception or prior authorization is pending, an SCC is submitted by the pharmacy on POS claims. Emergency Supply Transition Fills are allowed up to a cumulative 31 days supply except for oral brand solids which are limited to 14 day fills with exceptions as required by CMS guidance, unless submitted with an SCC of 21-36. These drug claims would otherwise reject for being Non-formulary or formulary with prior authorization, step therapy, quantity limit or daily dose less than FDA maximum labeled dose, or age edits secondary to Beneficiaries having exhausted TF new or renewing TF supply and/or being outside the TF window.
      ii. LTC ES is allowed, per calendar day, per Beneficiary, per drug, per pharmacy, per plan, for the cumulative days supply during a rolling month, based on benefit design.
      iii. These quantity plan limits may be greater based on the benefit design and will be limited by the amount prescribed

   b. LTC Level of Care Changes
      i. For LTC residents, an SCC is submitted by the pharmacy to allow transition fills and to override transition fill eligible rejects and Refill Too Soon rejects for new admissions. Level of Care Transition Fills are allowed up to an applicable month's supply except for oral brand solids which are limited to 14 day fills with exceptions as required by CMS guidance, unless submitted with an SCC 21-36. These drug claims would otherwise reject for being Non-formulary or formulary with utilization management edits.

ii. Levels of Care Transition Fills are allowed per calendar day, per Beneficiary, per drug, per pharmacy, per plan for a cumulative days supply.
iii. For all Beneficiaries who experience a Level of Care Change, if a dose change results in an "early refill" or Refill to Soon reject, the pharmacy may call the CVS Caremark Pharmacy Help Desk to obtain an override.

c. LICS III Beneficiaries
i. LICS III processing logic is allowed on a TF eligible claim for a LICS III with the appropriate pharmacy submitted codes.
ii. TF eligible LICS III claims are allowed 31 days supply per fill up to a 93 cumulative days supply.

8. Utilization Management Edits Not TF Eligible and TF Eligible Step Therapy and Prior Authorization processing
a. CVS Caremark codes the following utilization management edits on drugs such that transition fill overrides are not applied:
i. Drugs requiring Part A or B vs. Part D coverage determination as identified on the CVS Caremark drug database.
ii. Drugs excluded from Part D benefit as identified on the CVS Caremark Part D Services, L.L.C. drug database.
iii. Edits to support the determination of Part D drug status.
iv. DUR safety edits such as therapeutic duplication, cumulative acetaminophen, morphine milligram equivalent (MME), drug interaction, and age alerts are set up to reject instead of pay as TF.
b. TF eligible Step therapy, Prior Authorization and non-safety quantity limit edits are resolved at POS.

9. Cumulative Days Supply
a. Transition refills for supplies dispensed at less than amount written, or less than the days supply available under transition rules are allowed multiple fills up to at least an applicable month's supply.
b. For DUR edits that are based on an FDA maximum recommended daily dose, Transition Fill claims which are dispensed at less that the prescribed amount due to this edit are allowed during the TF Window.
c. CVS Caremark Part D Services, L.L.C. TF cumulative days supply accumulates at the drug GPI 14 level by Beneficiary and across plan. Transition fill will consider each unique Non-Formulary or Utilization Management Edit types and allow TF for each unique transition fill eligible edit type encountered on an individual GPI 14. LTC Emergency Supply and LTC Level of Care Change/New Patient benefits accumulate separately.

10. CVS Caremark Part D Services, L.L.C. transition process is coded such that if the distinction cannot be made between a brand-new prescription for a Non-formulary Drug and an ongoing prescription for a Non-formulary Drug at POS, the CVS Caremark Part D Services. L.L.C. transition process will be applied to the prescription as if it is ongoing drug therapy. This is referred to as the New Beneficiary process.

11. Transition Notices
    a. A written transition notice is mailed via US First Class mail to the Beneficiary within three business days after adjudication of a transition fill.
    b. For LTC TF for oral brand solids limited to a 14 days supply, a TF notice will be sent only after the first transition fill.
    c. The notice identifies the:
        i. Explanation of the temporary nature of the transition supply provided to the Beneficiary.
        ii. Instructions for working with MVP Health Care and prescriber to satisfy utilization management requirements or to identify therapeutically equivalent and appropriate formulary alternatives
        iii. An explanation of the Beneficiary's right to request a coverage determination.
        iv. A description of the procedures for requesting a coverage determination.
    d. MVP Health Care will utilize the current CMS "Model Part D Transition Notice" for notification to Beneficiaries of the reasons for their transition fills and recommendations for actions. Notwithstanding any reference in this policy to submitting a transition notice that uses the CMS model notice via the file an use system, since CMS has stated that this is not required, the model notice will not be submitted via the file and use process unless and until CMS requires this.
    e. CVS Caremark will provide a daily extract file containing all transition fill paid claims.
    f. Prescriber names and addresses are included on the daily transition fill extract file. Transition notices to prescribers are generated and mailed and/or faxed when a Beneficiary transition fill notice is produced. The content of this notice is based on the content of the Beneficiary transition fill notice, or CMS model notice if provided. Reasonable efforts are made to deliver the notice to the prescriber.
12. Availability of Prior Authorization and Exception Request Forms
    a. Prior authorization and Exception Request Forms will be available upon request to the Beneficiary or prescriber via a variety of means including by email, mail, fax, and the MVP Medicare or provider website. Beneficiaries may obtain forms by contacting the MVP Customer Care Center, phone number is on the back of their ID card. Providers may also obtain forms by contacting Provider Services.
13. The transition process for new Beneficiaries is coded to apply across Contract Years for Beneficiaries with an effective enrollment date of either November 1 or December 1 and who need access to a transition supply. These Beneficiaries are eligible for a TF from the date they enroll in the current Contract year (i.e. Nov or Dec 1) through the TF Window which starts on January 1 of the next plan year.
14. Beneficiaries and providers will find information on the Transition Process, including the Transition Supply Policy in a variety of plan materials, including the MVP Medicare web site, plan enrollment materials (ANOC), formulary document, and the

required link from the Medicare Prescription Drug Plan Finder to the MVP Medicare website. The Transition Supply policy will also be available in pre-and-post enrollment marking materials as directed by CMS.

15. Transition Extensions
    Extensions to the transition period will be reviewed on a case-by-case basis if the exception request, prior authorization request or appeal has been received during the transition period but not yet processed or is awaiting resolution (decision) at the end of the transition period (either through the switch to an appropriate formulary drug or a decision on the exception request). The extension process can be started through the MVP Customer or Provider Services Departments.
16. Consistent with the transition fill process to new Beneficiaries, CVS Caremark Part D Services, L.L.C. provides transition fills, to renewing Beneficiaries during the first 90 days of the Contract Year with history of utilization of impacted drugs when those Beneficiaries have not been transitioned to a therapeutically equivalent formulary drug; or for whom formulary exceptions/prior authorizations are not processed prior to the new Contract Year. This applies at POS to all renewing Beneficiaries including those residing in LTC facilities.
    a. Renewing Beneficiary Transition Fills are available to all Beneficiaries during the TF Window who are impacted by a negative formulary change. Renewing Beneficiaries need to have a history of utilization of the drug for which coverage is being requested.
    b. For these Beneficiaries, the CVS Caremark Part D Services, L.L.C. adjudication system automatically processes and pays transition fill-eligible claims and transmits POS messaging that these are paid under transition fill rules
    c. Additional transition supplies are available on a case-by-case basis through the MVP Health Care Customer or Provider Services Departments to ensure adequate transition. Pharmacies are not required to either submit, or resubmit a PAMC, or other transition fill-specific code for transition fill-eligible claims to adjudicate and pay.
    d. The quantity and time plan limits may be greater based on the benefit design and will be limited by the amount prescribed.

Implementation Statement (process implementation in conjunction with CVS Caremark Part D Services, L.L.C.)

The following is a summary statement for how eligible claims process under TF adjudication system rules upon point of sale (POS) and manual submission to allow the override of system edits that would otherwise result in rejected claims. The objective of these TF adjudication system rules is to ensure pharmacies are able to resolve and override TF-eligible edits at POS toward the goal of ensuring Beneficiary access to medications per Part D requirements and guidance.

1. TF Adjudication System ensures that:
    a. TF-eligible claims for new and ongoing prescriptions automatically adjudicate upon submission at POS for:

i. New Beneficiaries in the plan following the annual coordinated election period
ii. Newly eligible Medicare Beneficiaries from other coverage
iii. Beneficiaries who switch from another Part D plan after the start of a contract year
iv. Current Beneficiaries affected by negative formulary changes (including new utilization management requirements) from on Contract Year to the next.
v. Beneficiaries residing in LTC facilities

b. Transition fill processing is also available via manual overrides through the Pharmacy Help Desk.
c. Transition fill window and eligibility check is applied to the claim.
The Beneficiary's TF eligibility start date is provided by the Sponsor and based on plan design. TF logic is not invoked if a claim exceeds either transition fill window or cumulative days supply parameters based on Beneficiary eligibility.
d. TF processing allows for transition supplies of different drug strengths.
TF benefits (including Cumulative Days Supply) are set up based on Drug Generic Product Identifier (GPI) 14 to allow TF processing of different strengths of a drug under TF system rules. This ensures that a Beneficiary taking a drug with one strength is able to receive TF for same drug/different strength if they present with a new prescription within TF-eligible time period.
    i. For Beneficiaries who are new to plan, renewing Beneficiaries within first 90 days of Contract Year, and for LTC new patient admissions and emergency supplies, TF for dosage escalation is allowed, as appropriate, by manual override via the Delegated PBM Pharmacy Help Desk.
f. Med D Drugs only allowed for TF.
Non-Med D drugs are excluded from TF processing. Non-Med D drugs are identified with an "N" in the "Med D" field on the Delegated PBM drug database. This enables the system TF logic to exclude these from transition fill processing when claims for these drugs are submitted by pharmacies. Drugs that are covered under the Medicare Part D benefit and, therefore potentially eligible for TF, are identified with a "Y" on the Med D field on the Delegated PBM drug database.
g. Multi-Ingredient Compounds processed for TF.
TF processing for Multi-Ingredient Compound (MIC) drugs is based on the formulary status of the claim (topical MICs are considered Non-formulary and non-topical MICs are based on most expensive ingredient submitted). Non-formulary drugs will process under MIC TF rules. Step, QvT, daily dose and age edits may be bypassed for MIC drugs and claims paid outside of TF based on benefit design set-up. Since MICs are Non-formulary Drugs and generally covered only pursuant to an approved exception request, MIC drugs processed for TF are assigned the cost share applicable to the exception tier (i.e. the cost sharing applicable to Non-formulary Drugs approved pursuant to an exception request.)

Step 1: MIC adjudication determines the type of compound; determines if the MIC is a Part A or B or Part D drug. If the MIC is determined to be Part D eligible drug (no Part A or B ingredients and at least one Part D ingredient), then proceed to Step 2.

Step 2: Adjudication determines the formulary status of the Part D MIC claim based on the benefit design; benefit set up determines if it is either formulary or Non-formulary.

i. Topical compounds are Non-formulary, so the entire claim is considered Non-formulary and TF will apply.
ii. Non-topical compounds base the formulary status on the most expensive Part D ingredient.
    a. If the most expensive ingredient is a formulary drugs, then all Part D ingredients in the MIC pay at contracted rates.
    b. If the most expensive ingredient is Non-formulary and is eligible for TF, then all Part D ingredients in the MIC pay as a TF. The TF letter refers to this prescription as "compound" prescription
    c. If the most expensive ingredient is not eligible for TF, the entire MIC will reject/not pay as TF.

The following edits will not be bypassed for MIC claims: Step, QvT, daily dose and age.

2. This policy and procedure is updated at least annually in advance of the CMS TF attestation window with the process changes expected for the following year. The policy is also updated as needed for additional changes.
3. Claims for Non-formulary Drugs that are eligible for TF processing
    a. In the event of the launch of a new generic drug, the Sponsor elects whether to retain the brand on the formulary and not to add the generic to the formulary. A Beneficiary with the equivalent brand name drug in the look back history will not be eligible for a transition fill of the generic with the same formulation. The brand name drug would be available without the need for a transition fill. If a Beneficiary is currently taking a brand drug, a transition fill for the brand drug with a formulary change will be provided to allow Beneficiary sufficient time to work with the prescriber to obtain an appropriate switch to a therapeutically equivalent medication or the completion of an exception request to maintain coverage of an existing drug based on medical necessity reasons.
    b. Beneficiaries with a current claim for a drug that requires a quantity limit lower than the quantity limit on the beneficiary's history dose will be eligible for TF processing.
4. Systems capabilities exist to provide transition supplies at POS. Pharmacies are not required to either submit, or resubmit a PAMC or other TF-specific codes for a TF-eligible claim to adjudicate.
    a. POS Pharmacy Provider Notification
        i. Pharmacies are notified at POS that claims have paid under TF rules, which is intended to assist pharmacies with discussing next steps with Beneficiaries.
        ii. TF processing information and communications are sent to all network pharmacies. The TF processing information and communications include, though are not necessarily limited to the: Pharmacy Provider Manual and all related updates; and the Medicare Part D Information/Reminders document that is sent annually to network pharmacies prior to the beginning of each new Contract Year.

iii. Delegated PBM Pharmacy Help Desk (PHD): Pharmacies contacting the PHD are verbally informed of Beneficiary's TF availability, process and rights for requesting prior authorization and/or exception, and how to submit an automated TF request.

iv. Auto-pay of TF-Eligible Claims
When submitted claims are eligible for payment under TF rules, RxClaim adjudication system logic applies the TF PAMC 22223333444 to the claim, tags the claim as a paid TF, and returns the below messaging on paid TF claims. Pharmacies are not required to either submit, or resubmit a PAMC or other TF-specific codes for a TF-eligible claim to adjudicate. The TF-related codes and messaging returned to pharmacies on paid TF claims is compliant with Current NCPDP Telecommunication Claim Standards. In accordance with these standards, the "Paid under transition fill" messaging follows the ADDINS (additional insurance) and Brand/Generic Savings messaging when these apply. Otherwise, the "Paid under transition fill" is returned as the first message on paid TF claims. Non-TF eligible claims are rejected and are not paid under TF rules.

"Paid under transition fill. Non-formulary."
"Paid under transition fill. PA required."
"Paid under transition fill. Other reject." (Note: This includes Step, QvT, Daily Dose and Age requirements)

In addition to the POS messaging above, and in accordance with Current NCPDP Telecommunication Claim Standards, the below approval message codes are also returned on TF paid claims.

TF APPROVAL MESSAGE CODES

NCPDP Pharmacy Approval Message Code	TF Condition
005	TF claim is paid during transition period but required a prior authorization
006	TF claim is paid during transition period and was considered Non-formulary
007	TF claim is paid during transition period due to any other circumstance
009	TF claim is paid via an emergency fill scenario but required a prior authorization
010	TF claim is paid via an emergency fill scenario and was considered Non-formulary
011	TF claim is paid via an emergency fill scenario due to any other circumstance

013	TF claim is paid via a level of care change scenario but required a prior authorization
014	TF claim is paid via a level of care change scenario and was considered Non-formulary
015	TF claim is paid via a level of care change scenario due to any other circumstance

b. There are conditions under which it may be necessary for the Delegated PBM Pharmacy Help Desk (PHD) or Customer Care (CC) to enter a manual TF override. These situations include, but are not necessarily limited to:
   i. Non-LTC Beneficiary moves from one treatment setting to another, if not identified automatically through the adjudication process
   ii. Beneficiary has requested an exception and the decision is pending at the time the TF period expires, or the TF cumulative days supply exhausted
   iii. TF for dosage increase is needed

c. When manually entered with the TF PAMC, these TF overrides are adjudicated and tagged via the same processes as automated POS TF's. The same "Paid under transition fill…" messaging is returned to Pharmacies on manual TF overrides as returned on automated paid TF claims. TF letters are produced and sent to Beneficiary for manual TF overrides same as POS overrides.

5. TF Days Supply & Time Period Parameters (and LTC Days Supply for Statement 7)
   a.

Description	TF Days Supply
New & Renewing Beneficiaries	
	• These quantity and time plan limits may be greater based on the benefit design and will be limited by the amount prescribed • Non-LTC: cumulative applicable month's supply within first 90 days in the Plan: multiple fills up to a cumulative applicable month's supply are allowed to accommodate fills for amounts less than prescribed • LICS III: LICS III cumulative days supply as defined by the plan. Either non-LTC, LICS III or LTC parameters are applied according to the LICS level, and pharmacy submitted codes. • LTC: cumulative applicable month's supply within first 90 days in the plan, oral brand solids are limited to 14 days supply with exceptions as required by CMS guidance, unless submitted with an SCC 21-36; multiple fills for a

	cumulative applicable month's supply are allowed to accommodate fills for amounts less than prescribed / first 90 days
Non-LTC Resident Level of Care Change	
• Beneficiary released from LTC facility within past 30 days	• These quantity plan limits may be greater based on the benefit design and will be limited by the amount prescribed • Non-LTC: cumulative applicable month's supply; multiple fills up to a cumulative applicable month's supply are allowed to accommodate fills for amounts less than prescribed. • LICS III: LICS III cumulative days supply as defined by the plan. Either non-LTC, LICS III or LTC parameters are applied according to the LICS level and pharmacy submitted codes. • TF available at POS if identified through adjudication, otherwise through manual override via Pharmacy Help Desk on case-by-case basis
New and Renewing TF Extension	
• New or Existing Beneficiaries • Outside standard TF days supply or time period parameters • TF parameters have been reached and Beneficiary is still pending exception/coverage determination decision	• These plan limits will be limited by the amount prescribed • Non-LTC: Per MVP's plan design, via manual override, additional as needed as long as exception or coverage determination decision is pending • LTC: per MVP's plan design, via manual override, additional as needed as long as exception or coverage determination decision pending

b. Non-LTC Resident Level of Care Change
   i. For non-LTC residents, a transition fill may be provided automatically at POS, if the adjudication process indicates a Level of Care change from LTC to non-LTC and the claim is rejecting for Refill Too Soon (R79) or DUR (R88). Otherwise, the pharmacy may call the Delegated PBM Pharmacy Help Desk in order to obtain an override to submit a Level of Care transition fill request.
   ii. A Level of Care change from LTC to non-LTC is indicated in the adjudication process if the submitted drug matches a claim in the most recent 120 days of history on GPI 14 with a Patient Location Code indicating LTC. The non-LTC residents are allowed up to a cumulative applicable month's supply (or greater based on benefit

design); multiple fills up to a cumulative applicable month's supply are allowed to accommodate fills for amounts less than prescribed.

6. The adjudication system ensures that cost-sharing applied to TF's for low-income subsidy (LIS) Beneficiaries never exceeds statutory maximum co-pay amounts; and for non-LIS Beneficiaries, cost-sharing is based on one of the plan's approved cost-sharing tiers and is consistent with that charged for a Non-formulary drugs approved under a coverage exception. Non-formulary transition supply will receive the same cost sharing that would apply for a non-formulary exception and transition supply for formulary drugs with a UM edit will receive the same cost share as would apply if the UM criteria is met.
7. Processing for LTC Setting
   a. Pharmacy Network and Patient Residence Type Codes
      TF parameters can vary by network level (or list of networks) through the use of network or pharmacy lists. Therefore, different TF days supply can be accommodated for Retail, Mail, LTC and/or Home Infusion providers. The Pharmacy Service Type and Patient Residence Type codes on submitted claims are used to identify the submitting pharmacy as either non-LTC or LTC for purposes of reimbursement and allowed TF days supply.
      i. The values defined as being LTC pharmacy by Delegated PBM pharmacy network operations are cross-walked internally during RxClaim adjudication to the legacy system value "Patient Location Code" (PLC) 03.
   b. LTC TF cumulative days supply limits are allowed for qualified claims submitted with PLCs designating LTC.
   c. LTC Emergency Supply (ES) is allowed after the transition supply parameters are exhausted for new Beneficiaries and a coverage determination or exception is still pending. Transition supply parameters do not need to be exhausted for renewing Beneficiaries to receive LTC ES. The LTC ES transition policy provides for a cumulative 31 days supply, except for oral brand solids which are limited to 14 days supply with exceptions as required by CMS guidance, unless submitted with an SCC 21-36.
   d. TF LTC New Patient Admission/ Level of Care Change and LTC Emergency Supply are automated based upon specific POS claim submission rules. Pharmacies are instructed on how to correctly submit qualifying claims via Provider Manual updates and ongoing network communications so that these claims correctly process as TF under applicable LTC TF conditions.

LTC NEW PATIENT ADMISSION & LTC EMERGENCY SUPPLY	
Description	**TF Days Supply**
LTC New Patient Admission/Level of Care Change Beneficiary resides in LTC Facility (New Admission)	
• Beneficiary admitted to LTC facility within past 30 days	• These quantity plan limits may be greater based on the benefit design and will be limited by the amount prescribed

• New Patient Admission (NP) Level of Care Change (LOC)	• Cumulative applicable month's supply, except for oral brand solids which are limited to 14 days supply with exceptions as required by CMS guidance, unless submitted with an SCC 21-36: At POS submitted with: • Submission Clarification Code 420-DK Value "18" • Patient Location Code identified as LTC • Additional fills as needed are available via manual TF overrides through the Pharmacy Help Desk • Multiple fills allowed to accommodate LOC changes • TF LTC NP is allowed per calendar day, per Beneficiary, per drug, per pharmacy, per plan a cumulative days supply • New Beneficiaries must have TF days supply exhausted, or TF time period expired
LTC Emergency Supply Beneficiary resides in LTC facility	
• LTC Emergency Supply (ES)	• These supplies may be greater based on the benefit design and will be limited by the amount prescribed • Cumulative 31 days supply, except for oral brand solids which are limited to 14 days supply with exceptions as required by CMS guidance, unless submitted with an SCC 21-36. At POS submitted with: • Submission Clarification Code 420-DK Value "7" • Patient Location Code identified as LTC • POS automated TF LTC ES is set-up to allow either a one ES every rolling 30 days, limited to one ES per LTC stay.. The adjudication logic looks back 30 days starting the day after the date of fill depending. • LTC ES is allowed per calendar day, per Beneficiary, per drug, per pharmacy, per plan a cumulative days supply during a rolling month • New Beneficiaries must have TF day supply exhausted, or TF time period expired, and while an exception or prior authorization is pending

e. LTC New Patient Admission or Level of Care Change for Beneficiaries being admitted to or discharged from an LTC facility - early refill edits are not used to limit appropriate and necessary access to their Part D benefit, and such Beneficiaries are allowed access to a refill upon admission or discharge.

LTC NEW PATIENT & LTC EMERGENCY SUPPLY
REFILL TOO SOON (RTS) & DRUG UTILIZATION REVIEW (DUR) OVERRIDES

Description	Edit	Reject Code	Point of Sale	Manual Override Available
LTC New Patient	RTS/ Plan Option 15	79	Y	Y (if Drug Qualifies as TF, TF Override used)
LTC Emergency Supply	RTS/ Plan Option 15	79	N	Y (if Drug Qualifies as TF, TF Override used)
LTC New Patient	DUR – Plan Option 30	88	Y	Y (if Drug Qualifies as TF, TF Override used)
LTC Emergency Supply	DUR – Plan Option 30	88	N	Y (if Drug Qualifies as TF, TF Override used)

8. Transition Fill Edits
   a. **Override Edits Not Applied During TF**
      TF overrides are not applied at POS, or manually to drugs with dose limits based on maximum FDA labeling, A or B vs. D drugs requiring coverage determination prior to application of TF benefits, or drugs not covered by CMS under Part D program benefits, which include drugs that require a medically accepted indication.
      i. **Refill Too Soon (RTS)**
         Automated TF system logic for new and renewing Beneficiaries does not allow override of RTS (except for LTC New Patient Admission or Level of Care Change) edits. Instead, reject 79 (RTS) is returned to pharmacies when submitted claims hit these edits.
      ii. **DUR Safety Edits**
         Automated TF system logic for new and renewing Beneficiaries does not allow override of DUR safety edits that are set up at point of sale. Instead, reject 88 (DUR) is returned to pharmacies with appropriate instructions when submitted claims hit this edit
      iii. **Part A or B Only Drugs**
         Automated TF adjudication logic is not applied to Part A or B only drug claims. All Med A or B 'only' drugs are excluded from TF processes and payment under TF rules and are tagged with an "N" status in the "Med D" status field on the Delegated PBM drug database. Part A or B only drugs reject using the appropriate reject codes

and applicable Current NCPDP Telecommunication Claim Standards structured reject messaging.

iv. **Part A or B vs. Part D (A or B vs. D)**
Part A or B vs. D drugs are not provided a TF because coverage is available for the drugs. A determination is needed to identify what coverage will be applied to the drug. Part A or B vs. D drugs reject using the appropriate reject codes and applicable current NCPDP Telecommunication Claim Standards structured reject messaging. This allows pharmacy or Beneficiary to call Delegated PBM for clinical review to determine coverage. The identifier flag can be set up on the RxClaim Prior Authorization table to specify Med A or B vs. D drugs. Part B vs. D drugs reject using the appropriate reject codes and applicable Current NCPDP Telecommunication Claim Standards structured reject messaging. Med A or B v. D claims reject as A6 (B vs. D), A5 (Not D, not B. Not covered under Part D Law), A4 (This Product May Be Covered Under The Medicare- B Bundled Payment To An ESRD Dialysis Facility) or A3 (This Product May Be Covered Under Hospice-Medicare A). Plan-level phone numbers are returned in the reject messaging for formulary drug claims rejecting for A or B vs. D determinations to enable pharmacies to follow-up. Once the determination is made, if a drug is determined to be Part D eligible, a PA is entered. Non-formulary drugs in these categories, as a rule will not be covered under Part A or B or Part D. Therefore, a TF is provided to allow the enrollee to leave the pharmacy with a temporary supply and work with their prescribers to identify a formulary alternative.

v. **Excluded Drugs-not covered by CMS under Part D program benefits**
CMS requires some drugs be reviewed to determine the Part D drug status. These drugs will require a medically accepted indication based on the FDA approved label or the CMS approved compendia in determining if it is eligible for Part D coverage**.** Beneficiaries can request a Formulary Exception for these drug**s.** Drugs will only be approved for Beneficiaries who provide the diagnosis demonstrating that the drug is prescribed for a medically accepted indication**.** Beneficiaries who have a coverage determination (prior authorization or Formulary Exception) denied, will receive a denial letter indicating their drug is not a Part D drug. Beneficiaries will have the right to appeal the decision**.** If the drug is determined to be for a medically accepted indication and so a Part D drug, but any additional utilization management criteria are not met, then the claim is reviewed for TF eligibility and a PA is entered if appropriate.
Excluded drugs may reject for the following reasons:
1. Formulary drugs will reject for prior authorization (PA) required (R75).
2. Non-formulary drugs will reject as non-formulary (R70).

b. **TF-Eligible Edits**
TF day supply and time parameters are applied to submitted claims for:
- Non-formulary Drugs
- Formulary drugs with prior authorization, step therapy, QL (quantity vs. time, daily dose) or age edits. TF logic may or may not be applied, according to Sponsor benefit design, in situations where there is a maximum FDA labeled dosage that should not be exceeded for safety reasons. The following is the

order of processing for drugs to which edits are applied: Step Therapy; Prior Authorization; Quantity Limits (including daily dose and age).

The unique types of transition fill conditions are listed below.

i. **Non-formulary (NF)**
Drugs that are not covered on a closed formulary. NF TF overrides a reject code 70 for NDC Not Covered (Plan reject 70). National Drug Code (NDC).

ii. **Prior Authorization (PA)**
Drugs that are covered on the formulary but require prior authorization. PA TF overrides a reject code 75 for Prior Authorization.

iii. **Step Therapy**
Formulary drugs that reject for Step Therapy prerequisites may be eligible for TF. TF processing allows the Step Therapy reject to be overridden and the claim to process through Step Therapy program logic and post to history appropriately. A Step Therapy transition fill notice may be generated for this edit. For some drugs with step therapy edits where the Beneficiary obtained a TF ("grandfathered" or Type 2 ST-PA meaning submitted to CMS as step for new starts to therapy only), the TF itself satisfies the step therapy requirements for that drug. This means that the Beneficiary has already met the step requirements and will be able to continue to obtain future fills of that drug without encountering a reject. In these cases, Step TF Letters are not sent to either Beneficiaries or prescribers. **Quantity Limits (QL's)**
Quantity vs. Time (QvT) or Maximum Daily Dose (DD)
Drug quantity limits are used to establish the allowed amounts for coverage of selected drugs to specified values over a set period of time. For the purposes of TF, a quantity limit is considered a type of transition fill for drugs that require limited supply of a drug to be dispensed based on days supply or allowed quantity across time or maximum doses per day.

1. Drugs that would otherwise reject for quantity limitations when submitted for more than the allowed quantity are eligible for transition fill processing during the transition time period. TF system logic allows the quantity limit reject to be overridden and the claim to process through TF program logic and to post to history appropriately. If a claim is not eligible for TF override and rejects for quantity limits (i.e. TF days supply exhausted, or TF time period expired), it will continue to reject according to quantity limit parameters using Reject 76. TF overrides "quantity over time" edits that are set up to either count continuous fill history across Contract Years (quantity "period to date" Type D set-up), or to count fill history beginning January 1 of each Contract Year. QL/QvT TF overrides the reject code 76.
2. In addition to TF for QL/QvT, TF is available for DD drug edits. DD and QL/QvT edits are mutually exclusive. If both were ever to be set up together on the same plan, TF for the QL/QvT edits takes precedence over the DD TF. DD TF overrides reject 76.
3. For QvT TF and Plan Limitations, a QvT set up on drug NDC (Plan Option 10) and/or GPI (Plan Option 11) will override Plan Limitations

that are set up on Plan Options 26.1 and 26.2, Preferred Formulary. Therefore, when TF is allowed for QvT reasons, the Plan Limitations on 26.1 and 26.2 are also overridden. However, cumulative TF days supply does not override either once used/exhausted.

4. For QL changes, the system will look at the QL edit in history and compare it to the current/active QL edit. If the QL edits do not match, the QL edit is overridden and the claim processes through TF program logic.

v. **Age Edits**
TF is available for formulary drugs that are set up with Age Edits for safety reasons. Age Edit TF overrides a reject 76.

vi. **AG Reject**
An AG Reject is a claim reject due to a days supply limitation. Claims submitted for more than remaining allowed TF Days Supply return an "AG" reject code and message "Resubmit for Remaining Day Supply of XX" with XX being the number of remaining allowed TF cumulative days supply. The "AG" reject code is returned as the primary reject code, unless, per current NCPDP Telecommunication Claim Standards, this reject is required to follow either the ADDINS (additional insurance) and/or Brand/Generic Savings messaging when these apply. AG rejects are returned on both initial claims with no prior TF in history, as well as subsequent submissions when cumulative days TF supply have not been exhausted with previous paid TF. When a pharmacy reduces the claim days supply and resubmits, TF-eligible claims process via TF rules.

vii. **Unbreakable Pre-packaged Medication Logic**
Drugs for which the manufactured packaging cannot be split for the dispensing of a prescription may be considered an unbreakable pre-packaged medication for which the pre-packaged medication days supply may be dispensed.. The intent of this logic is to ensure a Beneficiary receives their entire TF days supply (DS) even though the DS exceeds the maximum benefit, due to the type of packaging for the drug. This logic will apply if the pre-packaged medication cumulative DS is less than the required benefit, prior to the current fill. If the pre-packaged medication cumulative DS including the current fill quantity exceeds the maximum benefit, and is the quantity of a single package of medication, the TF will pay. If the pre-packaged medication cumulative DS including the current fill quantity exceeds the maximum benefit, and the current fill quantity exceeds the quantity of a single package of medication, the pharmacy will be messaged to resubmit for a single package of the medication. The claim will retain the messaging and the rejects associated with the processing.

viii. **Beneficiary Level / Clinical Prior Authorizations (PA)**
Beneficiary level clinical prior authorizations will be entered to override all TF-eligible edits. Otherwise, a TF will be allowed for any TF-eligible edit for which the PA has not been entered. When a Beneficiary / clinical PA already exists on the Beneficiary record to override all TF-eligible edits, TF

processing is not applicable. Under this condition, claims do not process as TF and TF letters are not sent to Beneficiaries.

c. **Processed without TF**

i. **Protected Class Drugs (PCD) Logic**

The PCD Logic will pay the claim without TF according to the plan criteria. TF processing will apply to any TF-eligible edit which the PCD logic has not overridden.

ii. **Type 2 ST-PA Drug Logic**

Type 2 ST-PA Drug edits are edits submitted to CMS as Step for new starts to therapy only. CVS Caremark Part D Services, L.L.C. adjudication logic uses a 108-day minimum look back period for determining new starts. The Type 2 ST-PA Drug Logic will pay the claim without TF logic, according to the plan criteria. TF processing will apply to any TF-eligible edit which the Type 2 ST-PA Drug Logic has not overridden.

9. TF Claims History
   All history for a drug during the transition time period is counted, regardless of the dispensing pharmacy/network. POS, manually entered, and Beneficiary submitted (paper) claims for Retail, Mail, Long Term Care and Home Infusion networks are counted together to determine the total cumulative days supply for a drug. TF days supply limits are defined as cumulative supplies based on Part D days supply requirements to ensure that refills for TF-eligible drugs are available when TF is dispensed at less than the amount written secondary to quantity limits due to safety, or edits based on approved product labeling; the system automatically "counts" prior related TF claims to allow correct TF days supply accumulation parameters to apply.
10. If the distinction cannot be made between a brand-new prescription for a Non-formulary Drug and an ongoing prescription for a Non-formulary Drug at the POS, the transition process is applied to a brand-new prescription for a Non-formulary drug.
    a. Beneficiaries who are new to the plan include: new plan Beneficiaries at the start of Contract Year; newly eligible Beneficiaries from other coverage; and Beneficiaries who switch from one plan to another after the start of a Contract Year.
    b. Transition fills are available at POS through transition processing during the TF Window
    c. Additional transition supplies are available on a case-by-case basis through the MVP Customer or Provider Care line to ensure adequate transition

11. Transition Fill (TF) Letters are sent to Beneficiaries within three (3) business days of adjudicated TF claim; reasonable and best efforts are also made to identify a current prescriber address/contact information and provide notice of TF to prescribers to facilitate transitioning of Beneficiaries. For LTC residents dispensed multiple supplies of a Part D drug in increments of 14-days-or-less as required by CMS guidance, the written notice will be provided within 3 business days after adjudication

of only the *first* temporary fill. TF Letters are generated from the TF Claim and Letter Tags which are extracted to the daily TF Letter File.

a. TF Claim and Letter Tag Indicators Based on TF-eligible Edits
    i. TF Claim Tag: This is the adjudication system tag applied to the claim when adjudicated under TF system rules. This tag represents the reason the claim paid under TF processes and what edits were overridden by TF rather than rejecting as otherwise would happen when TF is not available. These tags can represent either a single TF reason (e.g. Non-formulary, PA, Step, or Qty Limit); or can also represent a combination of TF reasons (e.g. PA with Qty Limit; Non-formulary with Qty Limit, etc.).
    ii. TF Letter Tag: This tag is used to designate the specific TF letter language content for the TF notice to Beneficiaries and prescribers.
    iii. TF Combo Tag: This tag is used to designate the specific TF letter language content for the TF notice to Beneficiaries and prescribers for Sponsors who choose to print a paragraph for each edit that was overridden by TF.
b. Daily TF Letter File
    i. Paid TF claims are automatically extracted to a daily TF Claim File. For every paid TF claim, there is either a corresponding record on the correlated daily TF Letter File, or the record is captured on the daily internal Exception file with the reason the record is not included on the TF Letter File (example: same day paid/reversed).
    ii. The contents of the TF Letter file are used to drive production of the appropriate Beneficiary and prescriber TF letters.
    iii. Transition Fill Beneficiary communications are provided in other languages (CMS 5% threshold) when identified by MVP on TF implementation submissions and also identified on Beneficiary's eligibility language preference.

12. Prior Authorization and exception request forms available upon request to Beneficiaries, prescribers, pharmacies and others by a variety of means including mail, fax, email, and the MVP Medicare and Provider websites.
13. Delegated PBM transition process for new Beneficiaries is applied from the date of enrollment through the TF Window. The enrollment date does not need to be the start of the Contract Year and the transition process may be extended across Contract Years where the TF Window extends across Contract Years.
14. [Intentionally left blank to maintain consistent numbering between sections.]
15. TF Extensions are available for New or Existing Beneficiaries, non-LTC or LTC, through the PHD or CC. The request is reviewed for the following and processed according to Sponsor instructions:
    a. Outside standard TF days supply or time period parameters
    b. TF parameters have been reached and Beneficiary is still pending exception/coverage determination decision
16. Transition for Current Beneficiaries
    a. Renewing Beneficiaries need to have a history of utilization of the Non-formulary drugs(s). History utilization requires the following criteria:

i. History look back of 180 days from current date of fill, to identify the most recent qualifying history claim.
ii. History look back drug GPI 10 match
iii. History claim(s) for same drug not paid as transition fill(s)
    1. Or if only a paid transition fill is in history, the history transition fill reject reason must not match the incoming claim transition fill reject reason
    2. If the history TF reject reason does match the incoming claim TF reject reason and the reason is QL, the QL limits for each claim must be different.
iv. Beneficiary's clinical prior authorization(s) are not already effectuated.
v. For instances where the Beneficiary receives a partial transition fill, the logic will ensure that the renewing Beneficiary's remaining days supply is transition fill eligible during the TF Window. New Beneficiary, LTC ES and LTC NP & Beneficiary PA (reason TF) paid TF claims are not included in the look back calculation to determine if the renewing Beneficiary received a partial fill and has remaining days supply.
    b. Renewing Beneficiary logic has the following hierarchy: brand generic logic, transition fill reject reason comparison, then look back calculation for remaining day supply.
    c. The following processes are options MVP Health Care may request the Delegated PBM to implement for renewing Beneficiaries:
        i. Use the ANOC as advance notice of any formulary changes.
        ii. Prospectively work to educate and transition current Beneficiaries on medications that will no longer be on the formulary in the new Contract Year or that will require prior authorization, step therapy or quantity limit utilization management edits in the new Contract Year.
        iii. Encourage processing of formulary exceptions/prior authorizations prior to January 1 of a new Contract Year.
        iv. Consistent with the transition fill process provided to new Beneficiaries, Delegated PBM provides transition fills, to renewing Beneficiaries during the first 90 days of the Contract Year with history of utilization of impacted drugs when those Beneficiaries have not been transitioned to a therapeutically equivalent formulary drug; or for whom formulary exceptions/prior authorizations are not processed prior to the new Contract Year. This applies to all renewing Beneficiaries including those residing in Long Term Care facilities.

MVP Health Care Medical Policy

Nuedexta

Type of Policy:	**Drug Therapy**
Prior Approval Date:	**11/01/2022**
Approval Date:	**11/01/2023**
Effective Date:	**01/01/2024**
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
    - Other diagnoses that may cause laughing or crying spells (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 require current clinical chart notes documenting improvement in frequency of laughing and crying episodes and improvement in CNS-LS score from baseline.

Exclusions

- Concomitant use with other drugs containing quinidine, quinine, or mefloquine.
- Patients with a history of Nuedexta, quinine, mefloquine or quinidine-induced thrombocytopenia, hepatitis, bone marrow depression or lupus-like syndrome. Nuedexta is also contraindicated in patients with a known hypersensitivity to dextromethorphan.
- Patients taking monoamine oxidase inhibitors (MAOIs) or in patients who have taken MAOIs within the preceding 14 days, due to the risk of serious and possibly fatal drug interactions, including serotonin syndrome.
- Patients with a prolonged QT interval, congenital long QT syndrome or a history suggestive of torsades de pointes, and 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), as effects on QT interval may be increased.
- Patients with complete atrioventricular (AV) block without implanted pacemakers, or in patients who are at high risk of complete AV block
- Nuedexta to treat psychosis, delirium, or disruptive behavior.

References

1. NUEDEXTA (dextromethorphan hydrobromide and quinidine sulfate) capsules. Prescribing information. Aliso Viejo, CA: Avanir Pharmaceuticals, Inc. October 2010.
2. Ahmed A, Simmons Z. Pseudobulbar affect: prevalence and management. Ther Clin Risk Manag. 2013;9:483-9. doi: 10.2147/TCRM.S53906. Epub 2013 Nov 29. PMID: 24348042; PMCID: PMC3849173.

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

Onychomycosis

Type of Policy:	**Drug Therapy**
Prior Approval Date:	**04/01/2023**
Approval Date:	**04/01/2024**
Effective Date:	**06/01/2024**
Related Policies:	**N/A**

Drugs Requiring Prior Authorization

ciclopirox (Penlac®) if quantity is greater than 20ml per 365 days
efinaconazole (Jublia®)
itraconazole (generic) if quantity is greater than 360 capsules per 365 days or 3600ml per 365 days
tavaborole (Kerydin®)
Brand itraconazole products: Sporanox, Tolsura
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 patient 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.

Tolsura is FDA approved for the treatment of systemic fungal infections in adult patients including blastomycosis (pulmonary and extrapulmonary), histoplasmosis including chronic cavitary pulmonary disease and disseminated, non-meningeal histoplasmosis) and aspergillosis (pulmonary and extrapulmonary, in patients who are intolerant of or who are refractory to amphotericin B therapy). Tolsura is not indicated for the treatment

of onychomycosis. It is not interchangeable with other itraconazole products due to the difference in dosing.

Indications/Criteria

Terbinafine

Terbinafine does not require prior authorization for quantities less than 168 units per 365 days. Terbinafine is the drug of choice for the treatment of onychomycotic nails. It is associated with higher cure rate, fewer relapses, less side effects, and less drug interactions than itraconazole and ciclopirox.

Sporanox, , Tolsura Generic itraconazole does not require prior authorization for quantities less than 360 capsules per 365 days or 3600ml per 365 days.

Brand itraconazole products (Sporanox) 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:

1. Immunocompromised (e.g., HIV/AIDS, undergoing chemotherapy, transplant recipient) or has a history of peripheral vascular disease (e.g., diabetes), **OR**
2. Activities of daily living (ADLs) are significantly compromised due to pain caused by the infection **AND**
3. If the member has a documented failure, lack of indication, or other contraindications to terbinafine.
    - The use of Onmel and Sporanox for the treatment of onychomycosis will require documentation of why the use of generic itraconazole would not be appropriate for the member. Itraconazole dosing for onychomycosis:
        - Fingernail infections: **200mg bid x 1 week/month for 2 courses**
        - Toenail infections: **200mg QD for 12 weeks**

Systemic fungal infections

Itraconazole, including Tolsura, for the treatment of systemic fungal infections may be allowed for a longer duration of therapy. Documentation of specific diagnosis and culture results should be submitted to the Pharmacy Department for clinical review. Prior use of terbinafine is not required for systemic fungal infections.

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.

Julia

The use of **Julia** 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%

Kerydin

The use of **Kerydin** may be covered for onychomycosis of the toenail when

- The member meets ALL the above criteria for Julia **AND**
- Documentation of a failure of a 48-week trial of Julia

Exclusions

1. Combination therapy with more than one agent identified in this policy.
2. Onmel used for the treatment of conditions other than onychomycosis of the toenail
3. Age, dosing, frequency and/or duration of therapy outside of FDA approved package labeling

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References

1. Lamisil® (terbinafine) Tablets. Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; April 2012.
2. Sporanox® (itraconazole) Capsules/Oral Solution. Prescribing Information. Raritan, NJ: Ortho-McNeil-Janssen Pharmaceuticals, Inc.; April 2012.
3. Penlac® Nail Lacquer (ciclopirox) Topical Solution. Prescribing Information. Bridgewater, NJ: Sanofi Aventis US; July 2006.
4. Bel-Syer SEM, Hart R, Crawford F, Torgerson DJ, Tyrell W, Russell I. oral treatments for fungal infections of the skin of the foot. 2006 issue 1.
5. Gilbert DN, Meollering RC, Eliopoulos GM, et al. The Sanford Guide to Antimicrobial Therapy:2013
6. Jansen R, Redekop WK, Rutten FF. Cost effectiveness of continuous terbinafine compared with intermittent itraconazole in the treatment of dermatophyte toenail

onychomycosis: an analysis of based on results from the L.I.O.N. study. Lamisil versus Itraconazole in Onychomycosis. Pharmacoeconomics. 2001;19(4):401-10.

7. Tosti A, Piraccini BM, Stinchi C, et al. Treatment of dermatophyte nail infections: an open randomized study comparing intermittent terbinafine therapy with continuous terbinafine treatment and intermittent itraconazole therapy. J Am Acad Dermatol. 1996 Apr;34(4):595-600.
8. Jublia® (efinaconazole) topical Solution, 10%. Prescribing Information. Bridgewater, NJ: Valeant Pharmaceuticals LLC, February 2015
9. Kerydin® (tavaborole) topical solution, 5%. Prescribing Information. Palo Alto, CA: Anacor Pharmaceuticals, Inc; February 2015
10. Tolsura (itraconazole capsules). Prescribing Information. Greenville, NC: Maybe Pharma; December 2018.
11. Jublia® (efinaconazole) topical Solution, 10%. Prescribing Information. Bridgewater, NJ: Valeant Pharmaceuticals LLC, July 2020.
12. Phillip Rodgers, MD. And Mary Bassler, MD. Treating Onychomycosis. Am Fam Physician. 2001;63(4):663-673.
13. Westerberg DP, Voyack MJ. Onychomycosis: Current trends in diagnosis and treatment. Am Fam Physician. 2013 Dec 1;88(11):762-70. PMID: 24364524.

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.
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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).	

***Medical Management Requirements**

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

MVP Health Care Medical Policy

Omidubicel

Type of Policy:	Medical Therapy (administered by the pharmacy department)
Prior Approval Date:	NA
Approval Date:	02/01/2024
Effective Date:	02/01/2024
Related Policies:	Donislecel Experimental or Investigational Procedures, Behavioral Health Services, Drugs and Treatments, Off-Label use of FDA Approved Drugs, and Clinical Trials

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

Drugs Requiring Prior Authorization under the medical benefit

J3590 omidubicel (Omisirge), cell therapy suspension for infusion

Overview

Omidubicel is approved for use in hematopoietic stem cell transplant following myeloablative conditioning in patients with hematologic malignancies to reduce the time to neutrophil recovery and incidence of infection. It has been designated an orphan drug for this indication. Omidubicel is a nicotinamide-modified allogeneic hematopoietic progenitor cell therapy derived from cord blood indicated for use in adults and pediatric patients 12 years and older with hematologic malignancies who are planned for umbilical cord blood transplantation following myeloablative conditioning to reduce the time to neutrophil recovery and the incidence of infection.

Indications/Criteria

Hematologic Malignancy

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

- Member is 12 years of age or older
- Member has a documented hematologic malignancy, and the medication is being used to reduce the time to neutrophil recovery and incidence of infection.
- Documentation that the member has not received a prior allogeneic hematopoietic stem cell transplant (allo-HSCT)
- Documentation of planned umbilical cord blood transplantation
- Documentation that member will receive myeloablative conditioning.
- Prescribed by or in consultation with a hematologist or oncologist
- Must be administered at a transplant center who is activated and able to administer omidubicel
    - Treatment centers that can administer are: OMISIRGE™ (omidubicel-onlv) | Allogeneic Hematopoietic Progenitor Cell Therapy
- Documentation that administration of omidubicel will be under the supervision of a physician experienced in treatment of hematologic malignancies,
- Documentation that the member does not have a known allergy or hypersensitivity to the following:
    - Dimethyl sulfoxide (DMSO)
    - Dextran 40
    - Gentamicin aminoglycoside albumin
    - Bovine protein hypersensitivity

If approved, coverage will be for one infusion of Omidubicel and will not be renewed. Requests for replacement due to lost or damaged product will not be covered. Coverage is contingent on eligibility at the time of infusion.

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 May 2, 2023. Accessed December 6, 2023.

2. Prescribing Information. Omisirge. Gamida Cell, Inc. Boston, MA. Revised April 2023. Omisirge-final-PI.pdf (gamida-cell.com)

Member Product	Medical Management Requirements*
New York Products	
HMO	Prior Authorization
PPO in Plan	Prior Authorization
PPO OOP	Prior Authorization
POS in Plan	Prior Authorization
POS OOP	Prior Authorization
Essential Plan	Prior Authorization
MVP Medicaid Managed Care	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
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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
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Vermont Products	
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UVM Health Advantage Secure PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
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).	

***Medical Management Requirements**

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

MVP Health Care Medical Policy

Medicare Part B: Omidubicel

Type of Policy:	Medical Therapy (administered by the pharmacy department)
Prior Approval Date:	NA
Approval Date:	02/01/2024
Effective Date:	02/01/2024
Related Policies:	Donislecel Experimental or Investigational Procedures, Behavioral Health Services, Drugs and Treatments, Off-Label use of FDA Approved Drugs, and Clinical Trials

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

Drugs Requiring Prior Authorization under the medical benefit

J3590 omidubicel, cell therapy suspension for infusion

Overview/Summary of Evidence

Omidubicel is approved for use in hematopoietic stem cell transplant following myeloablative conditioning in patients with hematologic malignancies to reduce the time to neutrophil recovery and incidence of infection. It has been designated an orphan drug for this indication. Omidubicel is a nicotinamide-modified allogeneic hematopoietic progenitor cell therapy derived from cord blood indicated for use in adults and pediatric patients 12 years and older with hematologic malignancies who are planned for umbilical cord blood transplantation following myeloablative conditioning to reduce the time to neutrophil recovery and the incidence of infection.

Indications/Criteria

Hematologic Malignancy

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

- Member is 12 years of age or older
- Member has a documented hematologic malignancy, and the medication is being used to reduce the time to neutrophil recovery and incidence of infection.
- Documentation that the member has not received a prior allogeneic hematopoietic stem cell transplant (allo-HSCT)
- Documentation of planned umbilical cord blood transplantation
- Documentation that member will receive myeloablative conditioning.
- Prescribed by or in consultation with a hematologist or oncologist
- Must be administered at a transplant center who is activated and able to administer omidubicel
    - Treatment centers that can administer are: OMISIRGE™ (omidubicel-onlv) | Allogeneic Hematopoietic Progenitor Cell Therapy
- Documentation that administration of omidubicel will be under the supervision of a physician experienced in treatment of hematologic malignancies
- Documentation that the member does not have a known allergy or hypersensitivity to the following:
    - Dimethyl sulfoxide (DMSO)
    - Dextran 40
    - Gentamicin aminoglycoside albumin
    - Bovine protein hypersensitivity

If approved, coverage will be for one infusion of Omidubicel and will not be renewed. Requests for replacement due to lost or damaged product will not be covered. Coverage is contingent on eligibility at the time of infusion.

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 May 2, 2023. Accessed December 6, 2023.

2. Prescribing Information. Omisirge. Gamida Cell, Inc. Boston, MA. Revised April 2023. Omisirge-final-PI.pdf (gamida-cell.com)

MVP Health Care Medical Policy

Oral Allergen Immunotherapy Medications

Type of Policy: **Drug Therapy**
Prior Approval Date: **11/01/2022**
Approval Date: **11/01/2023**
Effective Date: **01/01/2024**
Related Policies: **N/A**

Drugs Requiring Prior Authorization

The following drugs listed are oral immunotherapy medications that may fall under prescription drug coverage. These drugs require a prior authorization and apply to this policy.

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 patient 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 the following criteria are met:

1. Must be 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; AND
3. Patient meets the age criteria approved for the oral allergen immunotherapy medication (see chart below); AND

4. Treatment is started before pollen season as specified below in chart.
5. Patient has failed at least three (3) of the following treatment options:
    a. Intranasal corticosteroids
    b. Oral or intranasal antihistamine
    c. Oral leukotriene receptor antagonist OR
    d. Intranasal cromolyn.

Cross-reactive allergen and approved age criteria:

Brand Name	Chemical/Generic name	Age Criteria	Strongly Cross-Reactive Allergen
Grastek®	Timothy Grass Pollen Allergen Extract	5 through 65 years of age	Members of the pooideae sub family (includes but not limited to orchard, fescue, ryegrass, June, and sweet vernal)
Odactra®	House dust mite allergen extract	12 through 65 years of age	(*Dermatophagoides farinae* and *Dermatophagoides pteronyssinus*)
Oralair®	Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass Mixed Pollens Allergen Extract	5 through 65 years of age	Members of the pooideae sub family (includes but not limited to orchard, fescue, ryegrass, June, and sweet vernal)
Ragwitek®	Short Ragweed Pollen Allergen Extract	5 through 65 years of age	Short, giant, western, and false ragweed

Initial therapies 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).	5 months

	Therapy should be initiated in January in Northeast	
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		

For continuation of treatment, the benefits of treatment must be documented in the member's chart along with medication compliance based on prescription claims review. 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.

Extensions for Oralair and Ragwitek will be through the end of pollen season, typically October in Northeast.

For continuation of daily therapy of Grastek after end of pollen season authorizations will be for 6 months. Extension will be contingent on compliance based on prescription claims review.

Extensions of Odactra will be up to 12 months

Treatment for all products beyond three years must be supported by documentation identifying clinical rationale for continued treatment.

Exclusions

1. Frequency exceeding FDA approved package of one tablet a day (exception is Oralair® Starter Pack which includes a 2-day titration of 3 100 IR tablets for ages 10-17)
2. Non-FDA approved indications without documentation of supporting clinical studies and failure of preferred treatments
3. If the cause is a non-IgE mediated allergy
4. The member has no significant reduction in symptoms after 24 weeks of therapy
5. Grastek® patients that were on active therapy daily for 3 consecutive years must wait at least 1 year until coverage may be reinitiated, unless patients experience a documented severe increase in symptoms compared to the past 3 years
6. Severe unstable or uncontrolled asthma

7. History of eosinophilic esophagitis
8. History of any severe system allergic reaction or any severe local reaction to sublingual allergen immunotherapy
9. If receiving subcutaneous allergen immunotherapy

References

1. Grastek® (Timothy Grass Pollen Allergen Extract). Prescribing Information. Whitehouse Station, NJ: Merck & Co., Inc.; September 2016. Revised March 2022.
2. Oralair® (Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass Mixed Pollens Allergen Extract). Prescribing Information. Antony, France: Stallergenes S.A.; 2014 Oct. Revised November 2018.
3. Ragwitek® (Short Ragweed Pollen Allergen Extract). Prescribing Information. Whitehouse Station, NJ: Merck & Co., Inc.; September 2016. Revised March 2022.
4. American Academy of Allergy, Asthma & Immunology/American College of Allergy, Asthma, & Immunology (AAAAI/ACAAI). Allergen immunotherapy: A practice parameter third update. J Allergy Clin Immunol. 2011 Jan;127(1 Suppl): S1-55.
5. Weber RW. Guidelines for using pollen cross-reactivity in formulating allergen immunotherapy. J Allergy Clin Immunol. 2008; 122:219-21.
6. Sur DK and Scandale S, Treatment of Allergic Rhinitis. Am Fam Physcian. 2010;81(12):1440-6.

Seidman MD, Gurgel RK, Lin SY, et al. Clinical practice guideline: Allergic rhinitis. Otolaryngol Head Neck Surg. 2015;152(1 Suppl): S1-43.

7. Odactra ® Prescribing information. Whitehouse Station, NJ: Merck & Co., Inc. March 2017. Revised January 2023.

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).	

***Medical Management Requirements**

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

MVP Health Care Medical Policy

Medicare Part B: Orphan Drug(s) and Biologicals

Type of Policy:	**Drug/Medical Therapy**
Prior Approval Date:	**11/01/2023**
Approval Date:	**08/01/2024**
Effective Date:	**10/01/2024**

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

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

Adagen® (J2504 Inj, pegademase bovine, 25 IU)
Aldurazyme® (J1931 Inj, laronidase, 0.1 mg)
Arikayce (J8499 amikacin liposome inhalation susp)
Brineura (J0567 cerliponase alfa inj. 1mg)
Cablivi (J3590, Inj Caplacizumab)
Ceprotin™ (J2724 Inj, protein C concentrate, IV 101U)
Clolar® (J9027 Inj, clofarabine, 1 mg)
Crysvita (J0584 inj, burosumab-twza 1 mg)
Elaprase® (J1743 Inj, idursulfase)
Elzonris (J9269 Inj, tagraxofusp-erzs)
Enjaymo™ (J1302 Inj, sutimlimab-jome)
Evkeeza™(J1305, evinacumab-dgnb)
Folotyn (J9307 Inj, pralatrexate, 1 mg)
Fusilev™ (J0641 Inj, levoleucovorin 0.5mg)
Gamifant (J9210, emapalumab-IZSG inj)
Ilaris® (J0638 Inj, canakinumab 1mg)
Kanuma (J2840 Inj, sebelipase alfa, 1mg)
Khapzory (J0642) levoleucovorin IV solution)
Lamzede (J0217, velmanase alfa-tycv, 10mg)
Lumizyme (J0221 Inj, alglucosidase alfa)
Mepsevii (J3397 Inj. Vestronidase alfa)

Naglazyme® (J1458 Inj, galsulfase, 1 mg)
Nexviazyme® (J0219, avalglucosidase alfa-ngpt)
Nulibry® (C9399, J3490, fosdenopterin)
Oxlumo® (J0224, lumasiran)
Pombiliti (J1203, cipaglucosidase alfa, powder for injection)
Poteligeo (J9204) Inj. mogamulizumab-kpkc)
Reblozyl (J0896, luspatercept-aamt, SQ injection)
Retisert® (J7311 fluocinolone acetonide, intravitreal implant)
Rystiggo (J9333, Rozanolixizumab SQ infusion)
Scenesse (J7352, afamelanotide implant 16mg)
Soliris® (J1300 Inj, eculizumab, 10 mg)
Sylvant (J2860 Inj, siltuximab, 10mg)
Ultomiris™ (J1303, ravulizumab-cwvz IV, inj)
Uplizna® (J1823, inebilizumab-cdon)
Veopoz (J9376, pozelimab-bbfg, injection, 1mg)
Vimizim (J1322, Inj, elosulfase alfa, 1mg)
Vyjuvek (J3401, beremagene geperpavec)
Vyvgart™ (J9332 Inj, efgartigimod alfa-fcab)
Vyvgart Hytrulo (J9334 Injection, efgartigimod alfa; hyaluronidase)
Xenpozyme™ (J0218 Inj, olipudase alfa)
Zynlonta (J9359, loncastuximab tesirine-lpyl)* *This list is subject to change based on FDA approval of new drugs and/or new indications*

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

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.

MVP Health Care Medical Policy

Orphan Drug(s) and Biologicals

Type of Policy:	**Drug/Medical Therapy**
Prior Approval Date:	**08/01/2023**
Approval Date:	**08/01/2024**
Effective Date:	**10/01/2024**

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

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

Adagen® (J2504 Inj, pegademase bovine, 25 IU)
Aldurazyme® (J1931 Inj, laronidase, 0.1 mg)
Arikayce (J8499 amikacin liposome inhalation susp)
Brineura (J0567 cerliponase alfa inj. 1mg)
Cablivi (J3590, Inj Caplacizumab)
Ceprotin™ (J2724 Inj, protein C concentrate, IV 101U)
Clolar® (J9027 Inj, clofarabine, 1 mg)
Crysvita (J0584 inj, burosumab-twza 1 mg)
Elaprase® (J1743 Inj, idursulfase)
Elzonris (J9269 Inj, tagraxofusp-erzs)
Enjaymo™ (J1302 Inj, sutimlimab-jome)
Evkeeza™(J1305, evinacumab-dgnb)
Folotyn (J9307 Inj, pralatrexate, 1 mg)
Fusilev™ (J0641 Inj, levoleucovorin 0.5mg)
Gamifant (J9210, emapalumab-IZSG inj)
Ilaris® (J0638 Inj, canakinumab 1mg)
Kanuma (J2840 Inj, sebelipase alfa, 1mg)
Lamzede (J0217, velmanase alfa-tycv, 10mg)
Khapzory (J0642) levoleucovorin IV solution)
Lumizyme (J0221 Inj, alglucosidase alfa)Mepsevii (J3397 Inj. Vestronidase alfa)
Naglazyme® (J1458 Inj, galsulfase, 1 mg)

Nexviazyme® (J0219, avalglucosidase alfa-ngpt)
Nulibry® (C9399, J3490, fosdenopterin)
Oxlumo® (J0224, lumasiran)
Pombiliti (J1203, cipaglucosidase alfa, powder for injection)
Poteligeo (J9204) Inj. mogamulizumab-kpkc)
Reblozyl (J0896, luspatercept-aamt, SQ injection)
Retisert® (J7311 fluocinolone acetonide, intravitreal implant)
Rystiggo (J9333, Rozanolixizumab SQ infusion)
Scenesse (J7352, afamelanotide implant 16mg)
Soliris® (J1300 Inj, eculizumab, 10 mg)
Sylvant (J2860 Inj, siltuximab, 10mg)
Ultomiris™ (J1303, ravulizumab-cwvz IV, inj)
Uplizna® (J1823, inebilizumab-cdon)
Veopoz (J9376, pozelimab-bbfg, injection, 1mg)
Vimizim (J1322, Inj, elosulfase alfa, 1mg)
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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)
Arcalyst™ (J2793 SQ Injection, rilonacept, 1 mg)
Ayvakit (avapritinib tablets)
Benznidazole tab (J8499 12.5mg 100mg tabs)
Bylvay™ (odevixibat)
Calquence (C9399/J8999 acalabrutinib cap 100mg)
Camzyos™ (mavacamten)
Carbaglu® (carglumic acid)
Cholbam (cholic acid oral capsules)
Cometriq (cabozantinib oral capsules)

Cystaran (cysteamine ophthalmic solution)
Cystadrops (cysteamine ophthalmic solution
Danyelza® (J9348, naxitamab-gqgk)
Daurismo™ (glasdegib oral tablets)
Diacomit (Stiripentol)
Empaveli® (pegcetacoplan)
Enspryng® (satralizumab-mwge)
Exjade® (deferasirox oral tablet for suspension)
Fintepla® (fenfluramine)
Firdapse® (amifampridine oral tablets)
Galafold (migalastat, 123mg capsule)
Givlaari (givosiran,189mg/mL solution for subcutaneous injection)
Imcivree™ (setmelanotide)
Impavido® (miltefosine, oral capsule)
Inrebic (Fedratinib)
Jakafi (ruxolitinib oral tablet)
Joenja (leniolisib oral tablet)
Juxtapid (lomitapide oral capsules)
Korlym (mifepristone, oral tablets)
Koselugo (selumetinib capsules)
Kynamro (mipomersen injection)
Livmarli® (maralixibat)
Mifepristone (oral tablets)
Myalept (SQ Inj, metreleptin, 11.3mg)
Nityr (Nitisinone Tablets)
Ocaliva (obeticholic acid, oral tablet)
Ojjaara (momelotinib, oral tablet)
Opfolda (miglustat, oral capsule)
Onureg® (azacitidine)
Orfadin (nitisinone, oral capsules)
Oxbryta (voxelotor oral tablet)
Oxervate™ (ophthalmic solution)
Pemazyre (pemigatinib tablets)
Pheburane® (sodium phenylbutyrate)
Procysbi (cysteamine oral capsule)
Ravicti (glycerol phenylbotyrate oral liquid)

Relyvrio™ (sodium phenylbutyrate and taurusodiol)
Retevmo™ (selpercatinib)
Revcovi (elapegademase-lylr IM injection)
Rezurock® (belumosudil)
Rozlytrek® (entrectinib)
Ruzurgi (Amifampridine)
Signifor (SQ Injection pasireotide)
Skyclarys (omaveloxolone capsules)
Sohonos (palovarotene, oral capsules)
Strensiq (asfotase alfa injection)
Tabrecta® (capmatinib)
Tavalisse (fostamatinib oral tablets)
Tazverik (tazemetostat HBR tablets)
Tiglutik (riluzole oral suspension)
Tibsovo (ivosidenib oral tablets)
Turalio (Pexidartinib)
Ukoniq (Umbralisib)
Viktravi® (larotrectinib oral capsules, oral solution)
Vijoice® (alpelisib)
Vizimpro® (dacomitinib oral tablets) Xospata® (gilteritinib oral tablets)
Vonjo™ (pacritinib)
Xpovio (Selinexor)
Xuriden (uridine triacetate, oral granules)
Zokinvy (lonafarnib)
Zolinza® (vorinostat oral capsule)
** This list is subject to change based on FDA approval of new drugs and/or new indications*

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

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.

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Physician and member must comply with all approved and/or limited distribution channels for the agent including specialty pharmacy vendors where applicable.

Drug and/or biological coverage is subject to the terms and conditions of the member's prescription drug rider and/or contract.

Documentation submitted must include baseline subjective/objective laboratory or test results (dependent on drug and diagnosis). If member started therapy while enrolled in a clinical trial, baseline laboratory or test results must be provided from prior to the start of the trial.

For continuation of therapy request documentation must show improvement in symptoms/condition from baseline.

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

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

MVP Medicare WellSelect Plus PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Patriot Plan PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess Complete D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess Plus D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Select PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Secure PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	
POS in Plan	Prior Auth
POS OOP	Prior Auth
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D
MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Select PPO	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Secure PPO	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D
MVP VT HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD
♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).	

***Medical Management Requirements**

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

MVP Health Care Medical Policy

Ozanimod

Type of Policy: **Drug/Medical Therapy**
Prior Approval Date: **10/01/2022**

Approval Date: **10/01/2023**
Effective Date: **12/01/2023**
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
- Documentation of a failure of preferred products Humira (adalimumab), Xeljanz (tofacitinib), Rinvoq (upadacitinib) and Stelara (ustekinumab).

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:

- Dosing/age and/or frequency outside of the FDA approved package labeling.
- Ozanimod in combination with immunomodulators, biologic therapy, or targeted synthetic drugs.

References

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2. Zeposia (ozanimod). Prescribing Information. Summit, NJ. Celgene Corporation. May 2021.
3. ACG Clinical Guidline: Ulcerative Colitis in Adults. The American Journal of Gastroenterology: March 2019 - Volume 114 - Issue 3 - p 384-413 doi:

10.14309/ajg.0000000000000152. Accessed: ACG Clinical Guideline: Ulcerative Colitis in Adults : Official journal of the American College of Gastroenterology | ACG (lww.com)

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
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).**

***Medical Management Requirements**

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

MVP Health Care Medical Policy

Pain Medications

Type of Policy: **Drug Therapy**
Prior Approval Date: **08/01/2023**
Approval Date: **08/01/2024**
Effective Date: **10/01/2024**
Related Policies: **Refer to the MVP Medicare website for the Medicare Part D formulary and policies for drugs covered under the Part D benefit.**

Drugs Requiring Step Therapy and/or Prior Authorization

Additional quantities exceeding the amounts identified in the chart below will require prior authorization. The member is responsible for the applicable pharmacy copayment at each prescription fill/refill including any difference in cost between the generic and the brand name drug if a generic is available. Quantity limits apply to all brand and generic products.

Brand Name	**Release Immediate (IR) Extended (ER)**	**Chemical/Generic Name**	**Requirement**	**Quantity Limit every 30 days except as noted**
+Actiq®	IR	fentanyl citrate	Prior authorization	60 lozenges
Arymo	ER	morphine sulfate	Step edit	90 tablets
Avinza®	ER	morphine sulfate	Step edit	30 capsules
Belbuca	IR	buprenorphine buccal film	Quantity limit	60 films

Butrans®	ER	buprenorphine	Step edit	4 patches/28 days
Conzip®	ER	tramadol	Quantity limit	30 capsules
Duragesic Patch	ER	fentanyl	Step edit	20 patches
Embeda®	ER	morphine/naltrexone	Step edit	60 capsules
Exalgo™	ER	hydromorphone	Step edit	30 tablets
+Fentora®	IR	fentanyl citrate	Prior authorization	60 tablets
Hysingla ER	ER	hydrocodone bitartrate	Step edit	60 tablets
Kadian®	ER	morphine sulfate	Step edit	90 capsules
+Lazanda®	IR	fentanyl citrate nasal	Prior Authorization	7 bottles (56 doses)
Morphabond	ER	morphine sulfate	Step edit	90 tablets
MS Contin®	ER	morphine sulfate	Step edit	90 tablets
Nucynta ER	ER	tapentadol	Quantity limit	60 tablets
Opana® ER	ER	oxymorphone HCL	Step edit	90 tablets
Oxycontin®	ER	oxycodone HCL	Step edit	90 tablets
Sprix™	IR	ketorolac tromethamine	Prior authorization	5 single-day spray bottles
+Subsys®	IR	fentanyl	Prior authorization	60-unit dose sublingual spray
Ultram® ER	ER	tramadol	Quantity limit	30 tablets
Xartemis XR	ER	oxycodone/acetaminophen	Step edit	120 tablets
Xtampza	ER	oxycodone HCL	Step edit	60 capsules
Zohydro™ER	ER	hydrocodone bitartrate	Step edit	60 capsules

+ Part of the single shared system REMS, the transmucosal immediate-release fentanyl (TIRF) REMS Access Program. This includes brand names and generics. Outpatients, prescribers who prescribe to outpatients, pharmacies, and distributors must enroll in the program. For inpatient administration (e.g. hospitals, hospices, and long-term care facilities that prescribe for inpatient use, patient and prescriber enrollment is not required

Overview

Pain medications are FDA approved for use in mild to severe pain. They are available in many dosage forms including tablets, capsules, nasal sprays, topical patches and other forms.

The World Health Organization has issued the following guideline for the treatment of cancer pain. If pain occurs, there should be prompt oral administration of drugs in the following order: nonopioids (aspirin and paracetamol); then, as necessary, mild opioids (codeine); then strong opioids such as morphine, until the patient is free of pain. To calm fears and anxiety, additional drugs – "adjuvants" – should be used. To maintain freedom from pain, drugs should be given "by the clock", that is every 3-6 hours, rather than "on demand". This three-step approach of administering the right drug in the right dose at the right time is inexpensive and 80-90% effective. Surgical intervention on appropriate nerves may provide further pain relief if drugs are not wholly effective.[1]

The Centers for Disease Control and Prevention (CDC)'s Clinical Practice Guidelines for Prescribing Opioids for Pain includes recommendations to clinicians providing pain care to patients aged 18 years and older. The guidelines address naloxone has part of a patient's comprehensive pain management plan to mitigate opioid related harms. Naloxone is available through the pharmacy benefit without utilization management restrictions.

Ketorolac nasal spray (Sprix) is indicated for short term (up to 5 days) management of moderate to moderately severe pain.

Narcotic extended-release formulations are controlled release formulations indicated for the relief of moderate to severe pain requiring continuous, around-the-clock opioid therapy for an extended period of time. They are not indicated for treatment of acute pain (excluding Xartemis XR) or titration of opiate naive patients.

Fentanyl and buprenorphine transdermal formulations are indicated for the management of persistent, moderate to severe chronic pain that requires continuous, around-the-clock opioid administration for an extended period of time, and cannot be managed by other means such as non-steroidal analgesics, opioid combination products, or immediate-release opioids.

Fentanyl buccal (Fentora®), fentanyl oral transmucosal solid dosage forms, (Actiq® and generic), sublingual tablets (Abstral), Subsys sublingual spray and Lazanda nasal spray are indicated specifically for breakthrough cancer pain.

Tramadol ER and tapentadol are centrally acting synthetic opioid analgesics indicated for moderate to severe chronic pain in adults who require around-the-clock treatment for an extended period of time.

Indications/Criteria

A. Opioids for chronic use, greater than 3 months, will be considered if the ALL following is met in addition to other criteria:

1. Must have current provider- patient opioid treatment agreement
2. Must have a documented pain management treatment plan that addresses taper
3. Must have documented verification of Prescription Monitoring Program Registry (if available)
4. Must have addressed opioid overdose risk management if MME >90
5. Documentation identifies at least one prescription for a chronic pain extended-release formulation in the preceding 90 days with immediate release formulations prescribed in quantities required for breakthrough pain

B. Immediate Release Narcotic Formulations

Fentanyl oral transmucosal, buccal, sublingual tablets, sublingual spray, and nasal spray dosage forms require prior authorization (for all quantities) and may be considered for coverage when all the following criteria are met:

1. Persistent breakthrough cancer pain and currently on an around-the-clock extended release narcotic formulation of any of the following: at least 60 mg of oral morphine/day, 25 mcg of transdermal fentanyl/hour, 30 mg of oxycodone/day, 8 mg oral hydromorphone/day, 25 mg oral oxymorphone/day or an equianalgesic dose of another opioid for at least seven days

2. Other formulary immediate release narcotic pain medications such as morphine and oxycodone have not provided adequate breakthrough pain relief or are contraindicated or not tolerated. After failure, contraindication, or intolerance to other formulary medications (e.g. morphine and oxycodone), fentanyl immediate release formulations must be tried in the following order:
    a. generic fentanyl
    b. brand name oral fentanyl dosage forms
    c. fentanyl sublingual spray
    d. fentanyl citrate nasal spray
3. Ordered by or pursuant to the consult of an oncologist or pain management specialist

4. Documentation identifies at least one prescription for a chronic pain extended release formulation such as a morphine derivative, fentanyl patch or an equianalgesic dose of another opioid along with an immediate-release (IR) medication within the preceding 90 days
5. If the request is for more than the quantity limit, documentation must demonstrate that the quantity is medically necessary. Documentation must support that the long-acting opioid is being titrated to maximize the around-the-clock dose and minimize the breakthrough pain (prn or "as needed") dosing for the fentanyl oral product

Initial approval will be for up to a maximum of 3 months and will be dose specific.

Extensions of therapy will be approved for a maximum of 6 months if documentation provided identifies continued benefit from therapy and "rescue" doses used in a 24-hour period and dosing of long-acting product has been evaluated and is appropriate. Increases in dose require a new request

C. Extended Release Formulations

Refer to chart for quantity limits that will be allowed per month by automated edit providing that the member's medication claim history has at least a seven-day supply for an immediate release opioid within the preceding 90 days. Medication history requirement does not apply to tramadol ER and tapentadol ER however criteria below will apply if quantity limit is exceeded

Requests for extended release dosage units in a quantity exceeding that available with the automated step edit described above may be considered medically necessary when all the following criteria are met:

1. Documentation identifies an inadequate response to or a contraindication to dosing at recommended intervals since the advantage of using long acting products is the extended dosing schedule
2. Documentation identifies persistent, moderate to severe pain that requires continuous, around-the-clock analgesia with a high potency opioid for an extended period of time (weeks to months) or longer
3. Documentation must identify that the strength of the long-acting product has been evaluated and the supplemental dose of the short-acting analgesic is appropriate. The number of "rescue" opioid doses during a

24-hour period can be a guide to determine whether the sustained release dose is appropriately dosed.

Initial approval will be up to 6 months

Extension requests will be approved up to 6 months if documentation provided identifies continued benefit from therapy and "rescue" doses used in a 24-hour period and dosing of long-acting product has been evaluated and is appropriate.

D. Sprix may be considered medically necessary in adults when all the following are met:

1. Moderate to severe pain post-surgery requiring analgesia at the opioid level
2. Not able to take oral medications including liquids, sublingual, etc
3. Approval will be for a maximum of 5 days per surgery
4. No evidence of peptic ulcer disease or history of GI bleed, suspected or confirmed cerebrovascular bleeding, bleeding tendency, incomplete hemostasis or at high risk of bleeding,
5. No evidence of advanced renal disease or risk for renal failure due to volume depletion

Initial approval will be for 5 days within 6 months

E. <u>7 Day Opioid Rule</u>

Initial prescriptions of immediate release opioids will be limited to a 7-day supply if the member has not filled the same opioid in the previous 60 days.

- Approval for greater than a 7-day supply will be granted when:
  - For new enrollees with no prescription history- if the provider submits documentation supporting previous use of the opioid during the previous 60 days
  - There is a change in dose of the same opioid product (i.e. morphine IR 15mg tablet to morphine IR 30mg tablet)
- This law will not apply to members with chronic pain due to cancer and sickle cell disease

Approvals will be one time only

F. <u>4 Opioid Prescriptions in 30 Day Rule</u>

- After 4 opioid prescriptions are filled in a 30-day period all additional opioid prescriptions will reject for the remainder of the 30 days.

- Approvals for greater than 4 opioid prescriptions will be allowed when:
    - The same opioid is being prescribed by providers in the same practice (i.e. multiple prescriptions for the same opioid during a 30-day period)
    - One immediate release product and one extended-release product are being prescribed by providers in the same practice
    - More than one opioid is being prescribed by providers in the same practice and rationale for multiple opioids or titration plan is provided
    - Members with a diagnosis of cancer or sickle cell or enrolled in hospice

  Approval will be for 3 months

- The following will **not** be approved:
    - Multiple providers not in the same practice prescribing opioids for member

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Exclusions

1. Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling
2. Fentanyl oral transmucosal, buccal, sublingual tablets, sublingual spray, or nasal spray dosage forms used as monotherapy
3. Extended release narcotic formulations in opioid naive members or for short-term/acute use (excluding Xartemis XR).
4. "As needed use" (also known as PRN) of an extended release opioid since the delivery mechanism is insufficient to treat pain immediately[10].
5. Coverage for use in non-approved indication not meeting MVP Experimental and Investigational policy.
6. Coverage for concomitant use of long-acting pain medications without documented failure of single agents at maximal doses.
7. Coverage for any pain medication in member with active and untreated alcohol or substance abuse without documentation of frequent ongoing evaluation including blood testing for abuse prevention.
8. Combination of buprenorphine medications with opioids

References

1. World Health Organization (WHO). WHO's pain ladder. Available: www.who.int/cancer/palliative/painladder/en/index.html. [Accessed 06/19/2015.]
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.
9. Oxycontin® (oxycodone hydrochloride) tablets. Prescribing Information. Stamford, CT: Purdue Pharma; July 2013
10. American Pain Society. (2003). Principles of analgesic use in the treatment of acute pain and cancer pain (5th ed.) Glenview, IL: American Pain Society.
11. Embeda® (morphine and naltrexone) extended release capsules. Prescribing Information. New York, NY: Pfizer, Inc.; April 2014
12. Exalgo™ (hydromorphone) extended release tablets. Prescribing Information. Hazelwood, MO: Mallinckrodt LLC; March 2013
13. Onsolis® (fentanyl) buccal soluble film. Prescribing Information. Sumerset, NJ: Meda Pharmaceuticals, Inc.; June 2012.
14. Butrans® (buprenorphine) Transdermal System. Prescribing Information. Stamford, CT: Purdue Pharma L.P.; July 2013
15. Abstral® (fentanyl citrate) sublingual tablets. Prescribing Information. Lincoln, NE: Novartis Consumer Health, Inc.; July 2013
16. Sprix™ (ketorolac) nasal spray. Prescribing Information. Menlo Park, CA: Luitpold/Rosro Pharma, Inc. October 2011.
17. Lazanda® (fentanyl citrate) nasal spray. Prescribing Information. Bedminster, NJ: Archimedes Pharma US Inc.; June 2012.
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19. Conzip (tramadol) capsules. Prescribing Information. Mississauga, ON: Cipher Pharmaceuticals. May 2010.
20. McEvoy GK, Miller J. Opiate agonists. In: AHFS Drug Information. Bethesda: American Society of Health-System Pharmacists, Inc; 2011.
21. Ultram ER (tramadol) tablets. Prescribing Information. Raritan, NJ: PriCara®, Division of Ortho-McNeil-Janssen Pharmaceuticals. . March 2010.
22. Subsys (fentanyl) sublingual spray. Prescribing Information. Washington, DC: Insys Therapeutics, Inc.; August 2012.

23. Center for Substance Abuse Treatment Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction. Treatment Improvement Protocol (TIP) Series 40. DHHS Publication No. (SMA) 04-3939. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2004. Available at http://buprenorphine.samhsa.gov/Bup_Guidelines.pdf. Accessed January 9, 2012.
24. Xartemis XR (oxycodone and acetaminophen) tablets. Prescribing Information. Hazelwood, MO: Mallinckrodt Pharmaceuticals. March 2014.
25. Clinical Pharmacaology. Methadone. Accessed April 21, 2017. https://www.clinicalpharmacology.com/Forms/drugoptions.aspx?cpnum=380&n=Methadone&t=0
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31. Centers for Disease Control and Prevention. CDC Clinical Practice Guideline for Prescribing Opioids for Pain. Last reviewed Nov. 2, 2022. Continuing Opioid Therapy | Healthcare Professionals | Opioids | CDC
32. Sprix™ (ketorolac) nasal spray. Prescribing Information. Wayna, PA: Zyla Life Sciences US, Inc. 4/2021.

Member Product	Medical Management Requirements*
New York Products	
HMO	Prior Auth
PPO in Plan	Prior Auth
PPO OOP	Prior Auth
POS in Plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Child Health Plus	Prior Auth
MVP Harmonious Health Care Plan	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Medicare Gold Giveback	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Secure HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.

MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare WellSelect PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare WellSelect Plus PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Patriot Plan PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess Complete D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess Plus D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Select PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Secure PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	
POS in Plan	Prior Auth
POS OOP	Prior Auth
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D
MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Select PPO	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Secure PPO	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D
MVP VT HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD
♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).	

***Medical Management Requirements**

Prior Auth	Prior Authorization Required
Potential for Retrospective Review	No Prior Authorization Required. May be subject to Retrospective Review.
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:	**11/01/2022**
Approval Date:	**11/01/2023**
Effective Date:	**01/01/2024**
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 peanut. Palforzia is approved for use in patients with a confirmed diagnosis of peanut allergy. Initial Dose Escalation may be administered to patients aged 4 through 17 years. Up-Dosing and Maintenance may be continued in patients 4 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.

Indications/Criteria

Initial Request

- Must be prescribed by a Board-Certified Allergist or Immunologist
- Documentation of allergy verified by skin testing
- Provider statement 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 statement indicating that the member currently has asthma under control
- 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
- Initial authorization for Palforzia will be approved for 6 months

Continuation Requests

- Must be prescribed by Allergist or Immunologist
- Member is compliant with therapy
- Controlled asthma
- Continued authorization will be for a period of one year

Exclusions

- Uncontrolled asthma
- History of eosinophilic esophagitis and other eosinophilic gastrointestinal disease.
- Outside FDA approved dosing, indications, age limits

References

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2. FDA New Release. FDA approves first drug for the treatment of peanut allergy for children. Accessed January 31, 2020. Available on the World Wide Web at https://www.fda.gov/news-events/press-announcements/fda-approves-first-drug-treatment-peanut-allergy-children?utm_campaign=013120_PR_FDA%20approves%20first%20drug%20for%20treatment%20of%20peanut%20allergy%20for%20children&utm_medium=email&utm_source=Eloqua

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).	

***Medical Management Requirements**

Prior Auth	Prior Authorization Required
Potential for Retrospective Review	No Prior Authorization Required. May be subject to Retrospective Review.
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:	**04/01/2023**
Approval Date:	**04/01/2024**
Effective Date:	**06/01/2024**
Related Policies:	**NA**

Drug Requiring Prior Authorization (covered under the medical benefit)

Parsabiv **J0606**, 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

- 18 years of age or older
- Has chronic kidney disease on hemodialysis
- 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)
- Patient 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
- Prescribed by or in consultation with an endocrinologist or nephrologist

- For patients with heart failure and/or risk factors for upper gastrointestinal bleeding (such as known gastritis, esophagitis, ulcers or severe vomiting), risks versus benefits of therapy have been evaluated.

Initial approval will be for 6 months, continuation requests up to 12 months.

- For continuation of coverage, patient must have at least a 30% reduction in PTH levels from baseline

Exclusions

- 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

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1.Parsabiv (etelcalcetide) injection [Package Insert]. Thousand Oaks, CA: KAI Pharmaceuticals, Inc; 2017. Revised 12/2019.

2. National Kidney Foundation. Secondary Hyperparathyroidism. [Internet]. 2017 [cited 2018 Sep 25]. Available from: https://www.kidney.org/atoz/content/secondary-hyperparathyroidism.

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5. Product Information: PARSABIV(R) intravenous injection, etelcalcetide intravenous injection. Amgen Inc (per FDA), Thousand Oaks, CA, 2019.

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

Essential Plan	Prior Auth
MVP Medicaid Managed Care	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Child Health Plus	Prior Auth
MVP Harmonious Health Care Plan	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
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MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
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♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).	
© 2024 MVP Health Plan, Inc. All rights reserved. Descriptions contained within MVP's Medical Policies are not a guarantee of coverage. Each MVP Group or Subscriber Contract contains specific limitations, exclusions and requirements that may affect a Policy. If there is any discrepancy between your Group or Subscriber Contract and a Policy, your Group or Subscriber Contract shall in all cases govern.	

***Medical Management Requirements**

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

MVP Health Care Medical Policy

Patient Medication Safety

Type of Policy:	**Administrative/Drug Therapy**
Prior Approval Date:	**07/01/2022**
Approval Date:	**08/01/2023**
Effective Date:	**10/01/2023**
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 for a broad range of safety edits prior to dispensing. The incoming prescription is compared to the patient'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
Over Use	• 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 patient 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

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 of 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 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 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

MVP Health Care Medical Policy

PCSK9 Inhibitors

Type of Policy: **Drug Therapy**
Prior Approval Date: **08/01/2023**
Approval Date: **08/01/2024**
Effective Date: **10/01/2024**

Related Policies: Orphan Drug Policy

Drugs Requiring Prior Authorization (covered under the pharmacy benefit)

Praluent (alirocumab)

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

Overview

Praluent is indicated for the following:

- To reduce the risk of myocardial infarction, stroke, and unstable angina requiring hospitalization in adults with established cardiovascular disease.
- As adjunct to diet, alone or in combination with other low-density lipoprotein cholesterol (LDL-C)-lowering therapies, in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH), to reduce LDL-C.
- As an adjunct to other LDL-C lowering therapies in adult members with homozygous familial hypercholesterolemia (HoFH) to reduce LDL-C.
- As an adjunct to diet and other LDL-C-lowering therapies in pediatric members aged 8 years and older with HeFH to reduce LDL-C.

Repatha is indicated for the following:

- in adults with established cardiovascular disease (CVD) to reduce the risk of myocardial infarction, stroke, and coronary revascularization

- as an 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 diet and other LDL-C-lowering therapies in pediatric members aged 10 years and older with HeFH, to reduce LDL-C
- as an adjunct to diet and other LDL-C-lowering therapies in pediatric members aged 10 years and older with HeFH, to reduce LDL-C

The 2018 American College of Cardiology/American Heart Association guidelines for the management of blood cholesterol indicate that PCSK9 Inhibitors be used in addition to other lipid lowering agents such as statins.

Praluent is the preferred PCSK9 Inhibitor.

Criteria

The following documentation must be provided:

- 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. 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 the treatment of Clinical Atherosclerotic Cardiovascular Disease (ASCVD)

1. 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

2. Must meet one of the following:
    a. 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
        i. High potency statins include atorvastatin 40mg, 80mg, and rosuvastatin 20mg, 40mg.
        ii. Member must be compliant with 3 months of high-intensity statin and ezetimibe therapy

iii. Claims history will be used to verify compliance

b. Current LDL-C level ≥ 70mg/dL and the member is intolerant to statin therapy (see appendix A)

All other excluded PCSK9 Inhibitors for the treatment of the indications listed above will require medical exception approval. Coverage will be considered on a case-by-case basis.

For the Treatment of Familial Hypercholesterolemia (FH) or Primary Hyperlipidemia

1. Must have diagnosis of heterozygous FH (see Appendix B) primary hyperlipidemia, or homozygous FH (see Appendix C)

2. Members with ASCVD must meet above criteria for ASCVD

3. Members without ASCVD must meet one of the following:
   a. 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
      i. High potency statins include atorvastatin 40mg, 80mg, and rosuvastatin 20mg, 40mg.
      ii. Member must be compliant with 3 months of high-intensity statin and ezetimibe therapy
      iii. Claims history will be used to verify compliance
   b. Current LDL-C level ≥ 100mg/dL and the member is intolerant to statin therapy (see appendix A)

All other excluded PCSK9 Inhibitors for the treatment of the indications listed above will require medical exception approval. Coverage will be considered on a case-by-case basis.

Initial approval and continuation of therapy

Initial approval will be for 3 months, LDL-C level obtained after week 8 of therapy must be submitted with initial extension request

Subsequent extension for one (1) year will be granted if 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:

1. 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
2. Muscle pain with a CK>5 x ULN
3. 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.

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13. Praluent™(alirocumab) injection. Prescribing Information. Bridgewater, NJ: Sanofi-aventis U.S. LLC. April 2021.
14. Praluent™(alirocumab) injection. Prescribing Information. Bridgewater, NJ: Sanofi-aventis U.S. LLC. March 2024.

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***Medical Management Requirements**

Prior Auth	Prior Authorization Required
Potential for Retrospective Review	No Prior Authorization Required. May be subject to Retrospective Review.
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: **07/01/2024**
Approval Date: **11/01/2024**
Effective Date: **08/01/2024**
Related Policies: **NA**

Codes Requiring Prior Authorization N/A

Overview

The Plan is committed to offering a comprehensive, cost-effective pharmacy benefit to those members and employer groups that elect prescription drug coverage. This policy is a guide to pharmacy programs under the MVP pharmacy benefits. This policy will be reviewed annually by the Pharmacy & Therapeutics (P&T) committee.

Formulary

MVP's formularies list covered generic and brand name medications. The formularies include FDA-approved legend drugs and biologics (NDA/ANDA/BLA). Formularies are published on the MVP website. Members and prescribers should refer to the formulary associated with the plan benefit (e.g. Commercial, Health Insurance Marketplace, or Medicare). Each formulary will include a guide (key) to assist members and prescribers in identifying the pharmacy management programs associated with a particular drug.

Pharmacy Management Programs

Prior Authorization

- MVP requires that the prescriber or member (depending on the member's benefit) obtain prior authorization approval for coverage of a medication before a prescription is filled.
- Medications subject to prior authorization are noted on the printed formularies.

- New drugs entering the marketplace also require prior authorization while under P&T Committee review for formulary and utilization management status. Members must have received and failed an adequate trial of all other medications to treat their condition (unless there is a contraindication), regardless of the prior authorization status of the other medications before a new drug will be approved. Sample use alone does not satisfy the criteria.
- Injectable medications with therapeutically equivalent oral formulations may require prior authorization.
- Medications may require prior authorization if being used for a medical condition that is not recognized as an FDA-approved indication or supported in the FDA-approved label, supported in one of the approved compendia, used in conjunction with a procedure or treatment that is not covered in the member's contract.
- No payment will be made for prescriptions filled or services rendered prior to the approval of a prior authorization request.
    - Members may be allowed a 72-hour emergency supply of a medication or a 5-day supply of a substance use medication while awaiting a review for a prior authorization or formulary exception request.
- Prior authorization processes are subject to the applicable state or federal regulations of the member's contract or certificate of coverage.
- Prior authorization approvals (medical and/or pharmacy) do not transfer with the member when a change in eligibility to another line of business occurs.

Step Therapy

- MVP may require the member to try select medications prior to approval of other medications to treat the medical condition. We will use recognized evidence-based and peer reviewed clinical review criteria that is appropriate for the medical condition.
- Medications subject to Step Therapy may be noted on the formulary or in a specific prior authorization policy.
- For NY Commercial, NY Exchange, and NY Medicaid, additional criteria for a step therapy protocol apply as follows: The request for a Step Therapy override must be submitted with a supporting rationale and documentation from the prescriber and <u>not</u> meet the following conditions:
    - The required prescription drug is contraindicated or will likely cause an adverse reaction or physical or mental harm to the member;

- The required prescription drug is expected to be ineffective based on the member's known clinical history, condition, and prescription drug regimen;
- The member has tried the required prescription drug while covered by MVP, or under previous health insurance coverage, or another prescription drug in the same pharmacologic class or with the same mechanism of action, and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event;
- The member is stable on a prescription drug selected by the requesting health care professional for the medical condition, unless the required prescription drug is an AB-rated generic equivalent; or
- The required prescription drug is not in the member's best interest because it will likely cause a significant barrier to adherence to or compliance with the member's plan of care, will likely worsen a comorbid condition, or will likely decrease the member's ability to achieve or maintain reasonable functional ability in performing daily activities.

- Standard Review. We will make a step therapy protocol override determination within 24 hours of receipt of the supporting rationale and documentation.

- If a determination is not made within the standard step therapy prior authorization timeframes, the step therapy protocol override request will be approved. If the preauthorization, concurrent or retrospective utilization review timeframes are also applicable to the step therapy protocol override prior authorization request, the shortest timeframe will apply.

Quantity Limits

- MVP may limit the quantity of a medication that may be obtained within a 30 day period.
- Medications subject to Quantity Limits will be noted on the formulary.

Formulary Exception **(NY Commercial (Lg Group), NY Exchange (Small Group, Individual, Essential Plan), VT Exchange; NY CHP and Medicaid excluded)**

- A prescriber or member (depending on the member's benefit) may request coverage of a medication that is non-formulary or excluded.

- Requests must be submitted with clinical documentation to support the medical necessity of the exception and may include:

    - Allergic/adverse reaction to all formulary agents
    - Therapeutic failure of all clinically appropriate formulary agents
    - Patient therapy stability issues where a formulary agent is contraindicated or a change in therapy is inadvisable
    - Patient-specific contraindication or reason formulary agents are inappropriate
    - Policy and/or benefit interpretation
    - Member contract and/or prescription drug rider
    - Sample use alone does not satisfy the criteria

- Standard Review. We will make a formulary exception determination within 72 hours upon provider receipt and documentation.

- Expedited (Urgent) Review. If the requesting health care professional asserts that the member has a medical condition that places the member's health in serious jeopardy without the prescription drug prescribed by the requesting health care professional the formulary exception will be made within 24 hours upon provider receipt and documentation

Brand/Generic Difference Program (refer to the member's contract to determine if this program applies)

- MVP encourages the use of FDA "A"-rated generics whenever available.
- When the prescriber writes Dispense as Written ("DAW") on the prescription for a Brand name drug when a therapeutically equivalent "A"-rated generic is available, the member will receive the brand name drug but will be responsible for the difference in cost between the generic and brand name drug plus their applicable generic copayment.
- The difference in cost between the brand and generic drug will not apply to the member's deductible or Out of Pocket maximum.

Patient Assistance Programs

- If a patient is eligible to receive a medication for no cost via a prescription assistance program, MVP will deny the claim and not provide coverage for the medication.

Member Submitted Prescription Claim

- Members are encouraged to use par pharmacy providers to obtain their prescriptions.
- Members who request reimbursement for a prescription obtained without using their MVP prescription benefit may submit their prescription claim for reimbursement subject to benefits as outlined in plan coverage documents. Members must complete the applicable claim reimbursement form in full and submit to CVS Caremark with a valid receipt. Reimbursement is based on the pharmacy network rate minus any applicable copayments as defined by the member's pharmacy benefit. All UM and DUR edits will apply to the adjudicated submitted claim.

Excluded Providers

- Prescribers who are excluded by CMS, OMIG, OIG, or other regulatory entity will be deemed "excluded" and prescriptions will reject at the pharmacy and request for coverage of medications will be denied.

Specialty Pharmacy

- Select oral and injectable medications require provider and/or member acquisition through a contracted specialty vendor.
- Medications which must be obtained through a contracted specialty pharmacy are noted on the printed formulary.
- Typically, specialty drugs are limited to a 30-day supply
- See Medicaid section for specialty pharmacy information

Preferred Pharmacies or Home Infusion Vendors

- MVP may require select pharmaceutical agents be obtained through a preferred pharmacy or home infusion vendor as noted in the clinical policy. Use of an alternative pharmacy or home infusion vendor requires a separate medical necessity review and may be subject to out-of-network cost sharing.

Site of Care Program

- MVP may direct members to the most cost effective clinically appropriate location to receive an infused drug.
- Requests for medications to be administered in a location other than home infusion will be directed to a preferred alternative site of care. Infusions for these medications are excluded from payment when administered in a non-preferred site of care.
- For medications included in the Site of Care Program:
    - A provider office cannot buy and bill
    - A provider office cannot obtain from specialty for office administration
    - Outpatient hospital cannot buy and bill
    - Outpatient hospital cannot obtain from specialty for hospital administration
- Site of Care program MVP Medicare and Medicaid, CHP members
- To prevent delay in care and allow adequate transition time, MVP will allow 60 days after prior authorization approval for members to transfer to a preferred infusion site.

Duplicate therapy overrides

- Duplicate therapy overrides for new onset allergy will be allowed. Duplicate therapy for other reasons, such as patient preference, will be the member responsibility.

Lost/stolen/damaged medications

- Replacement of lost, forgotten, stolen or damaged medications is the responsibility of the member.

Vacation overrides

- Vacation overrides are allowed dependent on the line of business when the member is traveling to an area without access to a network pharmacy where a refill may be obtained while traveling away from home. Members should attempt to use the Mail benefit whenever possible to ensure access to adequate medication or to assist with delivery of medication while away from home.
- Commercial and Off-Exchange: Plan allows for one (1) vacation override per drug per 180 days. Override cannot exceed the maximum allowable benefit (e.g. 90-day supply). Vacation overrides for controlled substances or specialty medications are not allowed.
- ASO: For requests for lost or stolen medication for ASO groups, refer to the pharmacy section of the group's SPD. For vacation overrides for ASO groups,

typically MVP standard is followed but MVP can check with the MVP Marketing representative for the group for requests for extended periods of time.

- On-Exchange: Plan allows for one (1) vacation override per drug per 180 days. Override cannot exceed the maximum allowable benefit (e.g. 30-day supply). Vacation overrides for controlled substances or specialty medications are not allowed.
- Medicaid/CHP and Essential Plan: No vacation overrides are allowed. Members who will not have an adequate supply of medication due to a temporary absence should make alternative arrangements.
- Medicare: Plan allows for one (1) vacation override per drug per 180 days if greater than 50% of the current prescription is used. Override cannot exceed the maximum allowable benefit (e.g. 90-day supply). Vacation overrides for controlled substances or specialty medications are not allowed.

Cancer Guidance Program

The Optum® Cancer Guidance Program promotes value-based care by following evidence-based guidelines and encourages the use of cancer therapy pathways. The clinical criteria that will be utilized for prior authorization review in Optum Cancer Guidance Program (CGP) determining coverage for oncology medications under medical (including, but not limited to chemotherapy, immunotherapy, targeted therapies, oral oncolytics, leucovorin, gonadotropin releasing hormonal analogs, bone modifying agents, somotostatin analogs, white blood cell growth factors, red blood growth factors, other supportive drugs) may be found in the Cancer Guidance Program-Oncology Medication Coverage and Review Policy.

Government Programs Variations

Medicare:

Prior Authorization, Step Therapy, Quantity Limits, Formulary Exceptions, and Tier Exceptions

- Prescribers and Medicare members with an MVP Medicare Part D benefit should refer to the Medicare Part D formulary on the MVP website.
- Medications that are subject to Step Therapy will be noted on the formulary and will follow Step Therapy Criteria.
- Prescribers and members may request an exception for a non-formulary medication or a tier exception for a medication on the formulary. Refer to the Medicare section of the MVP website for additional information.

- Some medications require a determination of benefit (B/D) before the medication can be dispensed.
- Physician-administered medications obtained by the member from the pharmacy will take the applicable Medicare Part D copay.
- Medicare Part B drug policies are reviewed at least annually by the MVP P&T Committee and a Utilization Management (UM) Committee led by a Medical Director. The UM Committee reviews utilization management, including prior authorization policies and keeps current of guidelines for Traditional Medicare, Local Coverage Determinations (LCDs), National Coverage Determinations (NCDs), and relevant current clinical guidelines. Medicare Part B policies are available at www.mvphealthcare.com.

Excluded Drugs

- CMS excludes specific medications or categories: DESI drugs, non-FDA approved drugs (NDA/ANDA/BLA), drugs used to treat sexual or erectile dysfunction, drugs used to promote weight gain or weight loss, vitamins and minerals, drug used to treat infertility, and drugs used for conditions not supported by FDA-approved labeling or approved compendia.
    - Some enhanced employer group riders may include coverage of excluded drugs. Prior authorization criteria and quantity limits for these medications.

Medicaid:

Prior Authorization, Step Therapy, and Formulary Exceptions

- Medications that are a pharmacy benefit are covered and billed to New York State Fee-For-Service (FFS) program NYRX. They are defined as medications that go through a retail or specialty pharmacy, including self administered injectable products. Pharmacy medications are subject to FFS's clinical criteria including (but not limited to) coverage, quantity limit, step therapy, and prior authorization. Pharmacy benefit information can be found here: https://www.emedny.org/info/fullform.pdf
- Medical drug request review for coverage (PA, ST, formulary exception) will be made within 24 hours of the receipt of the request.
- Foster Care Transition fills

- Transition fills apply to ensure access to care for medications that require prior authorization. Prior authorizations that were approved in Medicaid Fee-For-Service (FFS) will not carry through to MVP Medicaid Managed Care.
- A member is allowed a one-time fill up to a thirty (30) day supply within the first ninety (90) days of foster care placement as a transitional fill. This transition fill is not limited to new enrollees.
- Transition fill allows exceptions to refill timeframes and rapidly replace lost medications
- Transition fill applies to DME replacement

Emergency Supply of Medication

- Medications that are a pharmacy benefit are covered and billed to New York State Fee-For-Service (FFS) program. They are defined as medications that go through a retail or specialty pharmacy, including self administered injectable products. Pharmacy medications are subject to FFS's clinical criteria including (but not limited to) coverage, quantity limit, step therapy, and prior authorization. Pharmacy benefit information can be found here: https://www.emedny.org/info/fullform.pdf
- Members may be allowed immediate access without prior authorization to a 72-hour emergency supply of a medication for a member experiencing an emergency condition or a member with a behavioral health condition experiencing an emergency condition or Excluded Drugs:
    - Medicaid excludes specific medications or categories: drugs used to treat sexual or erectile dysfunction, weight loss drugs, select drugs used to treat infertility, cough and cold products, cosmetic, marked "sample" or "not for sale", DESI drugs, drugs without an NDC, non-FDA approved drugs (NDA/ANDA/BLA), used for radiological testing, packaged in unit dose when bulk packaging is available, regularly supplied to public free of charge, and viscosupplementation products.

Medicaid Non-Enrolled Providers

- Effective September 1, 2022, the NYS Department of Health Medicaid Program implemented a new policy which requires all Medicaid Managed Care network and out-of-network furnishing, ordering, prescribing, and referring providers and pharmacies to enroll in the NYS Medicaid Fee-for-Service (FFS) Program.

- Prescribing, ordering, referring practitioners must enroll with the NYS Medicaid Program as a billing provider or as an Order/Prescribe/Refer/Attend (OPRA) provider.
- Per NYS DOH, network overrides are allowed in the following situations
    - Emergency (such as traveling and requiring acute care)
    - Foster care, behavioral health and/or "unmet need"
    - Transition supplies

Specialty Pharmacy

For medical benefit drugs, buy and bill is the preferred method of obtaining. If the provider is unable to buy and bill, the provider can work with MVP's preferred medical pharmacy provider CVS Specialty to obtain the drug. CVS Specialty will then bill MVP via a medical claim. If CVS Specialty is unable to provide the medications, such as a limited distribution drugs, MVP would consider a single case agreement with an alternative pharmacy.

Medically Fragile Children

For medically fragile children, MVP conducts utilization reviews and coverage determinations that are not exclusively based on review standards applicable to adults. MVP considers the specific needs and circumstances pertaining to growth and development of a medical fragile child.

- Prescribers should refer to specific prior authorization policies for medical necessity criteria.
- Prescribers and members should refer to the member’s certificate of coverage or contract for more specific coverage requirements.

Exclusions

None

MVP Health Care Medical Policy

Phenylketonuria Agents

Type of Policy:	**Drug Therapy**
Prior Approval Date:	**03/01/2023**
Approval Date:	**02/01/2024**
Effective Date:	**04/01/2024**
Related Policies:	

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

Drugs Requiring Prior Authorization

(Both brands and generics will require prior authorization)

Kuvan™ (sapropterin dihydrochloride)
Palynziq™ (pegvaliase-pqpz) injection, for subcutaneous use

Overview

Kuvan™ (sapropterin dihydrochloride) is indicated to reduce blood phenylalanine (Phe) levels in patients with hyperphenylalaninemia (HPA) due to tetrahydrobiopterin (BH4)-responsive Phenylketonuria (PKU). Approximately 25-50% of patients with PAH deficiency are sapropterin-responsive. Kuvan is to be used in conjunction with a Phe-restricted diet.[1] 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.[4] Kuvan is a synthetic form of BH4, the cofactor for the enzyme phenylalanine hydroxylase (PAH). PAH hydroxylates Phe through an oxidative reaction to form tyrosine. In patients with PKU, PAH activity is absent or deficient. Treatment with BH4 can activate residual PAH enzyme, improve the normal oxidative metabolism of Phe, and decrease Phe levels in some patients[1].

Palynziq™ is indicated in adult patients with phenylketonuria (PKU) who have uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on existing therapies. Palynziq is a PEGylated phenylalanine ammonia lyase enzyme that metabolizes phenylalanine thereby reducing blood phenylalanine levels. It is a

substitute for the deficient phenylalanine hydroxylase enzyme in patients with phenylketonuria. It is only available through a REMS program.

Indications/Criteria

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

- The drug must be prescribed by a specialist or prescriber with experience in the intensive management of PKU patients.
- Patient, parents and caregivers (if minor) are motivated to control PKU and maintain dietary restrictions.
- Patient must have a have a history of adherence to routine follow-up for the diagnosis of PKU with at least annual visits.
- Diagnosis of phenylketonuria and current mean blood phenylalanine concentration above the upper limit of the recommended ranges which are:
  - Infants < 1 years of age: 120-360µmol per L (2-6mg/dL).[4,5]
  - Patients ≥2 years of age including pregnant women: 60-360µmol per L (1-6mg/dL). [4,5,6]
- Phe-restricted diet has been continuously and appropriately utilized for a period of at least 6 months prior to initiation of the request and a mean blood Phe concentration less than or equal to the **upper limits above** was not attainable during the period.
- While on the diet, adherence was substantiated by the availability of 3-day diet logs or food frequency questionnaires (FFQs) prior to a minimum of three (3) lab measurements within the past 6 months.
- Interventions by a dietitian and/or nutritionist for diet education and diet adjustment to meet recommended levels must be documented.
- If the patient has been using the medication prior to the initial MVP request, the above criteria must have been met prior to initiation and evidence demonstrating a 30% decrease from the baseline mean blood Phe concentration after one month of sapropterin must be documented in the medical record.

Initial authorization up to a maximum of 2 months. Continued authorization up to 3 years will be considered if documentation supports:

- Patient, including parents and caregivers (if minor), continue to be motivated to control PKU and maintain dietary restrictions.
- Patient adheres to follow-up appointments, 3-day diet logs or FFQs and lab visits.
- Phe-restricted diet has been continuously utilized since initiation of sapropterin treatment and a mean blood Phe concentration with at least a 30 percent decrease of blood Phe from mean pretreatment levels continues.

- Maintenance of diet which is at least as stringent as the pretreatment diet unless the dietary needs of the patient have changed.
- While on the sapropterin and diet, adherence was substantiated by the availability of 3-day diet logs or FFQs prior to a minimum of three (3) lab measurements within the past 6 months.

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

- Patient is 18 years of age or older
- Medication is being prescribed by a specialist in the management of PKU
- **Patient has a history of failure, contraindication, or intolerance to Kuvan**
- Patient has uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on existing management.
- Patient was adherent to both diet and previous therapy
- Patient has discontinued Kuvan at least 2 weeks and LNAAs (large neutral amino acids) at least 2 days before initiation of Palynziq.

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

- At least a 20% reduction in blood phenylalanine levels from pre-treatment baseline or a level less than 600 micromol/L
- Patient must maintain current diet and remain consistent while on therapy.

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Exclusions

Kuvan

- Neonates less than 1 month of age or infants < 2 years of age with blood Phe <360µmol per L.[1,4]
- Noncompliance with Phe-restricted diet.
- Non-responders (i.e. do not have a decrease in blood Phe with sapropterin treatment after one month of treatment at the maximum dose).
- Not maintaining Phe levels below baseline.
- Dosing exceeding 20mg/kg/day for Kuvan.
- Previous failure of Kuvan.

Palynziq

- Use with Kuvan
- Doses greater than 60 mg daily
- Does not respond to a trial of 60 mg daily for 16 weeks or Phe levels above 600 micromol/L despite therapy
- Those under the age of 18
- Those with a baseline Phe level less than 600 micromol/L

References

1. Kuvan™ (sapropterin). Prescribing Information. Novato, CA: BioMarin Pharmaceutical Inc; Mar 2020.
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.
3. Hellekson, KL. NIH consensus statement on phenylketonuria. Am Fam Physician. 2001 Apr 1;63(7):1430-2.
4. Vockley J, Andersson HC, Antshel KM, Braverman NE, Burton BK, et al. Phenylalanine hydroxylase deficiency: diagnosis and management guideline. ACMG Practice Guidelines. Genet Med 2014;16.2:188-200.
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.
6. Camp KM, Parisi MA, Acosta PB, Berry GT, Bilder DA, Blau N, et al. Phenylketonuria Scientific Review Conference: state of the science and future research needs. Mol Genet Metab 2014;112(2):87-122.
7. Palynziq™ (pegvaliase-pqpz). Prescribing Information. Novato, CA: BioMarin Pharmaceutical Inc; November 2020.
8. Thomas, Janet, et al. Pegvaliase for the treatment of phenylketonuria: Results of a long-term phase 3 clinical trial program (PRISM), Molecular Genetics and Metabolism 124 (2018) 27-38

Member Product	Medical Management Requirements*
New York Products	
HMO	Prior Authorization
PPO in Plan	Prior Authorization
PPO OOP	Prior Authorization
POS in Plan	Prior Authorization
POS OOP	Prior Authorization
Essential Plan	Prior Authorization
MVP Medicaid Managed Care	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Child Health Plus	Prior Authorization
MVP Harmonious Health Care Plan	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Medicare Gold Giveback	Refer to the MVP website for the Medicare Part B and Part D policies.

MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Secure HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare WellSelect PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare WellSelect Plus PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Patriot Plan PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess Complete D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess Plus D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Select PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Secure PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
Healthy NY	Prior Authorization
MVP Premier	Prior Authorization
MVP Premier Plus	Prior Authorization
MVP Premier Plus HDHP	Prior Authorization
MVP Secure	Prior Authorization
MVP EPO	Prior Authorization
MVP EPO HDHP	Prior Authorization
MVP PPO	Prior Authorization
MVP PPO HDHP	Prior Authorization
Student Health Plans	Prior Authorization
ASO	Prior Authorization
Vermont Products	
POS in Plan	Prior Authorization
POS OOP	Prior Authorization
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D
MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Select PPO	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Secure PPO	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D
MVP VT HMO	Prior Authorization
MVP VT Plus HMO	Prior Authorization
MVP VT HDHP HMO	Prior Authorization
MVP VT Plus HDHP HMO	Prior Authorization
MVP Secure	Prior Authorization
ASO	Prior Authorization
♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).	

***Medical Management Requirements**

Prior Auth	Prior Authorization Required
Potential for Retrospective Review	No Prior Authorization Required. May be subject to Retrospective Review.
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:	**02/01/2023**
Approval Date:	**02/01/2024**
Effective Date:	**04/01/2024**
Related Policies:	MVP Provider Policies

Drugs Requiring Prior Authorization: None

Overview

Participating physicians are eligible to write prescriptions within their scope of practice for members if the member has prescription drug coverage.
Physicians who terminate participation need to have their patients transitioned to alternate providers. This policy will define time frames for this transition.

Indications/Criteria

Prescriptions written by participating providers are covered subject to the terms of conditions of the prescription drug rider, contract or specific benefit design. Physicians terminating their participation will be subject to the following:

- **Physicians who terminate voluntarily:**
  Will be allowed a 90-day grace period at which time their patients should find another physician to write their prescriptions. Refills of existing prescriptions will be allowed for only 90 days.
- **Physicians who terminate involuntarily:**
  Will be allowed a 30-day grace period at which time their patients should find another physician to write their prescriptions. This 30-day notification is effective once the member has been notified, and is subject to review.

Exclusions

Members without the prescription drug coverage.

References None

MVP Health Care Medical Policy

Prescribers Treating Self or Family Members

Type of Policy:	**Drug Therapy**
Prior Approval Date:	**02/01/2023**
Approval Date:	**02/01/2024**
Effective Date:	**04/01/2024**
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.

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 as a result 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.

Except in emergency situations when access to alternative healthcare providers is not available, it is not appropriate for physicians to write prescriptions for themselves or immediate family members.

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.

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

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.

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

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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

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Respiratory Disorders

RESPIRATORY AGENTS

albuterol inh solution
arformoterol inh soln
budesonide suspension
budesonide/formoterol
fluticasone furoate/ vilanterol ellipta
fluticasone propionate HFA
fluticasone/salmeterol
ipratropium inh solution
levalbuterol inh soln
montelukast
terbutaline
zafirlukast
zileuton ext-rel
Breyna
Wixela Inhub
ACCOLATE
ADVAIR
ADVAIR HFA
AIRDUO RESPICLICK
ANORO ELLIPTA
ARMONAIR DIGIHALER
ARNUITY ELLIPTA
ASMANEXHFA
BROVANA
BREO ELLIPTA
FLOVENT DISKUS
FLOVENT HFA
INCRUSE ELLIPTA
PULMICORT
PULMICORT FLEXHALER
QVAR REDIHALER
SEREVENT DISKUS
SINGULAIR
SPRIVA HANDIHALER
SPIRIVA RESPIMAT 1.25 mcg
STIOLTO
SYMBICORT
XOPENEX
ZYFLO

SUPPLIES

PEAK FLOW METERS

DENTAL CARIES PREVENTION

PEDIATRIC MULTIVITAMINS WITH FLUORIDE—ALL MARKETED PRODUCTS

IMMUNOSUPPRESSIVE AGENTS

cyclosporine caps
everolimus
mycophenolate mofetil
mycophenolate sodium delayed-rel
sirolimus
tacrolimus
Gengraf
ASTAGRAF XL
CELLCEPT
ENVARSUS XR
MYFORTIC
NEORAL
PROGRAF
RAPAMUNE
SANDIMMUNE
ZORTRESS

PRENATAL VITAMINS

PRENATAL VITAMINS

Please note: This list represents brand products in CAPS, branded generics in upper- and lowercase italics or all uppercase italics, and generic products in all lowercase italics.

MVP Health Care Medical Policy

Preventive Services – Medication

Type of Policy: **Drug Therapy**
Prior Approval Date: **07/01/2023**
Approval Date: **07/01/2024**
Effective Date: **09/01/2024**
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 12-49 (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 • 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 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 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 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
Type 2 Diabetes	The USPSTF recommends screening for prediabetes and type 2 diabetes in adults aged 35 to 70 years who have overweight or obesity. Clinicians should offer or refer patients with prediabetes to effective preventive interventions	• Age limit 35 to 70 years old • 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.

References

1. U.S. Department of Health and Human Services. Available: http://www.hhs.gov/healthcare/facts/factsheets/2010/07/preventive-services-list.html#CoveredPreventiveServicesforAdults. Accessed 8/2015
2. U.S. Preventative Services Task Force. Available: http://www.uspreventiveservicestaskforce.org/BrowseRec/Index. Accessed June 1, 2021.
3. U.S. Preventative Services Task Force. Available: http://www.uspreventiveservicestaskforce.org/BrowseRec/Index. Accessed August 27, 2021.
4. Aspirin Use to Prevent Preeclampsia and related Morbidity and Mortality: Preventive Medication. September 28, 2021. U.S. Department of Health and Human Services. Available: Recommendation: Aspirin Use to Prevent Preeclampsia and Related Morbidity and Mortality: Preventive Medication | United States Preventive Services Taskforce (uspreventiveservicestaskforce.org). Accessed February 16, 2022.
5. U.S. Preventative Services Task Force. Available: Recommendation: Prediabetes and Type 2 Diabetes: Screening | United States Preventive Services Taskforce (uspreventiveservicestaskforce.org). Accessed July 8, 2022
6. Aspirin Use to Prevent Cardiovascular Disease: Preventive Medication. April 26, 2022. Available: Recommendation: Aspirin Use to Prevent Cardiovascular Disease: Preventive Medication | United States Preventive Services Taskforce (uspreventiveservicestaskforce.org). Accessed October 26, 2022

MVP Health Care Medical Policy

Prostate Cancer

Type of Policy:	**Drug Therapy/Medical**
Prior Approval Date:	**11/01/2022**
Approval Date:	**11/01/2023**
Effective Date:	**01/01/2024**

Codes Requiring Prior Authorization (covered under the medical benefit)

Q2043 Sipuleucel-T, minimum of 50 million autologous CD54+ cells (Provenge)

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

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

Overview

Prostate cancer is the most common cancer in American men. The American Cancer Society estimates that 1 man in 6 will be diagnosed with prostate cancer during his lifetime.[1] Prostate cancer can be a serious disease but most men will not die from prostate cancer. Treatment options for prostate cancer include active surveillance (watchful waiting), radical prostatectomy, radiotherapy, chemotherapy, cryosurgery, vaccine treatment and hormone therapy.

Provenge (sipuleucel-T) is made from the patient's own immune cells and is designed to stimulate the immune system and develop an immune response against the prostate cancer. Provenge is the first immunotherapy for prostate cancer to receive FDA approval.

Indications/Criteria

Provenge will be considered medically necessary when all of the following are met:

- Medication must be prescribed by an oncologist/hematologist or urologist
- Criteria and use of these agents 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

- Diagnosis of asymptomatic or minimally symptomatic, metastatic castrate-resistant (hormone-refractory) prostate cancer.
- The patient must have no liver metastases, a life expectancy greater than 6 months, and an ECOG performance status of 0-1.
- Radiologic evidence must identify progressive metastatic prostate cancer
- Documentation identifying progression following bilateral orchiectomy or after adequate hormone therapy (testosterone levels suppressed to <50 ng/dl)
- Studies do not support more than 3 doses per lifetime.

Approval for treatment will be for 16 weeks. Previous treatment (chemotherapy, radiation etc) must be discontinued.

Exclusions

- Combination therapy with agents in this policy will not be approved as medical literature does not support this at this time.
- Visceral metastases
- Small Cell/neuroendocrine prostate cancer
- Dose and/or frequency exceeding the FDA approved package labeling

References

1. National Comprehensive Cancer Network (NCCN). Prostate Cancer. NCCN Clinical Practice Guidelines in Oncology, v.2.2017.. Fort Washington PA:NCCN; 2017. Available at http://www.nccn.org/professionals/physician gls/PDF/prostate.pdf
2. Provenge® (Sipuleucel-T) Injection. Prescribing Information. Seattle, WA: Dendreon Corporation; June 2011 (October 2014.)

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	Prior Auth
MVP Medicare Secure HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP Medicare WellSelect PPO	Prior Auth
MVP Medicare WellSelect Plus PPO	Prior Auth
MVP Medicare Patriot Plan PPO	Prior Auth
MVP DualAccess D-SNP HMO	Prior Auth
MVP DualAccess Complete D-SNP HMO	Prior Auth
MVP DualAccess Plus D-SNP HMO	Prior Auth
UVM Health Advantage Select PPO	Prior Auth
UVM Health Advantage Secure PPO	Prior Auth
UVM Health Advantage Preferred 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
UVM Health Advantage Select PPO	Prior Auth
UVM Health Advantage Secure PPO	Prior Auth
UVM Health Advantage Preferred PPO	Prior Auth
MVP VT HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD
♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).	

***Medical Management Requirements**

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

MVP Health Care Medical Policy

Proton Pump Inhibitor Therapy

Type of Policy:	**Drug Therapy**
Prior Approval Date:	**03/01/2023**
Approval Date:	**10/01/2023**
Effective Date:	**12/01/2023**
Related Policies:	**NA**

Drugs Requiring Prior Authorization

See chart below under the Indications/Criteria section.

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

Overview

Proton Pump Inhibitors (PPIs) suppress gastric acid secretion by specific inhibition of the adenosine triphosphate enzyme system at the secretory surface of the gastric parietal cell. Therefore, they block the final step of acid production.

All PPIs are considered to be therapeutically equivalent and interchangeable in the management of gastric or duodenal ulcers, gastroesophageal reflux disease (GERD), erosive esophagitis (EE), and eradication of H. pylori infections. The literature does not demonstrate significant superiority of one or more PPI in comparison to the others in safety and/or efficacy.

Several published observational studies suggest that proton pump inhibitor (PPI) therapy may be associated with an increased risk for osteoporosis-related fractures of the hip, wrist, or spine. The risk of fracture was increased in patients who received high-dose, defined as multiple daily doses, and long-term PPI therapy (a year or longer). Patients should use the lowest dose and shortest duration of PPI therapy appropriate to the condition being treated. Patients at risk for osteoporosis-related fractures should be managed according to the established treatment guidelines[4,5,6,7,8].

The package labeling for PPIs include 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 patients. Hypomagnesemia has been reported rarely with prolonged treatment. Patients 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 patient. [15].

Indications/Criteria

Drugs requiring Prior Authorization and/or Quantity limits

Drug Name	Prior Authorization Required*	Quantity Limits
Aciphex	Yes	Yes (2 per day)
Dexilant	Yes	Yes (2 per day)
dexlansoprazole	No	Yes (2 per day)
esomeprazole	No	Yes (2 per day)
lansoprazole	No	Yes (2 per day)
Nexium	Yes	Yes (2 per day)
omeprazole	No	No
omeprazole & sodium bicarbonate	Yes	Yes (2 per day)
pantoprazole	No	Yes (2 per day)
rabeprazole	No	Yes (2 per day)
Prevacid Capsules	Yes	Yes (2 per day)
Prevacid Tabs/Packets	No	Yes (2 per day)
Prilosec	Yes	Yes (2 per day)
Protonix	Yes	Yes (2 per day)
Zegerid	Yes	Yes (2 per day)

Refer to formulary for tier based on product

Indications/Criteria

1. The use of Aciphex®(brand), Dexilant (brand), Prevacid® (brand) capsules and solutab, Prilosec® (brand), Protonix® (brand), Nexium (brand), Zegerid® (brand), or omeprazole/sodium bicarbonate (brand and generic) may be covered if:
    - Clinical chart notes documenting that the member has experienced treatment failure for a minimum trial of 4 weeks for ALL the following at the **maximum allowed quantity**:

- dexlansoprazole (or Dexilant) AND
- esomeprazole 40mg (or Nexium), omeprazole (or Prilosec) 40mg, AND
- lansoprazole (or Prevacid) 30 mg; AND
- pantoprazole (or Protonix); AND
- rabeprazole (or Aciphex)

OR

- The member has experienced significant intolerance (e.g. sensitivity, drug allergy, adverse effect) or has a contraindication to ALL of the following: dexlansoprazole (Dexilant), esomeprazole (Nexium), omeprazole (Prilosec), lansoprazole (Prevacaid), pantoprazole, rabeprazole (Aciphex)

- Prescription history or chart notes must be provided substantiating trial or intolerance for each medication.

2. Quantities of proton pump inhibitors greater than the quantity of 60 doses per month may be considered covered if the member has one of the following conditions:

- Barrett's Esophagus.
- Zollinger-Ellison Syndrome.
- Severe reflux with ulceration and/or stricture formation (after trial of omeprazole 40mg, or esomeprazole 40mg twice daily).

OR

Documentation must identify failure of the following at the **maximum allowed quantity of 2 per day** for a minimum of 4 weeks of:

- omeprazole 40mg or esomeprazole **AND**
- lansoprazole at 30mg; **AND**
- pantoprazole 40mg; **AND**
- rabeprazole 20mg; **AND**
- dexlansoprazole 60mg; **AND**
- requested drug

Initial approval for quantities greater than two per day may be considered up to a maximum of 6 months.

Extension of therapy may be approved for a maximum of 6 months if documentation provided identifies continued benefit from therapy AND prescription history identifies compliance.3. Prior authorization is NOT required for the treatment of H. pylori with

duodenal ulcer disease for up to 2 doses per day up to 14 days of therapy for formulary proton pump inhibitors.

4. First-Omeprazole and First-Lansoprazole will require prior authorization for members 7 years of age and older. Documentation must be submitted identifying why all commercially available proton pump inhibitors would not be appropriate.

Exclusions

- Age and diagnosis not indicated in FDA approved package labeling.
- Esomeprazole Strontium is excluded from 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 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).	

***Medical Management Requirements**

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

MVP Health Care Medical Policy

Pulmonary Hypertension (Advanced Agents) Commercial

Type of Policy:	**Drug/Medical Therapy**
Prior Approval Date:	08/01/2023
Approval Date:	06/01/2024
Effective Date:	06/01/2024
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)

Drugs Requiring Prior Authorization (covered under the pharmacy benefit except as noted above)
Adcirca, Alyq, Tadliq (tadalafil)
Adempas (riociguat)
Letairis (ambrisentan)
Opsumit (macitentan)
Orenitram (treprostinil)
Revatio suspension (sildenafil)
Revatio Oral Tablet (sildenafil)
Tracleer (bosentan)
Tyvaso (Inhalation solution, treprostinil)
Uptravi (selexipag)
Ventavis (iloprost)
Winrevair (sotatercept)

Medicare Variation

J7686 Tyvaso (Inhalation solution, treprostinil, 1.74mg) covered under the medical benefit and must be obtained through a pharmacy

Q4074 Ventavis (Inhalation solution, iloprost, up to 20mcg) covered under the medical benefit and must be obtained through a pharmacy

J3490 Revatio (Injection, sildenafil) B/D coverage dependent upon place of service

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Overview

Pulmonary arterial hypertension (PAH) is a condition resulting from restricted flow through the pulmonary arterial circulation causing increased pulmonary vascular resistance and ultimately right heart failure.[12] The World Health Organization (WHO) has classified the different types of pulmonary hypertension. The drugs identified in this policy are indicated for WHO Group I. The WHO classifications identify the causes of PAH. The New York Heart Association (NYHA) has developed classes of PAH according to the level of function and associated symptoms. The drugs identified in this policy are indicated for a variety of NYHA functional classes.

Class	WHO Modified New York Heart Association Functional Classification (WHO 1998)
I	Patients with pulmonary hypertension but without resulting limitation of physical activity. Ordinary physical activity does not cause undue dyspnea or fatigue, chest pain or near syncope.
II	Patients with pulmonary hypertension resulting in slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity causes undue dyspnea or fatigue, chest pain or near syncope.
III	Patients with pulmonary hypertension resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary activity causes undue dyspnea or fatigue, chest pain or near syncope.
IV	Patients with pulmonary hypertension with inability to carry out any physical activity without symptoms. These patients' manifest signs of right heart failure. Dyspnea and/or fatigue may be present at rest. Discomfort is increased by any physical activity.

Indications/Criteria

Drug/ PAH Indication	Chemical Name	Mechanism of Action
Adcirca , Alyq, Tadliqare indicated to improve exercise ability.	tadalafil tablets, suspension	phosphodiesterase 5 (PDE5) inhibitor

Adempas® is indicated to improve exercise capacity, improve WHO functional class, and to delay clinical worsening.	riociguat tablets	Stimulator of soluble guanylate cyclase (sGC)
Flolan® is indicated to improve exercise capacity	epoprostenol injection	prostacyclin vasodilator and platelet aggregation inhibitor
Letairis™ is indicated to improve exercise ability and delay clinical worsening.	ambrisentan tablets	endothelin receptor antagonist (ERA)
Opsumit® is indicated to delay disease progression which includes death, IV or subcutaneous prostanoids initiation, decreased 6-minute walk distance, worsened symptoms, and need for additional treatment. Also reduced hospitalization due to pulmonary arterial hypertension.	macitentan tablets	endothelin receptor antagonist
Orenitram® is indicated to improve exercise capacity	treprostinil tablets	prostacyclin vasodilator and platelet aggregation inhibitor
Remodulin™ is administered as a continuous SQ or IV (for those not able to tolerate SQ) infusion. It is indicated to diminish symptoms associated with exercise. It is also indicated to diminish the rate of clinical deterioration for patients requiring transition from epoprostenol.	treprostinil injection	prostacyclin vasodilator and platelet aggregation inhibitor
Revatio® oral tablets are indicated to improve exercise ability and delay clinical worsening (when used with epoprostenol)	sildenafil tablets	phosphodiesterase 5 (PDE5) inhibitor
Revatio® Injection is for patients who are currently prescribed oral Revatio and who are temporarily unable to take oral medication.	sildenafil injection	phosphodiesterase 5 (PDE5) inhibitor
Tracleer® is indicated to improve exercise ability and decrease the rate of clinical worsening.	bosentan tablets	endothelin receptor antagonist
Tyvaso® is to increase walk distance.	treprostinil inhalation soln	prostacyclin vasodilator and platelet aggregation inhibitor
Uptravi is indicated to delay disease progression and reduce risk of hospitalization	Selexipag tablets	Prostacyclin receptor agonist
Ventavis™ is to improve exercise ability, improve symptoms, and decrease the rate of clinical worsening.	iloprost inhalation soln	prostacyclin vasodilator and platelet aggregation inhibitor
Veletri is indicated to improve exercise capacity	epoprostenol injection	prostacyclin vasodilator and platelet aggregation inhibitor
Winrevair is indicated for the treatment of pulmonary hypertension (WHO Group 1) to increase exercise capacity, improve WHO functional class and redice the risk of clinical worsening events	Sotatercept, powder for injection	Activin signaling inhibitors for PAH

A. For all medications, all of the following criteria must be met in addition to the specific medication criteria in Section B:

- The specific medication is being prescribed for an FDA approved indication and is appropriate for the functional class diagnosis.
- Prescribed by or in consult with pulmonologist or cardiologist

- Member has a confirmed diagnosis of WHO Group I idiopathic Pulmonary Arterial Hypertension (PAH), heritable PAH, or PAH associated with connective tissue diseases.
    - A diagnosis of congenital heart disease with left-to-right shunts is also acceptable for Tracleer
    - A diagnosis of congenital systemic-to-pulmonary shunts is acceptable for Remodulin.
    - Adempas is also indicated for persistent/recurrent Chronic Thromboembolic Pulmonary Hypertension (WHO Group 4) if inoperable or after surgical treatment.
- Documented right heart catheterization identifying the following:
    - Mean pulmonary artery pressure (mPAP) greater than or equal to 20 mmHg at rest
- Documentation of vasoreactive testing
    - Documentation with rationale must be provided for members that have not been tested. A limited number of patients with idiopathic, familial, or anorexigen-induced PAH who are vasoreactive positive may respond favorably to calcium channel blockers.
- Documentation that PAH is not secondary to pulmonary venous hypertension (e.g., left sided atrial or ventricular disease, left sided valvular heart disease, etc.) or disorders of the respiratory system (e.g., chronic obstructive pulmonary disease, interstitial lung disease, obstructive sleep apnea or other sleep disordered breathing, alveolar hypoventilation disorders, etc.)[17].
- Baseline six-minute walk test results must be provided with initial request. Documentation of a current six-minute walk test must be provided with requests for continuation of therapy.
- Provider attestation that a risk/benefit evaluation and adequate patient counseling was performed for members who are pregnant and are prescribed these medications.
    - Note: Letairis, Opsumit, Tracleer, and Adempas are contraindicated in pregnancy and can only be prescribed and dispensed through a restricted distribution program.
- Oral agents are preferred for initial therapy except for patients that present with functional class IV.
- Member specific clinical documentation and supporting clinical literature will be reviewed for members not meeting the criteria contained in this policy.
- Combination requests will be reviewed when monotherapy has failed and supporting clinical literature is provided and is consistent with the American College of College of Cardiology consensus statement

B. Member must meet the criteria in Section A and the drug specific criteria below:

- Adempas
    - For new starts only: documented failure with either an oral PDE-5 inhibitor approved for the treatment of PAH OR an endothelin receptor antagonist
    -
- Flolan
    - When used for the treatment of pulmonary hypertension associated with scleroderma spectrum of disease, the documentation of one of the following is provided:
        - Rapidly progressive NYHA Class III **OR**
        - NYHA Class IV heart failure who have progressed while on Remodulin or Tracleer therapy.
- Orenitram
    - Documentation that Orenitram is add-on therapy after failure of maximized dose of oral PDE5 or ERA.
    - The use of inhaled treprostinil is preferred and documentation must identify contraindication to inhaled or rationale for oral use.
- Opsumit
    - For new starts only: documented failure with Letairis
- Remodulin
    - Oral agents are preferred for initial therapy for class II and class III.
- Revatio
    - For new starts only: Supporting documentation must identify failure or intolerance to Adcirca
- Tracleer
    - For new starts only: supporting documentation must identify failure or intolerance to Letairis.
    - For members with class II, documentation of risk of liver injury vs benefit must be provided
- Tyvaso
    - Documentation that Tyvaso is add-on therapy after failure of oral therapy of PDE5 or ERA.
- Uptravi
- Documentation that Uptravi is add-on therapy after failure of oral therapy of PDE5 or ERAVeletri
    - 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.

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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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ASO	See SPD
Vermont Products	
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MVP VT HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD
♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).	

***Medical Management Requirements**

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

MVP Health Care Medical Policy

Pulmonary Hypertension (Advanced Agents) Medicaid and HARP

Type of Policy:	**Drug/Medical Therapy**
Prior Approval Date:	**08/01/2023**
Approval Date:	**08/01/2024**
Effective Date:	**10/01/2024**
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)

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J1325 Veletri (Injection, epoprostenol, 0.5mg)

Overview

Pulmonary arterial hypertension (PAH) is a conditionresulting 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

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.

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				.fhsc.com/downloads/providers/NYRx_PDP_PDL.pdf
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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.

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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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 Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
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
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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).	

MVP Health Care Medical Policy

Quantity Limits for Prescription Drugs

Type of Policy: **Drug Therapy**

Prior Approval Date: **07/01/2023**

Approval Date: **04/01/2024**

Effective Date: **04/01/2024**

Related Policies: Pain Medications, Migraine Agents, Hypnotics (Select), Pharmacy Programs Administration, Male Hypogonadism, Proton Pump Inhibitor Therapy, Epinephrine Autoinjector, 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.

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.
- Documentation must demonstrate that the quantity exceeding that noted below is 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.
- Individuals will not be allowed to use multiple agents within each drug class per 30 days from date of first prescription filled in that class.

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
Aptensio XR
Concerta
Dexedrine caps
Focalin XR

Jornay PM
Metadate ER
Mydayis
Qelbree
Quillichew
Quillivant Suspension**-** 360ml/30 days
Relexxii
Ritalin LA

ADHD Non-Stimulant Medications

- Strattera/atomoxetine -- 3 capsules/day

Antibiotic/ Antiprotozoal

- Atovaquone suspension- 140ml per 180 days
- Ceftriaxone 250mg vial- 4 vials per 30 days
- Ceftriaxone 500mg vial- 8 vials per 30 days
- Minocycline ER: 84 capsules per 365 days
- Xifaxan **550mg**- 126 tablets per lifetime; Quantities exceeding the 126 tablets per lifetime will be reviewed on a case-by-case basis.
- Xifaxan **200mg**- 9 tablets per 180 days
- Oracea/Doxycycline DR tablets- 120 capsules per 365 days

Antiemetic Drugs

Brand Name	**Chemical Name**	**Quantity Limit every 30 days**
Akynzeo	netupitant/palonosetron	2 capsules
Anzemet 50mg	dolasetron	14 tablets
Anzemet 100mg	dolasetron	7 tablets
Bonjesta	doxylamine/pyridoxine	60 tablets
Diclegis	doxylamine/pyridoxine	60 tablets
Emend 40mg	aprepitant	1 capsule
Emend 80mg	aprepitant	8 capsules

Emend 125mg	aprepitant	2 capsules
Emend Tri-fold Pack	aprepitant	2 packs
Kytril 1mg	granisetron	14 tablets
Sancuso 3.1 mg /24 hours	granisetron	2 patches
Varubi 90mg tablet	rolapitant	4 tablets

Antimalarial Drugs

Brand Name	**Chemical Name**	**Quantity Limit per 365 days**
Aralen	Chloroquine 250mg & 500mg	16 tablets
Coartem	Artemether/lumefantrine	24 tablets
Daraprim	Pyrimethamine	8 tablets
Malarone	Atovaquone/proguanil	42 tablets
Mefloquine	Mefloquine	14 tablets
Primaquine	Primaquine phosphate	46 tablets
Qualaquin	Quinine	84 capsules

Antiretrovirals

- Paxlovid 150mg-100mg tablets- 40 tablets per 30 days
- Paxlovid 300mg-100mg tablets – 60 tablets per 30 days

Contraceptives

- Depo-Provera/Depo-SQ Provera (Medroxyprogesterone inj (IM & SQ)) – 4 injections per 300 days

Diabetic Medications and Supplies

- Victoza injection – 9ml 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
Stendra	Avanafil	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

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

Hyponatremia

- Samsca – 60 tablets every 180 days

Inhalers

- Armonair digihaler- 2 inhalers per 30 days

Smoking Cessation Medications

Brand Name	**Chemical Name**	**Quantity Limit**
Chantix	Varenicline, apo-varenicline	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)

*Only generic nicotine replacement products are covered

Opioid Withdrawal Agents

Brand Name	**Chemical Name**	**Quantity Limit**
Lucemyra	Lofexidine	168 tablets per 180 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	60 grams per 30 days
Clobetasol ointment	120 grams per 30 days

Diflorasone 0.05% ointment/cream	60 grams per 30 days
Flurandrenolide cream/ointment	60 grams per 30 days
Flurandrenolide lotion	120mL per 30 days
Hydrocortisone butyrate lotion 0.1%	59ml per 30 days

Wakefulness-promoting agents

Brand Name	Chemical Name	Quantity Limit per 30 days
Provigil®	modafinil	60 tablets
Nuvigil®	armodafinil	60 tablets
Sunosi®	solriamfetol	60 tablets

Weight loss products- brand and generic

- All medications listed in the chart below will be covered at a **maximum of 12 months per lifetime**. Coverage beyond 12 months will be reviewed on a case-by-case basis for life threating medical conditions related to obesity.

Drug Name	Chemical Name
Adipex-P®, Lomaira, Suprenza	phentermine
Bontril PDM®	phendimetrazine
Contrave	naltrexone/bupropion
Qsymia™	phentermine/topiramate
Regimex	benzphetamine
Tenuate®/Dospan®	diethylpropion
Xenical®	Orlistat
®	

Wound products

- Santyl 250unti/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

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

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Exclusions

- 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.

References:

1. Manufacturer 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 Medicare Gold Giveback	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Secure HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare WellSelect PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare WellSelect Plus PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Patriot Plan PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess Complete D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
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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
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UVM Health Advantage Secure PPO	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D
MVP VT HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth

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

***Medical Management Requirements**

Prior Auth	Prior Authorization Required
Potential for Retrospective Review	No Prior Authorization Required. May be subject to Retrospective Review.
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: **03/01/2023**

Approval Date: **11/01/2023**

Effective Date: **01/01/2024**

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.

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

- Prescribed by a Neurologist
- Chart notes identifying the diagnosis of ALS per the revised EL Escorial or Awaji criteria
- Diagnosis of ALS within the past 2 years
- Submission of the most recent ALS Functional Rating Scale-Revised (ALSFRS-R) score with results identifying a score of 2 points or better on each individual item showing that the member has functionality retained most activities of daily living. http://www.outcomes-umassmed.org/als/alsscale.aspx
- Chart notes identifying current % forced vital capacity (%FVC) greater than or equal to 80%
- The member is currently receiving riluzole unless contraindicated
- Documentation from provider identifying anticipated clinical benefit from Radicava therapy

Commercial and Exchange 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): Cycle 1=daily dosing for 14 days followed by 14-day drug free period and Cycle 2-6=daily dosing for 10 days out of 14-day period followed by 14-day drug free period.

For continuation of therapy:

- Patient must not be dependent on invasive ventilation
- Patient 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

- Dose above FDA approved maximum
- Patient dependent on invasive ventilation
- Patients require total assistants for activities of daily living
- Patients with a history of hypersensitivity to edavarone or any of the inactive ingredients in the product, including sulfite hypersensitivity

References

1. Costa J, Swash M, de Carvalho M. Awaji criteria for the diagnosis of amyotrophic lateral sclerosis: A systemic review. Arch Neurol. 2012;69(11):1410
2. Brooks BR, Miller RG, Swash M, et al. El Escorial revisited: Revised Criteria for the Diagnosis of Amyotrophic lateral Sclerosis. Amyotroph Lateral Scler Other Motor Neuron Disord. 2000;1(5):293
3. Radicava (edaravone) Injection. Prescribing Information. Jersey City, NJ: MT Pharma America, Inc. May 2017. Revised May 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 Medicare Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP Medicare WellSelect PPO	Prior Auth
MVP Medicare WellSelect Plus PPO	Prior Auth
MVP Medicare Patriot Plan PPO	Prior Auth
MVP DualAccess D-SNP HMO	Prior Auth
MVP DualAccess Complete D-SNP HMO	Prior Auth
MVP DualAccess Plus D-SNP HMO	Prior Auth
UVM Health Advantage Select PPO	Prior Auth
UVM Health Advantage Secure PPO	Prior Auth
UVM Health Advantage Preferred 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
UVM Health Advantage Select PPO	Prior Auth
UVM Health Advantage Secure PPO	Prior Auth
UVM Health Advantage Preferred PPO	Prior Auth
MVP VT HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD
♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).	

***Medical Management Requirements**

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

MVP Health Care Medical Policy

Medicare Part B: Radicava

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

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

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.

Indications/Criteria

- Prescribed by a Neurologist
- Chart notes identifying the diagnosis of ALS per the revised EL Escorial or Awaji criteria
- Diagnosis of ALS within the past 2 years

- Submission of the most recent ALS Functional Rating Scale-Revised (ALSFRS-R) score with results identifying a score of 2 points or better on each individual item showing that the member has functionality retained most activities of daily living. http://www.outcomes-umassmed.org/als/alsscale.aspx
- Chart notes identifying current % forced vital capacity (%FVC) greater than or equal to 80%
- The member is currently receiving riluzole unless contraindicated
- Documentation from provider identifying anticipated clinical benefit from Radicava therapy

Initial approval will be for 6 cycles or 24 weeks (64 doses): Cycle 1=daily dosing for 14 days followed by 14-day drug free period and Cycle 2-6=daily dosing for 10 days out of 14-day period followed by 14-day drug free period.

For continuation of therapy:

- Patient must not be dependent on invasive ventilation
- Patient 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

- Dose above FDA approved maximum
- Patient dependent on invasive ventilation
- Patients require total assistants for activities of daily living
- Patients with a history of hypersensitivity to edavarone or any of the inactive ingredients in the product, including sulfite hypersensitivity

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References

1. Costa J, Swash M, de Carvalho M. Awaji criteria for the diagnosis of amyotrophic lateral sclerosis: A systemic review. Arch Neurol. 2012;69(11):1410
2. Brooks BR, Miller RG, Swash M, et al. El Escorial revisited: Revised Criteria for the Diagnosis of Amyotrophic lateral Sclerosis. Amyotroph Lateral Scler Other Motor Neuron Disord. 2000;1(5):293
3. Radicava (edaravone) Injection. Prescribing Information. Jersey City, NJ: MT Pharma America, Inc. May 2017. Revised May 2022.

MVP Health Care Medical Policy

Respiratory Syncytial Virus/Synagis® (palivizumab)

Type of Policy: Medical *(administered by the pharmacy department)*
Prior Approval Date: **03/01/2023**
Approval Date: **11/01/2023**
Effective Date: **11/01/2023**
Related Policies: **Immunizations Childhood, Adolescent and Adults**

Codes Requiring Prior Authorization

90378 Synagis (palivizumab-rsv-igm, per 50mg)

Overview

Palivizumab is a monoclonal antibody indicated for the prevention of serious lower respiratory tract disease caused by RSV in certain pediatric patients. High risk pediatric patients include premature infants and children under age 2 with Chronic Lung Disease (CLD). Palivizumab has demonstrated safety and efficacy in reducing the incidence and days of RSV hospitalization. Palivizumab is administered intramuscularly for up to five monthly doses. The first dose is given in November, before the start of the RSV season if the child was born prior to November. (RSV season usually runs from November through March). Following the COVID-19 pandemic, there has been a change in RSV activity and circulation. The American Academy of Pediatrics has put out a statement supporting the use of palivizumab in eligible infants in any region, regardless of time of year in 2022, that is experiencing RSV rates that are similar to a typical fall-winter season. The data rates are available from the Centers for Disease Control (CDC) RSV Surveillance Data - NREVSS | CDC. Exposure to tobacco smoke should be restricted whenever feasible. High-risk infants should never be exposed to tobacco smoke.

Medicare Variation

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

Medicaid Variation

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

Indications/Criteria

A. For all requests, the following criteria must be met in addition to the criteria in section B.

- Palivizumab must be obtained from CVS Specialty Pharmacy Services or a participating network pharmacy able to dispense specialty medication. Requests for nursing services, if required, will be coordinated by case management or CVS Specialty. Documentation of medical necessity will be required for approval of the administration of palivizumab in settings other than the home.
- Approval will authorize one (1) dose every 28 days for up to the maximum of five (5) doses or through March 31. (Refer to Tables 1 and 2). Each monthly dose must be calculated based upon a recent weight and the appropriate combination of vials must be used to obtain the correct dose with the minimum of wastage.
- Infants living in a geographic region (e.g. southwest Florida) in which the RSV season has an earlier onset will be eligible to receive their doses at the start of the RSV season for that region.
- For all requests outside the typical RSV season or requests for more than 5 doses due to an atypical season will be reviewed on a **case-by case basis** in accordance with the current American Academy of Pediatrics and Centers of Disease Control (CDC) guidance
- Beyfortus (nirsevimab)
    - Documentation confirming Synagis is not coadministered 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.[1,2]
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.[1]
c. Infants with hemodynamically significant congenital heart disease (CHD) who are less than or equal to 12 months[1] 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.[1,2]
    i. No prospective studies or population based data are available to define risk of RSV hospitalizations in this population-will be considered on a **case by case basis**.
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.[1]
    i. Efficacy in this cohort is not known and will be considered on a **case-by-case basis.**

f. Infants younger than 12 months of age with pulmonary or neurological abnormality that impairs the ability to clear the upper airway.
g. Infants in their first year of life with cystic fibrosis AND nutritional compromise will be considered on a **case-by-case basis**.
h. Infants in their second year of life with cystic fibrosis who have abnormalities on chest radiography/computed tomography OR have weight less than the 10th percentile will be considered on a **case-by-case basis.**
i. Children under 2 years of age who have undergone cardiac transplantation during the RSV season.

Approvals for eligible infants will be for a maximum of 5 doses per season using Table 1 and Table 2 below

- Hospitalized infants who qualify for prophylaxis during the RSV season should receive the first dose of palivizumab 48 to 72 hours prior to discharge from the hospital (or promptly after discharge).

- Children less than 2 years who are receiving RSV prophylaxis with palivizumab should receive a post-operative dose after any cardiac bypass or extracorporeal membrane oxygenation.

- For all requests outside the typical RSV season or requests for more than 5 doses due to an atypical season will be reviewed on a **case-by case basis** in accordance with the current American Academy of Pediatrics and Centers of Disease Control (CDC) guidance

Table 1: Maximum Number of Monthly Doses of Palivizumab for Respiratory Syncytial Virus Prophylaxis[1]

Infants Eligible for a Maximum of 5 Doses
Preterm infants born at 28 weeks, 6 days of gestation or less who are less than 12 months old at the start of the RSV season.
Preterm infants born at 31 weeks, 6 days of gestation or less with Chronic Lung Disease (CLD) (see section 1 above)
Preterm infants now between age 1 and 2 who required medical support for CLD in the 6 months before the start of the RSV season (see section 1).
Infants younger than 12 months of age who require medical therapy for Congenital Heart Disease (see section 2).
Certain infants with Neuromuscular Disease or Anatomic Pulmonary Abnormalities.
Children younger than 24 months who will be profoundly immunocompromised during the RSV season.
Children younger than 24 months who undergo cardiac transplantation during the RSV season.

Table 2: Maximum Number of Palivizumab Doses for RSV Prophylaxis of Preterm Infants Without Chronic Lung Disease, on the Basis of Birth Date, and Gestational Age (Shown for Geographic Areas Beginning Prophylaxis on November 1st)[a, 2]

Maximum No. of Doses for Season Beginning November 1	
Month of Birth	**Born 28 Weeks, 6 Days of Gestation AND <12 Months of Age at Start of Season**
November 1–March 31 of previous RSV season	5[b]
April	5
May	5
June	5
July	5
August	5
September	5
October	5
November	5
December	4
January	3
February	2
March	1
[a]If infant is discharged from the hospital during RSV season, fewer doses may be required.	
[b]Some of these infants may have received 1 or more doses of palivuzimab in the previous RSV season if discharged from the hospital during that season; if so, they still qualify for up to 5 doses during their second RSV season.	

Exclusions

Palivizumab is NOT covered for infants with the following conditions:

- infants and children with hemodynamically insignificant heart disease (e.g. secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta or patent ductus ateriosus), or
- 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.[1,2]
- 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.[1]
- 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.[1]

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)

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	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
UVM Health Advantage Secure PPO	Potential for retrospective review
UVM Health Advantage Preferred PPO	Potential for retrospective review
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Potential for retrospective review
MVP EPO	Prior Auth
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	Potential for retrospective review
MVP Medicare Secure Plus HMO POS	Potential for retrospective review
UVM Health Advantage Select PPO	Potential for retrospective review
UVM Health Advantage Secure PPO	Potential for retrospective review
UVM Health Advantage Preferred PPO	Potential for retrospective review
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	Potential for retrospective review
ASO	See SPD
♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).	

***Medical Management Requirements**

Prior Auth	Prior Authorization Required
Potential for Retrospective Review	No Prior Authorization Required. May be subject to Retrospective Review.
Retro Review	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:	**10/01/2023**
Approval Date:	**12/01/2023**
Effective Date:	**02/01/2024**
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 – C9399, J3590, 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.

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.

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, or colorectal surgeon
- Must be prescribed for an FDA approved indication

B. Crohn's Disease

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

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

Medicare Part B Variation: Documentation of moderate to severely active disease. Patient 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 3 months

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

C. Plaque Psoriasis

Risankizumab may be considered for coverage for Plaque Psoriasis when the following criteria is met:

-
- 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:
    a. Crucial body areas (e.g. hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected OR
    b. At least 10% of the body surface area (BSA) is affected OR
    c. At least 3% of the body surface area (BSA) is affected AND the member meets any of the following criteria:
        i. Member has had an inadequate response or intolerance to either phototherapy (e.g. UVB, PUVA) OR
        ii. Member has had an inadequate response or intolerance to pharmacologic treatment with methotrexate, cyclosporine, or acitretin

Medicare Part B Variation: 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:

- 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 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.

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:

- Dosing, age, and/or frequency outside of the FDA approved package labeling.
- Combination therapy that is not supported by current guidelines
- History of serious hypersensitivity reaction to risankizumab-rzaa or any of the excipients

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References

1. Skyrizi (risankizumab) injection package insert. North Chicago, IL: AbbVie Inc.; June 2022
2. Singh, Jasvinder A., et al. "2018 American College of Rheumatology/National Psoriasis Foundation guideline for the treatment of psoriatic arthritis." *Arthritis & Rheumatology* 71.1 (2019): 5-32. Skyrizi [package insert]. North Chicago, IL: AbbVie Inc.; June 2022.
3. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 4: Guidelines of care for the management and treatment of psoriasis with traditional systemic agents. *J Am Acad Dermatol*. 2009;61(3):451-485.
4. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 6: Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. *J Am Acad Dermatol*. 2011;65(1):137-174.
5. 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.
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. 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.

8. 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.
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10. **Member Product**	**Medical Management Requirements***
New York Products	
HMO	Prior Auth
PPO in Plan	Prior Auth
PPO OOP	Prior Auth
POS in Plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Child Health Plus	Prior Auth
MVP Harmonious Health Care Plan	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP 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.
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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.
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).	

***Medical Management Requirements**

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

MVP Health Care Medical Policy

Ritlecitinib

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

1. Ritlecitinib. Clinical Pharmacology. Revised December 4, 2023. Accessed January 29, 2024.

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

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

4. Litfulo. Prescribing Information. Pfizer. Revised June 2023. labeling.pfizer.com/ShowLabeling.aspx?id=19638#section-2.1

Member Product	Medical Management Requirements*
New York Products	
HMO	Prior Auth
PPO in Plan	Prior Auth
PPO OOP	Prior Auth
POS in Plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Child Health Plus	Prior Auth
MVP Harmonious Health Care Plan	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Medicare Gold Giveback	Refer to the MVP website for the Medicare Part B and Part D policies.
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MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
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.
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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

Secukinumab

Type of Policy:	**Drug/Medical Therapy**
Prior Approval Date:	**10/01/2023**
Approval Date:	**02/01/2024**
Effective Date:	**02/01/2024**
Related Policies:	**Apremilast**
	Etanercept
	Infliximab
	Risankizumab
	Adalimumab
	Tofacitinib
	Upadacitinib
	Ustekinumab
	Ozanimod

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

Drugs Requiring Prior Authorization under the pharmacy benefit

Cosentyx prefilled syringes and pen (secukinumab)

Drugs Requiring Prior Authorization under the medical benefit

J3590 Cosentyx intravenous solution (secukinumab)

Overview

Secukinumab is a human IgG1 monoclonal antibody that selectively binds to the interleukin-17A (IL-17A) cytokine, inhibiting its interaction with the IL-17A receptor. It is FDA approved for several indication including ankylosing spondylitis, psoriasis and psoriatic arthritis. Secukinumab carries an increased risk of infection; members should be screened for immunologic and infectious disease prior to initiating therapy.

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

Indications/Criteria

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

- Prescription drugs covered under the pharmacy benefit must be self-administered. If office administration is being requested for SQ administration documentation must be provided identifying why the member or caregiver is unable to administer the medication
- Medical drugs covered under the medical benefit will require documentation identifying why the member or caregiver cannot use SQ administration
- Must be ordered by or with consult from an appropriate specialist: rheumatologist/immunologist/dermatologist
- Must be prescribed for an FDA approved indication and route of administration must be FDA approved for indication

B. Ankylosing Spondylitis & Non-Radiographic Axial Spondylarthritis

Secukinumab may be considered for coverage for Ankylosing Spondylitis and Non-Radiographic Axial Spondylarthritis when:

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

- Members **with pure axial manifestations** do not have to have a trial of nonbiologic disease modifying anti-rheumatic drugs (DMARDs)

Initial approval will be for 6 months

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

C. Psoriasis

Secukinumab may be considered for coverage for Psoriasis when:

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

Initial approval for **6 months**

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

D. Psoriatic Arthritis

Secukinumab may be considered for coverage for Psoriatic Arthritis when:

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

Initial approval will be for 6 months

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

E. Enthesitis- related arthritis

Secukinumab may be considered for coverage for enthesitis-related arthritis when:

- Failure of at least one NSAID at maximum tolerated dose unless the member has contraindications to NSAID therapy such as cardiovascular disease, peptic ulcer disease or renal disease

Initial approval will be for 6 months

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

F. Hidradenitis Suppurativa

Secukinumab may be considered for coverage for Hidradenitis Suppurativa when:

- Member has a documented diagnosis of moderate to severe disease (Hurley State II or III)

Initial approval will be for 6 months.

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

Exclusions

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

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling. Secukinumab in combination with other biologics is excluded from coverage
- Combination therapy that is not supported by guidelines

References

1. Clinical Pharmacology
2. Cosentyx (secukinumab) injection. Prescribing Information. East Hanover, NJ. Novartis Pharmaceuticals Corporation. January 2018.
3. Ward Michael, Atul Deodhar et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. Arthritis and Rheumatology. Vol 71 (No. 10). October 2019, pp 1599-1613. Available at: https://www.rheumatology.org/Portals/0/Files/AxialSpA-Guideline-2019.pdf
4. Ringold, Sarah; Angeles-Han Sheila et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Treatment Approaches for Non-Systemic Polyarthritis, Sacroilitis and Enthesitis. American College of Rheumatology. Vol 71 (No 6). June 2019, pp 717-734.
5. Ward MM, Deodhar A, Gensler LS, et al. 2019 update of the American college of rheumatology/spondylitis association of America/spondyloarthritis research and treatment network recommendations for the treatment of ankylosing spondylitis and nonradiographic axial spondyloarthritis. Arthritis Rheumatol. 2019;71(10):1599-1613. doi:10.1002/art.41042

6. Ali Aikhan, Christropher Sayed, et al. North American clinical management guidelines for hidradenitis suppurativa: A publication from the United States and Canadian Hidradenitis Suppurative Foundations. JAAD. 2019; 81(1):91-101.doi.org/10.1016/j.jaad.2019.02.068.

Member Product	Medical Management Requirements*
New York Products	
HMO	Prior Authorization
PPO in Plan	Prior Authorization
PPO OOP	Prior Authorization
POS in Plan	Prior Authorization
POS OOP	Prior Authorization
Essential Plan	Prior Authorization
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MVP PPO	Prior Authorization
MVP PPO HDHP	Prior Authorization
Student Health Plans	Prior Authorization
ASO	Prior Authorization
Vermont Products	
POS in Plan	Prior Authorization
POS OOP	Prior Authorization

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

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

MVP Health Care Medical Policy

Medicare Part B: Secukinumab

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

Related Policies: Infliximab, Risankizumab, Ustekinumab, Golimumab, Tocilizumab, Certolizumab

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

Drugs Requiring Prior Authorization under the medical benefit

J3590 Cosentyx intravenous solution (secukinumab)

Overview/Summary of Evidence

Secukinumab is a human IgG1 monoclonal antibody that selectively binds to the interleukin-17A (IL-17A) cytokine, inhibiting its interaction with the IL-17A receptor. It is FDA approved for several indications including ankylosing spondylitis, psoriasis and psoriatic arthritis. Secukinumab carries an increased risk of infection; members should be screened for immunologic and infectious disease prior to initiating therapy.

Indications/Criteria

A. For all indications, Secukinumab IV may be considered for **medical** coverage when:

- Prescribed for an FDA approved indication **AND**
- Ordered by or with consult from an appropriate specialist: rheumatologist/immunologist/dermatologist **AND**

- Member has coverage under Medicare Part B and meets the criteria below for a provider administered drug identified in this policy

B. Ankylosing Spondylitis & Non-Radiographic Axial Spondylarthritis

Secukinumab may be considered for coverage for Ankylosing Spondylitis and Non-Radiographic Axial Spondylarthritis when:

- Chart notes documenting a failure of at least one NSAIDS at maximum tolerated dose unless the member has contraindications to NSAID therapy such as cardiovascular disease, peptic ulcer disease or renal disease **AND**
- Documented significant clinical symptoms such as fatigue, spinal pain, arthralgia, inflammation of joints and tendons, morning stiffness duration and therapy **AND**
- Insufficient response to at least one local corticosteroid injection in patients with symptomatic peripheral arthritis **AND**
- Members **with pure axial manifestations** do not have to have a trial of nonbiologic disease modifying anti-rheumatic drugs (DMARDs)

Initial approval will be for 6 months

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

C. Psoriatic Arthritis

Secukinumab may be considered for coverage for Psoriatic Arthritis when:

- Member has a diagnosis of moderate to severe psoriatic arthritis as indicated by three or more tender joints AND three or more swollen joints on two separate occasions at least one month apart
- Chart notes documenting a failure of at least one NSAIDS at maximum tolerated dose unless the member has contraindications to NSAID therapy such as cardiovascular disease, peptic ulcer disease or renal disease **AND**Chart notes documenting a failure to respond to an adequate trial of at least one of the following nonbiologic disease modifying anti-rheumatic drugs (DMARDs): leflunomide, sulfasalazine, or methotrexate.
    - Members with **pure axial manifestations** do not have to have a trial of nonbiologic disease modifying anti-rheumatic drugs (DMARDs)

- If a trial of methotrexate is not appropriate due to alcohol use and both leflunomide and sulfasalazine are not clinically appropriate, chart notes must be provided indicating that the patient has been counseled on the need to abstain from alcohol use while taking methotrexate and is unwilling to abstain from alcohol use.

Initial approval will be for 6 months

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

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. January 2018. Revised November 2023.
3. Ward Michael, Atul Deodhar et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. Arthritis and Rheumatology. Vol 71 (No. 10). October 2019, pp 1599-1613. Available at: https://www.rheumatology.org/Portals/0/Files/AxialSpA-Guideline-2019.pdf
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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: 03/01/2023
Approval Date: **10/01/2023**
Effective Date: **12/01/2023**
Related Policies: N/A

Drugs Requiring Prior Authorization under the pharmacy benefit
Cuprimine (penicillamine oral capsule)
Syprine (trientine oral capsule)
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 patients with Wilson's disease. Penicillamine also is used in cystinuria to reduce excess cystine excretion and for the treatment of rheumatoid arthritis in patients 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 will 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) will 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

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

- Any non- FDA approved indications
- Doses above the FDA package label
- 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. October 2020.
2. Depen (penicillamine) tablets. Prescribing Information. Somerset, NJ: Meda Pharmaceuticals Inc. 2009
3. Syprine (trientine) capsules. Prescribing Information. Bridgewater, NJ: Baush Health US, LLC. Sep 2020.

Member Product	Medical Management Requirements*
New York Products	
HMO	Prior Auth
PPO in Plan	Prior Auth
PPO OOP	Prior Auth
POS in Plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Child Health Plus	Prior Auth
MVP Harmonious Health Care Plan	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Medicare 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).	

***Medical Management Requirements**

Prior Auth — Prior Authorization Required

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

eosinophilic infiltration, or eosinophil-rich granulomatous inflammation; neuropathy; pulmonary infiltrates; sino-nasal abnormality; cardiomyopathy; glomerulonephritis; alveolar hemorrhage; palpable purpura; anti neutrophil cytoplasmic antibody (ANCA) positive.

- Relapsing or refractory disease defined as:
    - Failure with an adequate trial of corticosteroid therapy
- Failure with at least one adequate trial of immunosuppressive therapy (i.e. azathioprine, methotrexate, mycophenolate, cyclosporine). Nucala IV will be considered for coverage if rationale and documentation is provided identifying why the member or caregiver is unable to self-administer **OR** member has coverage under Medicare Part B and meets the criteria for a provider administered drug identified in this policy

Initial approval will be for 6 months.
Continued authorization for up to 12 months will be considered if there is a documented decrease in symptoms and exacerbations.

C. Nasal Polyps

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

- Confirmed diagnosis of nasal polyps
- Documented failure, contraindication, intolerance or allergy to at least one intranasal corticosteroid indicated to treat nasal polyps.
- **Initial approval** will be for 6 months. **Continued authorization** must be accompanied by current chart notes identifying continued benefit. Extension of therapy for up to one year will be based upon a positive clinical response.

D. Hypereosinophilic Syndrome

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

- Prescribed by or in consultation with an allergist or immunologist
- Member as a documented diagnosis of hypereosinophilic syndrome (HES) for ≥ 6 months without an identifiable non-hematologic secondary cause
- Documentation of baseline eosinophil count and previous HES flares
- **Initial approval** will be for 6 months.
- **Continued authorization** must be accompanied by current chart notes identifying continued benefit. Extension of therapy for up to one year will be based upon a positive clinical response including a decrease in HES

MVP Health Care Medical Policy

Select Injectables for Asthma

Type of Policy:	**Drug Therapy**
Prior Approval Date:	**07/01/2023**
Approval Date:	**06/01/2024**
Effective Date:	**06/01/2024**
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)

Drugs Requiring Prior Authorization (covered under the pharmacy benefit)

Nucala (mepolizumab) autoinjector and prefilled syringe
Fasenra (benralizumab) autoinjector

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

Overview

Asthma is a chronic inflammatory disease of the airways. Asthma affects between 1-18% of the population. Nucala, Cinqair, and Fasenra are interleukin-5 antagonist monoclonal antibodies indicated for add-on maintenance treatment of patients with severe asthma with an eosinophilic phenotype. Nucala is also indicated for adult patients with eosinophilic granulomatosis with polyangiitis (EGPA).

Indications/Criteria:

Prescription drugs covered under the pharmacy benefit must be self-administered. Self administered products such as Nucala prefilled syringe and autoinjector cannot be approved under the medical benefit.

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

A. ASTHMA

<u>Nucala, Cinqair and Fasenra:</u>

Nucala, Cinqair or Fasenra may be considered for coverage for asthma when the following criteria are met:

- For Nucala and Fasenra:
    - Member must have a documented diagnosis of severe eosinophilic asthma with one of the following:
    - A peripheral blood eosinophil count of at least 150 cells/microliter **OR**
    - Member is dependent on systemic corticosteroids

- For Cinqair
    - A peripheral blood eosinophil count of at least 400 cells/microliter in the past 30 days **OR**
      Member is dependent on systemic corticosteroids
- Member must be followed by an allergist, immunologist or pulmonologist
- Documentation and prescription claim history must identify that the member is compliant with the use of a high-dose inhaled corticosteroid (ICS) and a long-acting beta$_2$-agonist (LABA)
- Member still experiencing poor asthma control and has had at least two asthma exacerbations in the previous year
    - Poor asthma controlled defined as limitations of physical activity or exacerbations affecting activities of daily living

    - Exacerbations must have required treatment with systemic corticosteroids, hospitalization, or an emergency room visit
- Be a non-smoker by history or have a successful smoking cessation for at least 6 weeks
- Documentation that other medical and environmental conditions known to exacerbate asthma have been evaluated and treated
- Provider administered medications under the medical benefit may be considered for coverage if the following is provided:
    - Rationale and documentation are provided identifying why the member or caregiver is unable to self-administer **OR**

Initial approval will be for 6 months.

Continued authorization for up to 12 months will be considered if there is a documented decrease in asthma symptoms and exacerbations.

B. Eosinophilic Granulomatosis with Polyangiitis

Nucala will be considered for coverage for Eosinophilic Granulomatosis with Polyangiitis when all the following are met:

- Member has a documented diagnosis of Eosinophilic Granulomatosis with Polyangiitis (EGPA) for at least 6 months confirmed by presence of:
    - Asthma plus eosinophilia (>1.0x10^9/Liter and/or >10% of leucocytes) AND at least two of the following additional features of EGPA
        - A biopsy confirming eosinophilic vasculitis, or perivascular eosinophilic infiltration, or eosinophil-rich granulomatous inflammation
        - Neuropathy;
        - Pulmonary infiltrates;
        - Sino-nasal abnormality;
        - Cardiomyopathy;
        - Glomerulonephritis;
        - Alveolar hemorrhage;
        - Palpable purpura;
        - Anti neutrophil cytoplasmic anti-body (ANCA) positive.
- Documentation of relapsing or refractory disease defined as:
    - Failure with an adequate trial of corticosteroid therapy
- Documented failure with at least one adequate trial of immunosuppressive therapy (i.e. azathioprine, methotrexate, mycophenolate, cyclosporine).

Provider administered medications under the medical benefit (i.e Nucala IV)may be considered for coverage when:

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

Initial approval will be for 6 months.

Continued authorization for up to 12 months will be considered if there is a documented decrease in symptoms and exacerbations.

C. Chronic Rhinosinusitis with Nasal Polyps

Nucala will be considered for coverage for Chronic Rhinosinusitis nasal polyps when all the following are met:

- Confirmed diagnosis of nasal polyps. Chart notes must document diagnosis confirmation by examination, endoscopy or sinus computed tomography (CT) scan.
- Prescribed by or in consultation with an allergist, otolaryngologist or immunologist
- Documented trial and failure of three (3) months to at least one intranasal corticosteroid indicated to treat nasal polyps.
- Documented failure, contraindication, intolerance, or allergy to other therapy used in the management of nasal polyps such as nasal saline irrigations, or antileukotriene agents (montelukast, zafirlukast, zileuton).
- Documentation of prior oral corticosteroid therapy and/or sinus surgery
- Nucala will be add on maintenance in combination with an intranasal corticosteriod

Initial approval will be for 6 months.

Continued authorization must be accompanied by current chart notes identifying continued benefit. Extension of therapy for up to one year will be based upon a positive clinical response.

D. Hypereosinophilic Syndrome

Nucala will be considered for coverage of Hypereosinophilic Syndrome when all the following are met:

- Prescribed by or in consultation with an allergist or immunologistMember as a documented diagnosis of hypereosinophilic syndrome (HES) for ≥ 6 months without an identifiable non-hematologic secondary cause
- Documentation of baseline eosinophil count and previous HES flares

Initial approval will be for 6 months.

Continued authorization must be accompanied by current chart notes identifying continued benefit. Extension of therapy for up to one year will be based upon a positive clinical response including a decrease in HES flares as well as documentation of decreasing eosinophil count from baseline.

Exclusions

- Nucala
    1. For hypereosinophilic syndrome (HES): members with non-hematologic secondary HES or FIP1L1-PDGFRα kinase positive HES
- Dosing, age, and/or frequency outside of the FDA approved package labeling
- Dual therapy with another monoclonal antibody that is not supported by current clinical guidelines
- Treatment of acute bronchospasm or status asthmaticus
- Cinqair given more frequently than every 4 weeks
- Use of Fasenra or Cinqair for the treatment of other eosinophilic conditions

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References

1. Ortega H, Liu MC, Pavord I, et al. Mepolizumab Treatment in Patients with Severe Eosinophilic Asthma. N Engl J Med 2014; 371:1198-1207
2. National Asthma Education and Prevention Program: Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma.

October 2007. Available at: http://www.nhlbi.nih.gov/guidelines/asthma/asthsumm.pdf
3. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2016. Available from www.ginasthma.org
4. Nucala (mepolizumab) for injection. Prescribing Information. Philadelphia, PA. GlaxoSmith Kline LLC.March 2023.
5. Cinqair (reslizumab) injection. Prescribing Information. Frazer, PA. Teva Respiratory LLC.February 2020.
6. Wechsler ME, Akuthota P, et al. Mepolizumab or Placebo for Eosinophilic Granulomatosis with Polyangiitis. N Engl J Med. 2017 May 18;376(20):1921-1932.
7. Prescribing Information. Fasenra (benralizumab) subcutaneous injection Wilmington, DE. Astra Zeneca. February 2021.GINA 2023 - Global Strategy for Asthma Management and Prevention (ginasthma.org)
8. American Academy of Allergy, Asthma & Immunology. Nasal Polyps. Nasal Polyps |AAAAI Reviewed May 1, 2023. Accessed April 18, 2024.
9. Global Strategy for Asthma Management and Prevention. 2023 Update. GINA Main Report 2023 Front Cover (ginasthma.org)

Member Product	Medical Management Requirements*
New York Products	
HMO	Prior Auth
PPO in Plan	Prior Auth
PPO OOP	Prior Auth
POS in Plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Child Health Plus	Prior Auth
MVP Harmonious Health Care Plan	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Medicare Gold Giveback	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Secure HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare WellSelect PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare WellSelect Plus PPO	Refer to the MVP website for the Medicare Part B and Part D policies.

MVP Medicare Patriot Plan PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess Complete D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess Plus D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Select PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Secure PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	
POS in Plan	Prior Auth
POS OOP	Prior Auth
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D
MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Select PPO	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Secure PPO	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D
MVP VT HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD
♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).	

***Medical Management Requirements**

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

MVP Health Care Medical Policy

Medicare Part B: Select Injectables for Asthma

Type of Policy: **Drug Therapy**
Prior Approval Date: **11/01/2023**
Approval Date: **06/01/2024**
Effective Date: **06/01/2024**
Related Policies: **Medicare Part B: Xolair**

Drug Requiring Prior Authorization (covered under the medical benefit)

J2182 Nucala® (Injection, mepolizumab, 1mg)
J2786 Cinqair® (Injection, reslizumab,1mg)
J0517 Fasenra® (Injection, benralizumab,1mg)

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

Overview/Summary of Evidence

Asthma is a chronic inflammatory disease of the airways. Asthma affects between 1-18% of the population. Nucala, Cinqair, and Fasenra are interleukin-5 antagonist monoclonal antibodies indicated for add-on maintenance treatment of patients with severe asthma with an eosinophilic phenotype. Nucala is also indicated for adult patients with eosinophilic granulomatosis with polyangiitis (EGPA).

Indications/Criteria:

Medications identified in this policy that are self-administered fall under the Medicare Part D (pharmacy) benefit. Refer to the MVP website for the Medicare Part D formulary and prior authorization criteria for drugs that may covered under the Part D benefit.

A. ASTHMA

Nucala, Cinqair and Fasenra:

Nucala, Cinqair or Fasenra may be considered for coverage for asthma when the following criteria are met:

- For Nucala and Fasenra
    - Member must have a documented diagnosis of severe eosinophilic asthma with one of the following:
    - A peripheral blood eosinophil count of at least 150 cells/microliter **OR**
    - Member is dependent on systemic corticosteroids
- For Cinqair:
    - Must have a peripheral blood eosinophil count of at least 400 cells/microliter in the past 30 days OR
    - Member is dependent on systemic corticosteroids

- Member must be followed by an allergist, immunologist or pulmonologist
- Documentation and prescription claim history must identify that the member is compliant with the use of a high-dose inhaled corticosteroid (ICS) and a long-acting beta$_2$-agonist (LABA)
- Member still experiencing poor asthma control and has had at least two asthma exacerbations in the previous year
    - Poor asthma controlled defined as limitations of physical activity or exacerbations affecting activities of daily living
    - Exacerbations must have required treatment with systemic corticosteroids, hospitalization, or an emergency room visit
- Be a non-smoker by history or have a successful smoking cessation for at least 6 weeks
- Documentation that other medical and environmental conditions known to exacerbate asthma have been evaluated and treated
- Provider administered medications under the medical benefit may be considered for coverage if the following is provided:
    - Rationale and documentation are provided identifying why the member or caregiver is unable to self-administer **OR**
    - Member has coverage under Medicare Part B and meets the criteria for a provider administered drug identified in this policy.

Initial approval will be for 6 months.

Continued authorization for up to 12 months will be considered if there is a documented decrease in asthma symptoms and exacerbations.

B. Eosinophilic Granulomatosis with Polyangiitis

Nucala will be considered for coverage for Eosinophilic Granulomatosis with Polyangiitis when all the following are met:

- Member has a documented diagnosis of Eosinophilic Granulomatosis with Polyangiitis (EGPA) for at least 6 months confirmed by presence of:
    - Asthma plus eosinophilia (>1.0x10^9/Liter and/or >10% of leucocytes) plus at least two of the following additional features of EGPA
        - a biopsy confirming eosinophilic vasculitis, or perivascular eosinophilic infiltration, or eosinophil-rich granulomatous inflammation
        - neuropathy
        - pulmonary infiltrates
        - sino-nasal abnormality
        - cardiomyopathy
        - glomerulonephritis
        - alveolar hemorrhage
        - palpable purpura
        - anti neutrophil cytoplasmic anti-body (ANCA) positive.
- Documentation of relapsing or refractory disease defined as:
    - Failure with an adequate trial of corticosteroid therapy
- Documented failure with at least one adequate trial of immunosuppressive therapy (i.e. azathioprine, methotrexate, mycophenolate, cyclosporine).

Provider administered medications under the medical benefit (i.e Nucala IV)may be considered for coverage when:

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

Initial approval will be for 6 months.

Continued authorization for up to 12 months will be considered if there is a documented decrease in symptoms and exacerbations

C. Chronic Rhinosinusitis with Nasal Polyps

Nucala will be considered for coverage for Chronic Rhinosinusitis nasal polyps when all the following are met:

- Confirmed diagnosis of nasal polyps. Chart notes must document diagnosis confirmation by examination, endoscopy or sinus computed tomography (CT) scan.
- Prescribed by or in consultation with an allergist, otolaryngologist or immunologist
- Documented trial and failure of three (3) months, to at least one intranasal corticosteroid indicated to treat nasal polyps.
- Documented failure, contraindication, intolerance, or allergy to other therapy used in the management of nasal polyps such as nasal saline irrigations, or antileukotriene agents (montelukast, zafirlukast, zileuton).
- Documentation of prior oral corticosteroid therapy and/or sinus surgery
- Nucala will be add on maintenance in combination with an intranasal corticosteriod

Initial approval will be for 6 months.

Continued authorization must be accompanied by current chart notes identifying continued benefit. Extension of therapy for up to one year will be based upon a positive clinical response.

D. Hypereosinophilic Syndrome

Nucala will be considered for coverage of Hypereosinophilic Syndrome when all the following are met:

- Prescribed by or in consultation with an allergist or immunologist
- Member as a documented diagnosis of hypereosinophilic syndrome (HES) for ≥ 6 months without an identifiable non-hematologic secondary cause
- Documentation of baseline eosinophil count and previous HES flares

Initial approval will be for 6 months.

Continued authorization must be accompanied by current chart notes identifying continued benefit. Extension of therapy for up to one year will be based upon a positive clinical response including a decrease in HES flares as well as documentation of decreasing eosinophil count from baseline.

Exclusions

- Nucala
    1. For hypereosinophilic syndrome (HES): members with non-hematologic secondary HES or FIP1L1-PDGFRα kinase positive HES
- Dosing, age, and/or frequency outside of the FDA approved package labeling Dual therapy with another monoclonal antibody that is not supported by current clinical guidelines Treatment of acute bronchospasm or status asthmaticus
- Cinqair given more frequently than every 4 weeks
- Use of Fasenra or Cinqair for the treatment of other eosinophilic conditions

References

1. Ortega H, Liu MC, Pavord I, et al. Mepolizumab Treatment in Patients with Severe Eosinophilic Asthma. N Engl J Med 2014; 371:1198-1207
2. National Asthma Education and Prevention Program: Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma. October 2007. Available at: http://www.nhlbi.nih.gov/guidelines/asthma/asthsumm.pdf
3. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2016. Available from www.ginasthma.org
4. Nucala (mepolizumab) for injection. Prescribing Information. Philadelphia, PA. GlaxoSmith Kline LLC.March 2023.
5. Cinqair (reslizumab) injection. Prescribing Information. Frazer, PA. Teva Respiratory LLC.February 2020.
6. Wechsler ME, Akuthota P, et al. Mepolizumab or Placebo for Eosinophilic Granulomatosis with Polyangiitis. N Engl J Med. 2017 May 18;376(20):1921-1932.
7. Prescribing Information. Fasenra (benralizumab) subcutaneous injection Wilmington, DE. Astra Zeneca. February 2021.GINA 2023 - Global Strategy for Asthma Management and Prevention (ginasthma.org)

MVP Health Care Medical Policy

Select Oral Antipsychotics

Type of Policy:	Drug Therapy
Prior Approval Date:	11/01/2022
Approval Date:	11/01/2023
Effective Date:	01/01/2024
Related Policies:	N/A

*Drugs Requiring Prior Authorization

Nuplazid (pimavanserin tartrate) oral tablets

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

Overview

Nuplazid (pimavanserin) is an atypical antipsychotic indicated for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis (PDP). Nuplazid is NOT approved for the treatment of patients with dementia-related psychosis.

Indications/Criteria

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

1. Patient is 18 years of age or older

   Chart notes documenting a diagnosis of Parkinson's disease for at least one year and that hallucinations/delusions started post Parkinson's diagnosis
2. Health care provider attestation that external or secondary causes of PDP have been ruled out, nonessential offending agents have been discontinued, and anti-PD drugs with the greatest potential for psychosis induction has been evaluated for reduction or discontinuation.
3. Prescription claim history supports the diagnosis of Parkinson's disease

Initial approval will be for a maximum of 12 months. Continued therapy will be considered annually with documented benefit and prescription history identifying compliance.

Exclusions

1. Non-FDA approved or indication that does not meet the Experimental or Investigational Procedures, Behavioral Health Services, Drugs, Treatments, Off-Label use of FDA Approved Drugs, and Clinical Trials
2. Doses exceeding the FDA package label
3. For the treatment of dementia-related psychosis

References

1. American Psychiatric Association. Practice guideline for the treatment of patients with schizophrenia. 2nd ed. Arlington (VA): American Psychiatric Association; 2010
2. Lehman AF et al. Guideline Watch (September 2009): Practice guideline for the treatment of patients with schizophrenia. Second edition. Arlington (VA): American Psychiatric Association; 2009 Sep 10p.
3. Nuplazid (pimavanserin) tablets, for oral use. Prescribing Information. San Diego, CA: Acadia Pharmaceuticals; April 2016.
4. Olanow CW, Watts RL, Koller WC. An algorithm (decision tree) for the management of Parkinson's disease (2001): treatment guidelines. *Neurology*. 2001;56(11 suppl 5):S1-S88.

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

Skysona

Type of Policy: **Drug/Medical Therapy**
Prior Approval Date: **12/01/2022**
Approval Date: **12/01/2023**
Effective Date: **02/01/2024**
Related Policies: **CAR-T Therapy**

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

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

Drugs Requiring Prior Authorization under the medical benefit

J3590 Skysona (elivaldogene autotemcel)

Overview

Skysona is one time an autologous hematopoietic stem cell (HSC)-based gene therapy that is prepared from the patients HSCs through apheresis procedure. Skysona is indicated to slow the progression of neurologic dysfunction in boys 4-17 years of age with early, active cerebral adrenoleukodystrophy (CALD). Early, active CALD refers to asymptomatic or mildly symptomatic (neurologic function score, NFS ≤ 1) boys who have gadolinium enhancement on brain magnetic resonance imaging (MRI) and Loes scores of 0.5-9.

CALD is a rare, progressive, neurodegenerative disease that primarily affects young boys and causes irreversible, devastating neurologic decline, including major functional disabilities such as loss of communication, cortical blindness, requirement for tube feeding, total incontinence, wheelchair dependence, or complete loss of voluntary

movement. Nearly half of patients who do not receive treatment die within five years of symptom onset. Prior to the approval of Skysona treatment, effective options were limited to allogeneic hematopoietic stem cell transplant (allo-HSCT), which is associated with the risk of serious potential complications including death, that can increase dramatically in patients without a human leukocyte antigen (HLA) matched donor.

Indications/Criteria

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

- Documented diagnosis of early active cerebral adrenoleukodystrophy (CALD) and documentation of the following:
    - Neurologic function score (NFS)≤ 1
    - Current brain magnetic resonance imaging (MRI) with use of Gadolinium Enhancement (GdE +) demonstrating demyelinating lesions
    - Loes scores of 0.5-9 based on assessment of brain MRI
    - Elevated very long chain fatty acid (VLCFA) confirmed by laboratory documentation
- Confirmed mutations on the ABCD1 gene (not full deletion of the gene) If applicable, confirmed that anti-retroviral therapy will stop at least one month prior to initiating medications for stem cell mobilization and for the expected duration for elimination of the medications and until all cycles of apheresis are complete. Anti-retroviral medications may interfere with manufacturing of the apheresed cells.
- Member's sex is male
- Member is 4 years to 17 years of age
- Documentation that the member has been screened for the following: hepatitis B virus (HBV), hepatitis C virus (HCV), human immunodeficiency virus 1 and 2 (HIV-1, HIV-2), human T-lymphotropic virus 1 and 2 (HTLV-1, HTLV-2).
    - Laboratory documentation indicates that the member is negative for HIV-1, HIV-2, HTLV-1, and HTLV-2

- Confirm that member has not received any vaccinations at least 6 weeks prior to the start of myeloablative conditioning

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 outside of FDA approved labeling
- CALD secondary to head trauma
- Requests for replacement due to lost or damaged product will not be covered
- Active infection
- Member is positive for HIV-1, HIV-2, HTLV-1, and /or HTLV-2
- Full deletion of the ABCD1 gene (may result in rapid loss of efficacy due to immune response)

References

1. Skysona (elivaldogene autotemcel). Prescribing Information. Somerville, MA. Bluebird Bio Inc. September 2022.
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 Authorization

PPO in Plan	Prior Authorization
PPO OOP	Prior Authorization
POS in Plan	Prior Authorization
POS OOP	Prior Authorization
Essential Plan	Prior Authorization
MVP Medicaid Managed Care	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Child Health Plus	Prior Authorization
MVP Harmonious Health Care Plan	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Medicare Gold Giveback	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Secure HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare WellSelect PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare WellSelect Plus PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Patriot Plan PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess Complete D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess Plus D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Select PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Secure PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
Healthy NY	Prior Authorization
MVP Premier	Prior Authorization
MVP Premier Plus	Prior Authorization
MVP Premier Plus HDHP	Prior Authorization
MVP Secure	Prior Authorization
MVP EPO	Prior Authorization
MVP EPO HDHP	Prior Authorization
MVP PPO	Prior Authorization
MVP PPO HDHP	Prior Authorization
Student Health Plans	Prior Authorization
ASO	See SPD
Vermont Products	
POS in Plan	Prior Authorization
POS OOP	Prior Authorization
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D
MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Select PPO	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Secure PPO	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D
MVP VT HMO	Prior Authorization
MVP VT Plus HMO	Prior Authorization
MVP VT HDHP HMO	Prior Authorization
MVP VT Plus HDHP HMO	Prior Authorization
MVP Secure	Prior Authorization

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

***Medical Management Requirements**

Prior Auth	Prior Authorization Required
Potential for Retrospective Review	No Prior Authorization Required. May be subject to Retrospective Review.
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: **NA**
Approval Date: **1/01/2024**
Effective Date: **01/01/2024**
Related Policies: **N/A**

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

Drugs Requiring Prior Authorization under the medical benefit

J3590 Skysona (elivaldogene autotemcel)

Overview/Summary of Evidence

Skysona is one time an autologous hematopoietic stem cell (HSC)-based gene therapy that is prepared from the patients HSCs through apheresis procedure. Skysona is indicated to slow the progression of neurologic dysfunction in boys 4-17 years of age with early, active cerebral adrenoleukodystrophy (CALD). Early, active CALD refers to asymptomatic or mildly symptomatic (neurologic function score, NFS ≤ 1) boys who have gadolinium enhancement on brain magnetic resonance imaging (MRI) and Loes scores of 0.5-9.

CALD is a rare, progressive, neurodegenerative disease that primarily affects young boys and causes irreversible, devastating neurologic decline, including major functional disabilities such as loss of communication, cortical blindness, requirement for tube feeding, total incontinence, wheelchair dependence, or complete loss of voluntary movement. Nearly half of patients who do not receive treatment die within five years of symptom onset. Prior to the approval of Skysona treatment, effective options were limited to allogeneic hematopoietic stem cell transplant (allo-HSCT), which is associated

with the risk of serious potential complications including death, that can increase dramatically in patients without a human leukocyte antigen (HLA) matched donor.

Indications/Criteria

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

- Documented diagnosis of early active cerebral adrenoleukodystrophy (CALD) and documentation of the following:
    - Neurologic function score (NFS)≤ 1
    - Current magnetic brain resonance imaging (MRI) with use of Gadolinium Enhancement (GdE +) demonstrating demyelinating lesions
    - Loes scores of 0.5-9 based on assessment of brain MRI
    - Elevated very long chain fatty acid (VLCFA) confirmed by laboratory documentation
    - Confirmed mutations on the ABCD1 gene (not full deletion of the gene)
- If applicable, confirmed that anti-retroviral therapy will stop at least one month prior to initiating medications for stem cell mobilization and for the expected duration for elimination of the medications and until all cycles of apheresis are complete. Anti-retroviral medications may interfere with manufacturing of the apheresed cells.
- Member's sex is male
- Member is 4 years to 17 years of age
- Documentation that the member has been screened for the following: hepatitis B virus (HBV), hepatitis C virus (HCV), human immunodeficiency virus 1 and 2 (HIV-1, HIV-2), human T-lymphotropic virus 1 and 2 (HTLV-1, HTLV-2).
    - Laboratory documentation indicates that the member is negative for HIV-1, HIV-2, HTLV-1, and HTLV-2
- Confirm that member has not received any vaccinations at least 6 weeks prior to the start of myeloablative conditioning

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 outside of FDA approved labeling
- CALD secondary to head trauma
- Requests for replacement due to lost or damaged product will not be covered
- Active infection
- Member is positive for HIV-1, HIV-2, HTLV-1, and /or HTLV-2
- Full deletion of the ABCD1 gene (may result in rapid loss of efficacy due to immune response)

References

1. Skysona (elivaldogene autotemcel). Prescribing Information. Somerville, MA. Bluebird Bio Inc. September 2022.
2. Clinical Pharmacology. Skysona. Accessed October 3, 2022.
3. X-linked adrenoleukodystrophy - About the Disease - Genetic and Rare Diseases Information Center (nih.gov)
4. Clinical Pharmacology. Skysona. Accessed November 1, 2023.
5. Micromedex Healthcare Series. Skysona. Accessed November 1, 2023.
6. Eichler F, Duncan C, Musolino PL, et al. Hematopoietic Stem-Cell Gene Therapy for Cerebral Adrenoleukodystrophy. The New England journal of medicine. 2017;377(17):1630-1638. doi:https://doi.org/10.1056/NEJMoa1700554 Accessed November 1, 2023.

MVP Health Care Medical Policy

Soliris (Eculizumab)

Type of Policy:	**Medical Therapy**
Prior Approval Date:	**NA**
Approval Date:	**10/01/2023**
Effective Date:	**12/01/2023**
Related Policies:	Orphan Drug(s) and Biologicals

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

Drugs Requiring Prior Authorization under the medical benefit
J1300 Injection, eculizumab 300 mg/30 mL solution for injection (Solitis)

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 patients 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. Must be prescribed for an FDA approved indication.

b. Prescriber is enrolled in Soliris REMS program.
c. 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 administer in accordance with ACIP guidelines.
    i. If eculizumab must be initiated immediately and the meningococcal vaccination is administered less than 2 weeks before eculizumab initiation, documentation of a 2-week course of antibacterial drug prophylaxis is required.

A. Paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis

a. Flow cytometric confirmation of large population (>50%) of glycosylphosphatidylinositol-anchored proteins (GPI-AP) deficient polymorphonuclear cells (PMNs)
b. Documentation demonstrating clinical or biochemical evidence of intravascular hemolysis (serum concentration of lactate hydrogenase [LDH], bilirubin [fractionated], and haptoglobin)
c. Documentation of medical necessity including side effects or drug failure of an adequate trial of Ultomiris

B. Atypical hemolytic uremic syndrome (aHUS) to prevent complement-mediated thrombotic microangiopathy.

a. Documentation of the absence of Shiga toxin
b. ADAMTS 13 activity level above 5%
c. Documentation of baseline platelet count and LDH
d. Documentation of medical necessity including side effects or drug failure of an adequate trial of Ultomiris

C. Anti-acetylcholine receptor antibody positive generalized myasthenia gravis (gMG) in adult patients 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 immunosuppressive therapies (ISTs) listed below or failed at least one IST listed below and required chronic plasmapheresis or plasma exchange or IVIG :
    i. Azathioprine

ii. Cyclosporine
iii. mycophenolate mofetil
iv. tacrolimus
v. methotrexate
vi. cyclophosphamide
vii. rituximab

e. Documentation of medical necessity including side effects or drug failure of an adequate trial of Ultomiris

D. Anti-aquaporin-4 (AQP4) antibody positive neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive.

a. Confirmed diagnosis of anti-aquaporin-4 (AQP4) antibody positive NMOSD

Initial approval will be for 6 months

Extension requests will be approved for up to 12 months if the members meeting the following criteria per applicable indication:

PNH

No evidence of disease progression while on current regimen and documentation of positive response to therapy (reduction in blood transfusions, stabilization in hemoglobin concentrations, reduction of exacerbation rate, improved quality of life scores/fatigue, and/or normalization of LDH levels).

aHUS

No evidence of disease progression while on the current regimen and documentation of a positive response to therapy (e.g., normalization of lactate dehydrogenase (LDH) levels, platelet counts).

gMG

No evidence of disease progression while on the current regimen and documentation of a positive response to therapy (e.g., improvement in MG-ADL score, changes compared to baseline in Quantitative Myasthenia Gravis (QMG) total score).

NMOSD

No evidence of disease progression while on current regimen and documentation of a positive response to therapy (e.g., reduced corticosteroid administration to treat acute relapse and plasma exchange treatments).

Exclusions

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

- For the treatment of patients with Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS).
- Indication, dosage, frequency, duration of therapy, and age outside of FDA approved labeling.
- Patients with unresolved Neisseria meningitidis infection
- Patients who are not currently vaccinated against Neisseria meningitidis, unless the risks of delaying treatment outweigh the risks of developing a meningococcal infection

References

1. Soliris (eculizumab) package insert. Boston, MA: Alexion Pharmaceuticals, Inc.;2020 Nov.
2. Clinical Resource*, Drugs With Prescribing, Dispensing, or REMS Requirements. Pharmacist's Letter/Pharmacy Technician's Letter/Prescriber's Letter*. February 2023. [390223]
3. Parker CJ. Update on the diagnosis and management of paroxysmal nocturnal hemoglobinuria. Hematology Am Soc Hematol Educ Program. 2016;2016(1):208-216
4. Cancado RD et al. Consensus statement for diagnosis and treatment of paroxysmal nocturnal hemoglobinuria. Hematology, Transfusion, and Cell Therapy. 2021;43(3):341-348.
5. Sanders D, Wolfe G, Benatar M et al. International consensus guidance for management of myasthenia gravis. Neurology. 2021; 96 (3) 114-122.

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	Prior Auth
MVP Medicare Secure HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP Medicare WellSelect PPO	Prior Auth
MVP Medicare WellSelect Plus PPO	Prior Auth
MVP Medicare Patriot Plan PPO	Prior Auth
MVP DualAccess D-SNP HMO	Prior Auth
MVP DualAccess Complete D-SNP HMO	Prior Auth
MVP DualAccess Plus D-SNP HMO	Prior Auth
UVM Health Advantage Select PPO	Prior Auth
UVM Health Advantage Secure PPO	Prior Auth
UVM Health Advantage Preferred 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
UVM Health Advantage Select PPO	Prior Auth
UVM Health Advantage Secure PPO	Prior Auth
UVM Health Advantage Preferred PPO	Prior Auth
MVP VT HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD
♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).	

***Medical Management Requirements**

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

MVP Health Care Medical Policy

Spesolimab

Type of Policy:	**Drug Therapy**
Prior Approval Date:	**06/01/2023**
Approval Date:	**04/01/2024**
Effective Date:	**06/01/2024**
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)

Overview

Spesolimab is an interleukin-36 receptor (IL36R) antagonist indicated for the treatment of generalized pustular psoriasis (GPP) flares in adults. It is administered by intravenous infusion over 90 minutes and an additional infusion may be administered one week after the initial dose if symptoms persist. Members should be screened for immunologic and infectious disease prior to initiating therapy and avoid the use of live vaccines when treated with spesolimab.

Indications/Criteria

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 **AND**
- Chart notes are provided documenting all of the following:
    - 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 approval for a **current flare** will be for two doses within 3 months

Subsequent approval for a **new flare** will be considered when the following criteria is met:

- Member has not received two doses of Spevigo for treatment of the current flare **AND**
- For a new flare, at least 12 weeks has passed since the last dose of Spevigo **AND**
- Medication is ordered by or with consult from a dermatologist **AND**
- Chart notes are provided indicate previous use and clinical benefit from Spevigo
- Subsequent approvals for a new flare will be for two doses within 3 months.

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
- More than two (2) doses per current flare
- Prescribed for an indication outside of the FDA approved package labeling

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References

1. Spesolimab. Clinical Pharmacology. Revision date September 03, 2022. Accessed on May 4, 2023.

2. Spevigo (spesolimab-sbzo) injection, for intravenous use. Prescribing Information. Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT. Revised September 2022.

3. Bachelez H, Choon SE, Marrakchi S, et al. Trial of spesolimab for generalized pustular psoriasis. N Engl J Med. 2021;385(26):2431-2440. doi:10.1056/NEJMoa2111563.

4. Shah M, Al Aboud DM, Crane JS, et al. Pustular Psoriasis. [Updated 2023 Aug 8]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK537002/

Member Product	Medical Management Requirements*
New York Products	
HMO	Prior Auth
PPO in Plan	Prior Auth
PPO OOP	Prior Auth
POS in Plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Child Health Plus	Prior Auth
MVP Harmonious Health Care Plan	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Medicare Gold Giveback	Refer to the MVP website for the Medicare Part B and Part D policies.
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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.
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).	

***Medical Management Requirements**

Prior Auth	Prior Authorization Required
Potential for Retrospective Review	No Prior Authorization Required. May be subject to Retrospective Review.
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:	**11/01/2023**
Approval Date:	**04/01/2024**
Effective Date:	**06/01/2024**
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)

Overview/Summary of Evidence

Spesolimab is an interleukin-36 receptor (IL36R) antagonist indicated for the treatment of generalized pustular psoriasis (GPP) flares in adults. It is administered by intravenous infusion over 90 minutes and an additional infusion may be administered one week after the initial dose if symptoms persist. Members should be screened for immunologic and infectious disease prior to initiating therapy and avoid the use of live vaccines when treated with spesolimab.

Indications/Criteria

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 **AND**
- Chart notes are provided documenting all of the following:
    - 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 approval for a **current flare** will be for two doses within 3 months

Subsequent approval for a **new flare** will be considered when the following criteria is met:

- Member has not received two doses of Spevigo for treatment of the current flare **AND**
- For a new flare, at least 12 weeks has passed since the last dose of Spevigo **AND**
- Medication is ordered by or with consult from a dermatologist **AND**
- Chart notes are provided indicate previous use and clinical benefit from Spevigo
- Subsequent approvals for a new flare will be for two doses within 3 months.

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
- More than two (2) doses per current flare
- Prescribed for an indication outside of the FDA approved package labeling

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References

1. Spesolimab. Clinical Pharmacology. Revision date September 03, 2022. Accessed on May 4, 2023.

2. Spevigo (spesolimab-sbzo) injection, for intravenous use. Prescribing Information. Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT. Revised September 2022.

3. Bachelez H, Choon SE, Marrakchi S, et al. Trial of spesolimab for generalized pustular psoriasis. N Engl J Med. 2021;385(26):2431-2440. doi:10.1056/NEJMoa2111563.

4. Shah M, Al Aboud DM, Crane JS, et al. Pustular Psoriasis. [Updated 2023 Aug 8]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK537002/

MVP Health Care Medical Policy

Spinal Muscular Atrophy (SMA)

Type of Policy:	**Medical Therapy *(administered by the pharmacy department)***
Prior Approval Date:	**03/01/2023**
Approval Date:	**11/01/2023**
Effective Date:	**01/01/2024**
Related Policies:	**NA**

Codes Requiring Prior Authorization (covered under the medical benefit)
J2326 Spinraza® (Nusinersen)
J3399 Zolgensma (Onasemnogene abeparvovex-xioi)

Drugs requiring Prior Authorization (covered under the pharmacy benefit)
Evrysdi (Risdiplam)

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

Overview

Nusinersen (Spinraza) is an intrathecal injection that is FDA approved for the treatment of spinal muscular atrophy (SMA) in pediatric and adult patients. SMA is caused by a deletion or mutation of both copies *SMN1* gene that results in a mutated SMN protein. Nusinersen (Spinraza) is an antisense oligonucleotide that binds a specific sequence in the intron downstream of exon 7 of the *SMN2* mRNA transcript. This leads to an increased production of functional full length SMN protein. At the beginning of therapy, nusinersen is administered as a sequence of four loading doses; the first three doses are administered every 14 days and the fourth dose is administered 30 days after the third dose. The patient then receives a maintenance dose which is administered every 4 months.

Spinraza is considered an orphan drug by the FDA and received fast track designation for approval. SMA is an autosomal recessive disease that is caused by a mutation/deletion of the *SMN1* gene. This leads to progressive muscle weakness and muscle atrophy due to degeneration of spinal and lower bulbar motor neurons.

Zolgensma (Onasemnogene abeparvovex-xioi) is a one-time infusion gene therapy FDA approved for the treatment of Spinal Muscular Atrophy (SMA) in pediatric patients under 2 years old. SMA is an inherited neuromuscular disease that causes progressive loss of muscle function. It is caused by a deletion or mutation of both copies *SMN1* gene that results in a mutated SMN protein. Zolgensma (Onasemnogene abeparvovex-xioi) addresses the root cause of SMA by replacing the defective or missing SMN1 gene, thus halting gene progression and improving motor neuron function and survival.

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

Evrysdi (risdiplam) is an oral medication that is FDA approved for the treatment of spinal muscular atrophy (SMA) in pediatric and adult patients. Risdiplam is designed to treat patients with mutations in chromosome 5q that lead to SMN protein deficiency. Risdiplam is a SMN2 splicing modifier that was shown to increase exon 7 inclusion in SMN2 mRNA. An increase in exon 7 inclusion leads to an increase in production of full length SMN proteins. Risdiplam is taken orally once daily via an oral syringe after a meal at approximately the same time each day. The recommended dosage is determined by age and body weight.

The FDA granted Evrysdi (risdiplam) orphan drug designation and fast track designation approval.

Indications/Criteria

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

I. SPINRAZA

Spinraza is FDA approved for:

- Intrathecal injection in pediatric and adult patients for the treatment of spinal muscular atrophy (SMA)

Patient must meet all of the following criteria for initiating Spinraza therapy:

- The patient must be diagnosed with Type 1, 2, or 3 spinal muscular atrophy (SMA) AND
- Medical records must be received demonstrating 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 must be prescribed by a neurologist or geneticist **AND**
- Patients must have motor functioning exams performed at baseline using an exam appropriate for the patient's age and functioning. Examples of the exams include:
    - Hammersmith Functional Motor Scale Expanded (HFMSE)
    - Hammersmith Infant Neurological Exam (HINE)
    - Upper Limb Module Test (ULM)
    - Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND)

Initial approval will be for 3 months, 4 doses to determine the efficacy of the treatment

Patient must meet the following criteria for continuing Spinraza therapy:

- The patient 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)

Spinraza maintenance doses will be approved for 2 doses over an eight-month period.

II. ZOLGENSMA

Zolgensma is FDA approved for:

- One-time infusion in patients younger than 2 years old for the treatment of spinal muscular atrophy (SMA)

Patient must meet all of the following criteria for initiating Zolgensma therapy:

- Must be < 2 years old
- The patient must be diagnosed with SMA
- Medical records must be received demonstrating genetic testing that indicates:
    - Bi-allelic gene mutation of *SMN1* **AND**
    - At least two *SMN2* copies **AND**
- Zolgensma must be prescribed by a neurologist or geneticist
- Patients must have motor functioning exams performed at baseline using an exam appropriate for the patient'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

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III. EVRYSDI

Evrysdi is FDA approved for:

- Oral solution in pediatric and adult patients for the treatment of spinal muscular atrophy (SMA)

Patient must meet all of the following criteria for initiating Evrysdi therapy:

- The patient must be diagnosed with Type 1, 2, or 3 spinal muscular atrophy (SMA) AND
- Medical records must be received demonstrating 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 must be prescribed by a neurologist or geneticist **AND**
- Patients must have motor functioning exams performed at baseline using an exam appropriate for the patient's age and functioning. Examples of the exams include:

- Hammersmith Functional Motor Scale Expanded (HFMSE)
- Hammersmith Infant Neurological Exam (HINE)
- Upper Limb Module Test (ULM)
- Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND)
- 6-Minute Walk Test (6MWT)

Initial approval will be for a duration of 6 months. Coverage of lost, damaged, or mishandled product will not be covered.
Quantity is limited to the 3 bottles (240ml) per 30 days.

Patient must meet the following criteria for continuing Evrysdi therapy:

- The patient 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)

Evrysdi maintenance doses will be approved for a duration of 12 months. Coverage of lost, damaged, or mishandled product will not be covered.

Quantity is limited to the 3 bottles (240ml) per 30 days.

ASO Variation: Refer to ASO benefit grid for drugs that may be covered

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 patient has SMA that is caused by a mutation other than a *SMN1* deletion/mutation on chromosome 5

- Medical records indicate patient has SMA type 4
- The patient has respiratory insufficiency that requires invasive ventilation.
- The patient has respiratory insufficiency that requires non-invasive ventilation for ≥16 hours per day

II. Zolgensma (Onasemnogene abeparvovex-xioi) is not considered medically necessary and, therefore, is not covered when any of the following are true:

- No documentation of genetic testing confirming SMA in the medical record
- The patient has SMA that is caused by a mutation other than a *SMN1* deletion/mutation on chromosome 5
- The patient 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)
- Patient 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
- Patient with single base mutation in SMN2
- Combination therapy with Spinraza (nusinersen)
- More than one dose

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 patient has SMA that is caused by a mutation other than a SMN1 deletion/mutation on chromosome 5
- Medical records indicate patient has SMA type 4
- The patient has respiratory insufficiency that requires invasive ventilation or tracheostomy
- The patient has respiratory insufficiency that requires non-invasive ventilation for ≥16 hours per day
- Combination therapy with Spinraza (nusinersen)

References

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5. Ionis Pharmaceuticals, Inc. A Study to Assess the Efficacy and Safety of IONIS-SMN Rx in Infants with Spinal Muscular Atrophy. *Clinical Trials.gov*. retrieved from: https://clinicaltrials.gov/ct2/show/study/NCT02193074?term=ENDEAR&rank=4&view=record
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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 Preferred Gold HMO POS	Prior Auth
MVP Medicare Secure HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP Medicare WellSelect PPO	Prior Auth
MVP Medicare WellSelect Plus PPO	Prior Auth
MVP Medicare Patriot Plan PPO	Prior Auth
MVP DualAccess D-SNP HMO	Prior Auth
MVP DualAccess Complete D-SNP HMO	Prior Auth
MVP DualAccess Plus D-SNP HMO	Prior Auth
UVM Health Advantage Select PPO	Prior Auth
UVM Health Advantage Secure PPO	Prior Auth
UVM Health Advantage Preferred 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
UVM Health Advantage Select PPO	Prior Auth
UVM Health Advantage Secure PPO	Prior Auth
UVM Health Advantage Preferred PPO	Prior Auth
MVP VT HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD
♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).	

***Medical Management Requirements**

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

MVP Health Care Medical Policy

Spravato® (Esketamine)

Type of Policy: **Medical Therapy *(administered by the pharmacy department)***
Prior Approval Date: **08/11/2022**
Approval Date: **11/01/2023**
Effective Date: **01/01/2024**
Related Policies: **NA**

Codes Requiring Prior Authorization covered under the medical benefit
S0013, G2082, G2083 Spravato® (Esketamine) nasal spray 1 mg

Overview

Spravato (esketamine) is an intranasal spray that is FDA approved to treat two major depressive disorder (MDD) subpopulations of adults (≥18 years) when used in combination with an oral antidepressant: adults with "treatment resistant depression" (TRD) and adults with depressive symptoms with acute suicidal ideation or behavior. TRD is defined as a failure of at least 2 currently available antidepressants at adequate doses for 8 weeks. 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 was designated by the FDA as a "breakthrough therapy," indicating a serious unmet need and compelling early evidence in favor of the drug. It was granted priority review, shortening the approval process from 12 months to 6 months.

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.

Indications/Criteria

- Spravato is indicated for intranasal administration in adults (≥18 years) for treatment resistant major depressive disorder in conjunction with an oral antidepressant and for the treatment of depressive symptoms in patients with MDD with suicidal thoughts or actions in conjunction with an oral antidepressant.

Criteria (must meet all criteria as listed below for the specific indication)	**TRD**	**MDD with suicidal ideation**
The patient must be diagnosed with Major Depressive Disorder based on DSM-5 criteria	x	x
Medical records must be received demonstrating: o 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 is inappropriate, clinical rationale must be documented in the medical record and will be considered on a case by case basis **AND** o Medical records documenting failure of therapy optimization (trial of antidepressant medications from at least two different antidepressant medication classes concomitantly for an adequate duration (8 weeks), such as: SSRI/SNRI/TCA or any other combination of non-MAOI antidepressants), unless contraindicated or intolerable, **AND** o Inadequate response to antidepressant in the current depression episode. Claims history must demonstrate compliance with current antidepressant.	x	
Medical records must be received documenting patient has experienced acute suicidal ideation or behavior and patient is receiving standard of care (including hospitalization if clinically warranted).		x

Spravato must be prescribed **AND** administered by a certified provider who is able to properly monitor patient after administration at a REMS certified clinic.	x	x
Patient must be assessed using an appropriate diagnostic instrument such as PHQ-9 Patient Depression Questionnaire or Montgomery-Asberg Depression Rating Scale (MADRS) at baseline prior to dose and after each week prior to dose	x	x

Initial approval for TRD indication will be for 8 weeks. MADRS or PHQ-9 Patient Depression Questionnaire score at week 4 (after induction phase) and most current MADRS or PHQ-9 Patient Depression Questionnaire score must be submitted with the initial extension request.

Initial approval for MDD with acute suicidal ideation or behavior indication will be for 4 weeks. Continuation requests require evidence of therapeutic benefit with evaluation to determine need for continued treatment.

Subsequent extensions for 3 months will be granted if the following are met:

- The patient must have met all criteria specified in the "initiating therapy" section above
  AND
- Medical records must include current PHQ-9 Patient Depression Questionnaire or MADRS score and must demonstrate score and symptom improvement from baseline. Claims history must show compliance with concurrent oral antidepressant and Spravato therapy.

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).
- 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).

Extension requests 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).

Initial approval for MDD with acute suicidal ideation or behavior indication will be for 4 weeks. Continuation requests 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:

- Patient is not using Spravato in conjunction with an oral antidepressant
- Patient is less than 18 years of age
- Spravato is being prescribed for anesthetic use
- Spravato is being prescribed outside of the FDA approved dosing
- Patient is pregnant or planning to become pregnant
- Patient has severe hepatic impairment (Child-Pugh class C)
- Patient has history of aneurysm (e.g., aneurysmal vascular disease including thoracic and abdominal aorta, intracranial, and peripheral arterial vessels), arteriovenous malformation, and a history of intracranial bleeding (intracerebral hemorrhage).
- The patient has 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
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

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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
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MVP DualAccess D-SNP HMO	Prior Auth
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UVM Health Advantage Preferred 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
UVM Health Advantage Select PPO	Prior Auth
UVM Health Advantage Secure PPO	Prior Auth
UVM Health Advantage Preferred PPO	Prior Auth
MVP VT HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD
♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).	

***Medical Management Requirements**

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

MVP Health Care Medical Policy

Medicare Part B: Spravato® (Esketamine)

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

Codes Requiring Prior Authorization covered under the medical benefit
S0013 Spravato® (Esketamine) nasal spray 1 mg

Overview/Summary of Evidence

Spravato (esketamine) is an intranasal spray that is FDA approved to treat two major depressive disorder (MDD) subpopulations of adults (≥18 years) when used in combination with an oral antidepressant: adults with "treatment resistant depression" (TRD) and adults with depressive symptoms with acute suicidal ideation or behavior. TRD is defined as a failure of at least 2 currently available antidepressants at adequate doses for 8 weeks. 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 was designated by the FDA as a "breakthrough therapy," indicating a serious unmet need and compelling early evidence in favor of the drug. It was granted priority review, shortening the approval process from 12 months to 6 months.

Indications/Criteria

- Spravato is indicated for intranasal administration in adults (≥18 years) for treatment resistant major depressive disorder in conjunction with an oral

antidepressant and for the treatment of depressive symptoms in patients with MDD with suicidal thoughts or actions in conjunction with an oral antidepressant.

Criteria (must meet all criteria as listed below for the specific indication)	**TRD**	**MDD with suicidal ideation**
The patient must be diagnosed with Major Depressive Disorder based on DSM-5 criteria	x	x
Medical records must be received demonstrating: o 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 is inappropriate, clinical rationale must be documented in the medical record and will be considered on a case by case basis **AND** o Medical records documenting failure of therapy optimization (trial of antidepressant medications from at least two different antidepressant medication classes concomitantly for an adequate duration (8 weeks), such as: SSRI/SNRI/TCA or any other combination of non-MAOI antidepressants), unless contraindicated or intolerable, **AND** o Inadequate response to antidepressant in the current depression episode. Claims history must demonstrate compliance with current antidepressant.	x	
Medical records must be received documenting patient has experienced acute suicidal ideation or behavior and patient is receiving standard of care (including hospitalization if clinically warranted).		x
Spravato must be prescribed **AND** administered by a certified provider who is able to properly monitor patient after administration at a REMS certified clinic.	x	x
Patient must be assessed using an appropriate diagnostic instrument such as PHQ-9 Patient Depression Questionnaire or Montgomery-Asberg Depression Rating	x	x

Scale (MADRS) at baseline prior to dose and after each week prior to dose		

Initial approval for TRD indication will be for 8 weeks. MADRS or PHQ-9 Patient Depression Questionnaire score at week 4 (after induction phase) and most current MADRS or PHQ-9 Patient Depression Questionnaire score must be submitted with the initial extension request.

Initial approval for MDD with acute suicidal ideation or behavior indication will be for 4 weeks. Continuation requests require evidence of therapeutic benefit with evaluation to determine need for continued treatment.

Subsequent extensions for 3 months will be granted if the following are met:

- The patient must have met all criteria specified in the "initiating therapy" section above
  AND
- Medical records must include current PHQ-9 Patient Depression Questionnaire or MADRS score and must demonstrate score and symptom improvement from baseline. Claims history must show compliance with concurrent oral antidepressant and Spravato therapy.

Exclusions

Spravato (esketamine) is not considered medically necessary and therefore is not covered when any of the following are true:

- Patient is not using Spravato in conjunction with an oral antidepressant
- Patient is less than 18 years of age
- Spravato is being prescribed for anesthetic use
- Spravato is being prescribed outside of the FDA approved dosing
- Patient is pregnant or planning to become pregnant
- Patient has severe hepatic impairment (Child-Pugh class C)
- Patient has history of aneurysm (e.g., aneurysmal vascular disease including thoracic and abdominal aorta, intracranial, and peripheral arterial vessels), arteriovenous malformation, and a history of intracranial bleeding (intracerebral hemorrhage).

- The patient has 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
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
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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.

MVP Health Care Medical Policy

Syfovre

Type of Policy:	**Medical Therapy**
Prior Approval Date:	**12/01/2023**
Approval Date:	**02/01/2024**
Effective Date:	**02/01/2024**

Related Policies: **Orphan Drug(s) and Biologicals**

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

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 20/300

Initial approval will be for 6 months.

Subsequent approvals will be for up to 1 year duration and require documentation of clinical benefit.

Exclusions

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

- Members with ocular or periocular infections
- Members with active intraocular inflammation
- Age, dosage, and/or frequency outside of the FDA approved package labeling
- GA secondary to a condition other than AMD such as Stargardt disease in either eye

References

1. Syfovre (pegcetacoplan). Clinical Pharmacology. Revised February 24, 2023. Accessed June 5, 2023.

2. Syfovre (pegcetacoplan). Prescribing Information. Apellis Pharmaceuticals, Inc. Waltham, MA. Revised February 2023. PI_SYFOVRE.pdf (apellis.com).

3. Apellis. (2023, April). *SyfovreTM (Pegcetacoplan Injection)*. Syfovre. https://syfovreecp.com/

4. Prevent Blindness (n.d.). *Eye Diseases & Conditions*. Retrieved June 5, 2023, from https://preventblindness.org/geographic-atrophy/

Member Product	Medical Management Requirements*
New York Products	
HMO	Prior Authorization
PPO in Plan	Prior Authorization
PPO OOP	Prior Authorization
POS in Plan	Prior Authorization
POS OOP	Prior Authorization
Essential Plan	Prior Authorization
MVP Medicaid Managed Care	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Child Health Plus	Prior Authorization

MVP Harmonious Health Care Plan	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Medicare Gold Giveback	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Secure HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare WellSelect PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare WellSelect Plus PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Patriot Plan PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess Complete D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess Plus D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Select PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Secure PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
Healthy NY	Prior Authorization
MVP Premier	Prior Authorization
MVP Premier Plus	Prior Authorization
MVP Premier Plus HDHP	Prior Authorization
MVP Secure	Prior Authorization
MVP EPO	Prior Authorization
MVP EPO HDHP	Prior Authorization
MVP PPO	Prior Authorization
MVP PPO HDHP	Prior Authorization
Student Health Plans	Prior Authorization
ASO	Prior Authorization
Vermont Products	
POS in Plan	Prior Authorization
POS OOP	Prior Authorization
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Select PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Secure PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP VT HMO	Prior Authorization
MVP VT Plus HMO	Prior Authorization
MVP VT HDHP HMO	Prior Authorization
MVP VT Plus HDHP HMO	Prior Authorization
MVP Secure	Prior Authorization
ASO	Prior Authorization
♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).	

***Medical Management Requirements**

Prior Auth	Prior Authorization Required
Potential for Retrospective Review	No Prior Authorization Required. May be subject to Retrospective Review.
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:	**01/01/2024**
Approval Date:	**02/01/2024**
Effective Date:	**02/01/2024**

Related Policies: **Orphan Drug(s) and Biologicals**

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

Drugs Requiring Prior Authorization under the medical benefit

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 20/300

Initial approval will be for 6 months.

Subsequent approvals will be for up to 1 year duration and require documentation of clinical benefit.

Exclusions

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

- Members with ocular or periocular infections
- Members with active intraocular inflammation
- Age, dosage, and/or frequency outside of the FDA approved package labeling
- GA secondary to a condition other than AMD such as Stargardt disease in either eye

References

1. Syfovre (pegcetacoplan). Clinical Pharmacology. Revised February 24, 2023. Accessed June 5, 2023.
2. Syfovre (pegcetacoplan). Prescribing Information. Apellis Pharmaceuticals, Inc. Waltham, MA. Revised February 2023. PI_SYFOVRE.pdf (apellis.com).
3. Apellis. (2023, April). *SyfovreTM (Pegcetacoplan Injection)*. Syfovre. https://syfovreecp.com/
4. Prevent Blindness (n.d.). *Eye Diseases & Conditions*. Retrieved June 5, 2023, from https://preventblindness.org/geographic-atrophy/

MVP Health Care Medical Policy

Tepezza (teprotumumab-trbw)

Type of Policy:	**Drug Therapy**
Prior Approval Date:	**02/01/2023**
Approval Date:	**10/01/2023**
Effective Date:	**12/01/2023**
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

Prior authorization for Tepezza is not required under the medical benefit.

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

Overview

TEPEZZA (teprotumumab-trbw) is a fully human monoclonal antibody IV infusion indicated for the treatment of thyroid eye disease (TED). Thyroid eye disease, also known as Grave's ophthalmopathy, is an inflammatory condition primarily impacting the extraocular muscles (the muscles that move the eye) and the orbit (bone cavity in the skull that holds the eyeball). The disease course transitions from an active progressive period characterized by inflammation to a stable and fibrotic (inactive) period. Diagnosis is made based on clinical signs and symptoms including feeling irritation/grittiness in the eyes, red or inflamed conjunctiva, excessive tearing or dry eyes, eyelid swelling, light sensitivity, diplopia (double vision), and proptosis (bulging or displacement of the eyes). The pathogenesis of thyroid eye disease is incompletely understood at this time which has resulted in inconsistently effective treatment of the disease and uncertain modification of the disease outcome itself. Such treatments have included high-dose corticosteroids and radiotherapy of the eye. In many patients with thyroid eye disease, radiotherapy and glucocorticoids result in dose-limiting adverse effects and minimal improvement in proptosis. Unlike these other methods of treating thyroid eye disease, TEPEZZA is an insulin-like growth factor 1 receptor (IGF-1R) antagonist, blocking its activation and signaling therefore working to attenuate the underlying autoimmune processes involved in ophthalmopathy. IGF-1R has roles in the body in development, metabolism, and immune processes and strong evidence has implicated the IGF-1R in the pathogenesis of TED. In multiple placebo-controlled randomized control trials, TEPEZZZA improved both diplopia and proptosis in patients with

active moderate-severe thyroid eye disease at 24 weeks. It also improves the signs and symptoms of Thyroid Eye Disease including eye pain, redness, and swelling.

Indications/Criteria

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

- Patient is at least 18 years of age
- Documented diagnosis of Graves' eye disease, also called Graves' Ophthalmopathy or Thyroid Eye disease
- Patient must be euthyroid or with mild hypothyroidism or hyperthyroidism, defined as free thyroxine (T4) and free triiodothyronine (T3) levels less than 50% above or below the normal limits for the testing laboratory
- Must be prescribed by, or in consultation with, a specialist in ophthalmology, endocrinology, oculoplastic surgery, or neuro-ophthalmology
- For female patients, healthcare provider has documented the patient is not pregnant and that highly effective contraceptive methods have been implemented prior to, during, and for 6 months after treatment has been discussed with the patient.
- For patients 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; January 2020.
2. Smith TJ, Kahaly GL, Ezra DG, et al. Teprotumumab for Thyroid-Associated Ophthalmopathy [internet]. NEJM; 2017 [cited 2021 Aug 23]. Available from: https://www.nejm.org/doi/10.1056/NEJMoa1614949

3. Douglas R, Kahaly GL, Patel A, et al. Teprotumumab for the Treatment of Active Thyroid Eye Disease [internet]. NEJM; 2020 [cited 2021 Aug 24]. Available from: https://www.nejm.org/doi/10.1056/NEJMoa1910434
4. TEPEZZA (teprotumumab-trbw) [prescribing information] Horizon Therapeutics; Revised: 12/2022.

Member Product	Medical Management Requirements*
New York Products	
HMO	Prior Auth
PPO in Plan	Prior Auth
PPO OOP	Prior Auth
POS in Plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Prior Auth
MVP Child Health Plus	Prior Auth
MVP Harmonious Health Care Plan	Prior Auth
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
UVM Health Advantage Secure PPO	Potential for Retrospective Review
UVM Health Advantage Preferred PPO	Potential for Retrospective Review
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Potential for Retrospective Review
MVP EPO	Prior Auth
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	Potential for Retrospective Review
MVP Medicare Secure Plus HMO POS	Potential for Retrospective Review
UVM Health Advantage Select PPO	Potential for Retrospective Review
UVM Health Advantage Secure PPO	Potential for Retrospective Review
UVM Health Advantage Preferred PPO	Potential for Retrospective Review
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	Potential for Retrospective Review
ASO	See SPD

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

***Medical Management Requirements**

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

MVP Health Care Medical Policy

Teplizumab-mzwv

Type of Policy: **Drug Therapy**
Prior Approval Date: **02/01/2023**
Approval Date: **02/01/2024**
Effective Date: **04/01/2024**
Related Policies:

Drugs Requiring Prior Authorization under the medical benefit

J9381 Tzield (teplizumab-mzwv)

Overview

Tzield is an IV administered anti-CD3 antibody, designed to bind to certain immune system cells, moderate the body's immune response, and delay progression to stage 3 type 1 diabetes (T1D) in adults and pediatric patients 8 years of age and older with stage 2 T1D. T1D is an autoimmune disease resulting from inability to make insulin and requiring insulin replacement.

Indications/Criteria

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

- Prescribed by, or in consultation with an endocrinologist
- Diagnosis of stage 2 type 1 diabetes with documentation of the **ALL** following:
    - At least TWO positive pancreatic islet cell autoantibodies (Glutamic acid decarboxylase 65 autoantibody, Insulin autoantibody, Insulinoma-

associated antigen 2 autoantibody, Zinc transporter 8 autoantibody, or Islet cell autoantibody) confirmed within the past 6 months

- Evidence of dysglycemia without overt hyperglycemia using an oral glucose tolerance test.
    - Dysglycemia defined as a fasting glucose level of 110 to 125mg/dL, a 2-hour postprandial plasma glucose level of at least 140 mg/dL and less than 200mg/dL or an intervening postprandial glucose level at 30, 60, or 90 minutes of greater than 200mg/dL on two occasions within the past 60 days.

- Confirmation that member does not have type 2 diabetes
- Documentation of complete blood count confirming member has hemoglobin greater than 10 g/dL, lymphocyte count greater than 1,000 lymphocytes/mcL, platelet count greater than 150,000 platelets/mcL, and absolute neutrophil count greater than 1,500 neutrophils/mcL.
- Documentation that member does not have alanine aminotransferase (ALT) or aspartate aminotransferase (AST) concentrations greater than 2 times the upper limit of normal (ULN) or bilirubin concentration greater than 1.5 times the ULN.
- Member is 8 years of age or older

Initial approval will be for 14 consecutive infusions within two months. Additional courses and requests for replacement due to lost or damaged product will not be covered.

Exclusions

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

- Dosing, age, and/or frequency outside of the FDA approved package labeling
- Diagnosis of type 2 diabetes

- In patients with active serious infection or chronic infection, other than localized skin infections, or in patients with laboratory or clinical evidence of acute infection with Epstein-Barr virus (EBV) or cytomegalovirus (CMV).

References

1. Tzield (teplizumab-mzwv) injection package insert. Red Bank, NJ: Provention Bio, Inc.; 2022 Nov.

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

MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	
POS in Plan	Prior Auth
POS OOP	Prior Auth
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D
MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Select PPO	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Secure PPO	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D
MVP VT HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD
♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).	

***Medical Management Requirements**

Prior Auth	Prior Authorization Required
Potential for Retrospective Review	No Prior Authorization Required. May be subject to Retrospective Review.
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:	**11/01/2023**
Approval Date:	**02/01/2024**
Effective Date:	**04/01/2024**
Related Policies:	**N/A**

Drugs Requiring Prior Authorization under the medical benefit

J9381 Tzield (teplizumab-mzwv)

Overview/Summary of Evidence

Tzield is an IV administered anti-CD3 antibody, designed to bind to certain immune system cells, moderate the body's immune response, and delay progression to stage 3 type 1 diabetes (T1D) in adults and pediatric patients 8 years of age and older with stage 2 T1D. T1D is an autoimmune disease resulting from inability to make insulin and requiring insulin replacement.

Indications/Criteria

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

- Prescribed by, or in consultation with an endocrinologist
- Diagnosis of stage 2 type 1 diabetes with documentation of the **ALL** following:
    - At least TWO positive pancreatic islet cell autoantibodies (Glutamic acid decarboxylase 65 autoantibody, Insulin autoantibody, Insulinoma-

associated antigen 2 autoantibody, Zinc transporter 8 autoantibody, or Islet cell autoantibody) confirmed within the past 6 months

- Evidence of dysglycemia without overt hyperglycemia using an oral glucose tolerance test. Dysglycemia defined as a fasting glucose level of 110 to 125mg/dL, a 2-hour postprandial plasma glucose level of at least 140 mg/dL and less than 200mg/dL or an intervening postprandial glucose level at 30, 60, or 90 minutes of greater than 200mg/dL on two occasions within the past 60 days.

- Confirmation that member does not have type 2 diabetes
- Documentation of complete blood count confirming member has hemoglobin greater than 10 g/dL, lymphocyte count greater than 1,000 lymphocytes/mcL, platelet count greater than 150,000 platelets/mcL, and absolute neutrophil count greater than 1,500 neutrophils/mcL.
- Documentation that member does not have alanine aminotransferase (ALT) or aspartate aminotransferase (AST) concentrations greater than 2 times the upper limit of normal (ULN) or bilirubin concentration greater than 1.5 times the ULN.
- Member is 8 years of age or older

Initial approval will be for 14 consecutive infusions within two months. Additional courses and requests for replacement due to lost or damaged product will not be covered.

Exclusions

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

- Dosing, age, and/or frequency outside of the FDA approved package labeling
- Diagnosis of type 2 diabetes
- In patients with active serious infection or chronic infection, other than localized skin infections, or in patients with laboratory or clinical evidence of acute infection with Epstein-Barr virus (EBV) or cytomegalovirus (CMV).

References

1. Tzield (teplizumab-mzwv) injection package insert. Red Bank, NJ: Provention Bio, Inc.; 2022 Nov.

MVP Health Care Medical Policy

Tocilizumab

Type of Policy:	**Medical Therapy**
Prior Approval Date:	**03/01/2023**
Approval Date:	**02/01/2024**
Effective Date:	**04/01/2024**
Related Policies:	**Apremilast, Adalimumab , Infliximab, Risankizumab, Secukinumab, Tofacitinib, Upadacitinib, Ustekinumab, Ozanimod, Abatacept, Golimumab, Certolizumab**

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

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

Drugs Requiring Prior Authorization under the pharmacy benefit

Actemra SQ is non-preferred under the pharmacy benefit

Drugs Requiring Prior Authorization under the medical benefit

J3262 tocilizumab, 1mg injection (Actemra injection)

Overview

Tocilizumab is a humanized interleukin-6 (IL-6) receptor-inhibiting monoclonal antibody produced in mammalian (Chinese hamster ovary) cells. It is FDA approved to treat moderate to severe rheumatoid arthritis (RA), polyarticular and systemic juvenile idiopathic arthritis (pJIA and sJIA), giant cell arteritis (GCA or temporal arteritis), systemic sclerosis-associated interstitial lung disease (SSc-ILD), and cytokine release syndrome

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

Indications/Criteria

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

A. For all indications, Tocilizumab SQ (Actemra) is non-formulary and will only be considered for **pharmacy** coverage when:
    - Documented failure, contraindication or ineffective response to all preferred/formulary therapies for the specific indication.

B. For all indications, Tocilizumab IV (Actemra) may be considered for **medical** coverage when:
    - Must be prescribed for an FDA approved indication **AND**
    - Must be ordered by or with consult from a rheumatologist/immunologist **AND**
    - Documentation identifies failure of **preferred** self-administered biologic therapies to treat the condition **AND**
    - Rationale and documentation is provided identifying why member or caregiver is unable to self-administer

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 12/22/2022. Accessed 01/04/2023
2. Fraenkel et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care & Research Vol. 73, No. 7, July 2021, pp 924–939 DOI 10.1002/acr.24596. Available at: 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis (contentstack.io).
3. Actemra (tocilizumab) injection, for intravenous or subcutaneous use. Genentech, Inc. San Francisco, CA. Revised December 2022.
4. 2021 American College of Rheumatology Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Oligoarthritis, Temporomandibular Joint Arthritis, and Systemic Juvenile Idiopathic Arthritis. Arthritis and Rheumatology. Vol 74 No. 4 April 2022, pp553-569. Available at: https://www.rheumatology.org/Portals/0/Files/ACR-JIA%20Guideline-Oligo-TMJ-sJIA-EarlyView.pdf

Member Product	Medical Management Requirements*
New York Products	Prior Auth
HMO	Prior Auth
PPO in Plan	Prior Auth
PPO OOP	Prior Auth
POS in Plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Child Health Plus	Prior Auth
MVP Harmonious Health Care Plan	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Medicare Gold Giveback	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Secure HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.

MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare WellSelect PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare WellSelect Plus PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Patriot Plan PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess Complete D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess Plus D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Select PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Secure PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	
POS in Plan	Prior Auth
POS OOP	Prior Auth
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D
MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Select PPO	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Secure PPO	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D
MVP VT HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD
♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).	

***Medical Management Requirements**

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

MVP Health Care Medical Policy

Medicare Part B: Tocilizumab

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

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

Drugs Requiring Prior Authorization under the medical benefit

J3262 tocilizumab, 1mg injection (Actemra injection)

Overview/Summary of Evidence

Tocilizumab is a humanized interleukin-6 (IL-6) receptor-inhibiting monoclonal antibody produced in mammalian (Chinese hamster ovary) cells. It is FDA approved to treat moderate to severe rheumatoid arthritis (RA), polyarticular and systemic juvenile idiopathic arthritis (pJIA and sJIA), giant cell arteritis (GCA or temporal arteritis), systemic sclerosis-associated interstitial lung disease (SSc-ILD), and cytokine release syndrome (CRS). Members should be screened for immunologic and infectious disease prior to initiating therapy.

Indications/Criteria

A. For all indications, Tocilizumab IV (Actemra) may be considered for **medical** coverage when:
   - Must be prescribed for an FDA approved indication **AND**
   - Must be ordered by or with consult from a rheumatologist/immunologist **AND**
   - Member has coverage under Medicare Part B and meets the criteria below for a provider administered drug identified in this policy

B. **Giant Cell Arteritis**

   Tocilizumab may be considered for coverage for Giant Cell Arteritis when the above criteria is met **AND**:
   - Treatment must be directed by or in consultation with a Rheumatologist or Immunologist
   - Member has received high-dose glucocorticoids (prednisone 40mg to 60mg) but is unable to taper without disease flare **OR**
   - The member has a contraindication to the use of glucocorticoids

Initial approval for **6 months**.

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

C. **Juvenile Idiopathic Arthritis**

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

Initial approval for **6 months**.

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

D. **Rheumatoid Arthritis**

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

Documentation identifies failure of nonbiologic disease modifying anti-rheumatic drugs (DMARDs) and NSAIDs if indicated

Initial approval for **6 months**.

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

Exclusions

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

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

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References

1. Clinical Pharmacology. Tocilizumab (Actemra). Revised 12/22/2022. Accessed 01/04/2023
2. Fraenkel et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care & Research Vol. 73, No. 7, July 2021, pp 924–939 DOI 10.1002/acr.24596. Available at: 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis (contentstack.io).
3. Actemra (tocilizumab) injection, for intravenous or subcutaneous use. Genentech, Inc. San Francisco, CA. Revised December 2022.
4. 2021 American College of Rheumatology Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Oligoarthritis, Temporomandibular Joint Arthritis, and Systemic Juvenile Idiopathic Arthritis. Arthritis and Rheumatology. Vol 74 No. 4 April 2022, pp553-569. Available at: https://www.rheumatology.org/Portals/0/Files/ACR-JIA%20Guideline-Oligo-TMJ-sJIA-EarlyView.pdf

MVP Health Care Medical Policy

Tofacitinib

Type of Policy:	**Drug Therapy**
Prior Approval Date:	**03/01/2023**
Approval Date:	**10/01/2023**
Effective Date:	**12/01/2023**
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 being requested documentation must be provided identifying why the member or caregiver is unable to administer the medication.
- Must be ordered by or with consult from a rheumatologist, immunologist, dermatologist, gastroenterologist, or colorectal surgeon

- Must be prescribed for an FDA approved indication

B. Rheumatoid Arthritis (RA)

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

- Member has a diagnosis of moderate to severe active adult **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 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 **6 months**.

Extensions requests will be approved **up to 12 months** 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 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 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 **6 months**.

Extensions requests will be approved **up to 12 months** 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 **6 months**.

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

E. Ulcerative Colitis (UC)

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

- A diagnosis of moderate to severe Ulcerative Colitis
- Chart notes are provided documenting an inadequate response, intolerance, or contraindication to conventional therapy for maintenance of remission (i.e.:, anti-inflammatory aminosalicylates [e.g., mesalamine (5-ASA), sulfasalazine], 6-mercaptopurine, and azathioprine)
    - If conventional therapy is not considered medically appropriate, documentation must be provided
- Chart notes are provided documenting an inadequate response or intolerance to one tumor necrosis factor (TNF) inhibitor
    - Documentation must be provided if TNF inhibitor therapy is not considered medically appropriate

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

Extensions requests will be approved **up to 12 months** 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 **6 months**.

Extensions requests will be approved **up to 12 months** 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:

- Dosing, age, and/or frequency exceeding the FDA approved package labeling.
- Combination therapy that is not supported by current guidelines
- Should not be used for members at high risk for infections or who have active infections including chronic or localized infections
- Avoid using tofacitinib in members that may be at increased risk of thrombosis and thromboembolism; use with caution in those with thromboembolic disease
- Known malignancy or risk factors in developing malignancy
- Lymphocyte count less than 500 cells/mm^3, ANC less than 1000
- Hemoglobin less than 8.0 g/dL
- Liver function tests greater than 3 times upper limit of normal
- Administration of live vaccine 6 weeks prior to start of tofacitinib

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References

1. Xeljanz™ (tofacitinib) tablets. Prescribing Information. New York, NY: Pfizer Labs. Revised January 2022.

2. 2013 Update of the 2011 American College of Rheumatology Recommendations for the Treatment of Juvenile Idiopathic Arthritis. Arthritis & Rheumatism. Vol. 65, October 2013, 2499-2512

3. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis

4. 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)

5. 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

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

7. 2021 American College of Rheumatology Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Oligoarthritis, Temporomandibular Joint Arthritis, and Systemic Juvenile Idiopathic Arthritis. Arthritis and Rheumatology. Vol 74 No. 4 April 2022, pp553-569. Available at: https://www.rheumatology.org/Portals/0/Files/ACR-JIA%20Guideline-Oligo-TMJ-sJIA-EarlyView.pdf

Member Product	Medical Management Requirements*
New York Products	
HMO	Prior Auth
PPO in 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	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
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MVP Medicare Preferred Gold HMO POS	Refer to Part D Coverage
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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).	

***Medical Management Requirements**

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

MVP Health Care Medical Policy

Topical Agents for Pruritus

Type of Policy:	Drug Therapy
Prior Approval Date:	04/01/2023
Approval Date:	04/01/2024
Effective Date:	06/01/2024
Related Policies:	**NA**

Drugs Requiring Prior Authorization

Zonalon (doxepin cream 5%)
Prudoxin (doxepin cream 5%)
Doxepin cream 5%

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

Overview

Doxepin 5% cream is used for management of moderate pruritus in adult patients with atopic dermatitis or lichen simplex chronicus. It is indicated for short- term use only (8 days). There is no safety or efficacy data for its use past the 8 days.

Indications/Criteria

- Chart notes documenting a diagnosis of moderate pruritus secondary toatopic dermatitis **OR** lichen simplex chronicus
- Documentation of a failure or contraindication to at least two of the following:
    - Topical corticosteroids

AND

- Topical calcineurin inhibitors (i.e., Elidel (pimecrolimus) cream or (Protopic) tacrolimus ointment)
- Topical PDE-4 Inhibitors (i.e. Eucrisa (crisaborle))

Approval will be for one 45gram tube to allow 8 days of therapy. Greater quantities may be approved based on surface area that is being treated.

Exclusions

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling.
- untreated narrow angle glaucoma
- Tendency for urinary retention

References

1. Eichenfield LF, Tom WL, Berger TG, Krol A, Paller AS, Schwarzenberger K, et al. Guidelines of care for the management of atopic dermatitis: section 2. Management and treatment of atopic dermatitis with topical therapies. J Am Acad Dermatol. 2014 Jul;71(1):116-32
2. Elmariah, Sarina B., and Ethan A. Lerner. "Topical Therapies for Pruritus." *Seminars in cutaneous medicine and surgery* 30.2 (2011): 118–126. *PMC*. Web. 1 Sept. 2017.
3. Zonalon (doxepin hydrochloride) Cream, 5%. Prescribing Information. Morgantown, WV: Mylan Pharmaceuticals Inc.; June 2017.
4. Prudoxin (doxepin hydrochloride) Cream, 5%. Prescribing Information. Morgantown, WV: Mylan Pharmaceuticals Inc.; June 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
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MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	
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POS OOP	Prior Auth
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UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D
MVP VT HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD
♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).	

***Medical Management Requirements**

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

MVP Health Care Medical Policy

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

Type of Policy: Drug Therapy
Prior Approval Date: 02/01/2023
Approval Date: 02/01/2024
Effective Date: 04/01/2024
Related Policies:

Gender Dysphoria Treatment (Commercial and Medicare)
Gender Dysphoria Treatment (Medicaid and HARP)
Transgender Hormone Policy (Medicaid/HARP)
Experimental or Investigational Procedures, Behavioral Health Services, Drugs and Treatments, Off-Label use of FDA Approved Drugs, and Clinical Trials

Drugs Requiring Prior Authorization

Conjugated estrogens
Estradiol
Injectable Testosterone formulations
Topical Testosterone formulations

Drugs subject to Retrospective Review

The following gonadotropin-releasing hormone agents (pubertal suppressants)

- Lupron Depot

Overview

Gender dysphoria is defined as a marked difference between the individual's expressed/experienced gender and the gender others would assign them, continuing for at least six months. Gender dysphoria is manifested in a variety of ways, including strong desires to be

treated as another gender or to be rid of one's sex characteristics, or a strong conviction that one has feelings and reactions typical of another gender.[2]

Indications/Criteria

MVP health Care recognizes that gender dysphoria affects people of all genders, and is not limited to people with binary gender identities. Coverage of medically necessary services is allowed for binary and non-binary gender identities. Testosterone (injectable and topical), conjugated estrogens or estradiol may be considered medically necessary when the following criteria are met:

- Patient is at least 16 years old
    - Requests for coverage of cross-sex hormones for members less than 16 years old will be reviewed on case-by-case basis.
- Diagnosis of gender dysphoria
- Must be used for a Food and Drug Administration (FDA) approved indication, or use supported in at least one of the Official Compendia as defined in federal law under the Social Security Act section 1927 (g)(1)(B)(i), (k)(2)
- For patients that have undergone gender reassignment surgery, post-transition care will be covered

Approvals will be for a period of one year.

Gonadotropin-releasing hormone agents (pubertal suppressants) are subject to retro-review and will be approved if all the following criteria are met:

- Patient has a diagnosis of gender dysphoria;
- Patient has experienced puberty to at least Tanner stage 2, and pubertal changes have resulted in an increase in gender dysphoria;
- Patient does not suffer from psychiatric comorbidity that interferes with a diagnostic work-up or treatment
- Patient has adequate psychological and social support during treatment
- Patient demonstrates knowledge and understanding of the expected outcomes of treatment with pubertal suppressants and cross-sex hormones, as well as the medical and social risks and benefits of sex reassignment.

Exclusions

- Hormone products that do not meet MVP Experimental and Investigational Policy will not be covered

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References

1. New York State Department of Health. Medicaid Update. Volume 31. March 2015
2. "Gender Dysphoria." American Psychiatric Association, 2013. Web. http://www.dsm5.org/documents/gender%20dysphoria%20fact%20sheet.pdf. Accessed July 7, 2015.
3. New York State Department of Health. Medicaid Update. Volume 33. January 2017
4. New York State Department of Health. Criteria Standards for the Authorization and Utilization Management of Hormone Therapy and Surgery for the Treatment of Gender Dysphoria. July 2018
5. New York State Office of Mental Health. Memorandum. March 18, 2020. Clinical Review Criteria for the Treatment of Gender Dysphoria (ny.gov)
6. New York State Department of Financial Services. Department of Financial Services Announces Final Regulation to Prevent Discrimination Against Transgender and Gender Non-Conforming Individuals. April 29, 2020. Press Release - April 29, 2020: Department of Financial Services Announces Final Regulation to Prevent Discrimination Against Transgender and Gender Non-Conforming Individuals | Department of Financial Services (ny.gov)
7. New York State Department of Financial Services. Insurance Circular Letter No. 13 (2020). June 28, 2020. Insurance Circular Letter No. 13 (2020): Discrimination Based on Sexual Orientation, Gender Identity or Expression, and Transgender Status and Coverage for Preventive Care and Screenings | Department of Financial Services (ny.gov)

Member Product	Medical Management Requirements*
New York Products	
HMO	Prior Auth
PPO in Plan	Prior Auth
PPO OOP	Prior Auth
POS in Plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Child Health Plus	Prior Auth
MVP Harmonious Health Care Plan	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Medicare Gold Giveback	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Secure HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare WellSelect PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare WellSelect Plus PPO	Refer to the MVP website for the Medicare Part B and Part D policies.

MVP Medicare Patriot Plan PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess Complete D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess Plus D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Select PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Secure PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	
POS in Plan	Prior Auth
POS OOP	Prior Auth
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D
MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Select PPO	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Secure PPO	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D
MVP VT HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD
♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).	

***Medical Management Requirements**

Prior Auth	Prior Authorization Required
Potential for Retrospective Review	No Prior Authorization Required. May be subject to Retrospective Review.
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: **03/01/2023**
Approval Date: **02/01/2024**
Effective Date: **04/01/2024**
Related Policies:
Gender Reassignment Surgery (Medicaid and Harp)
Transgender Hormone Policy (Commercial/Exchange/Child Health Plus)
Experimental or Investigational Procedures, Behavioral Health Services, Drugs and Treatments, Off-Label use of FDA Approved Drugs, and Clinical Trials

Drug subject to retrospective review

The following fonadotropin-releasing hormone agents (pubertal suppressants)

- Lupron Depot

Overview

Gender dysphoria is defined as a marked difference between the individual's expressed/experienced gender and the gender others would assign them, continuing for at least six months. Gender dysphoria is manifested in a variety of ways, including strong desires to be treated as the other gender or to be rid of one's sex characteristics, or a strong conviction that one has feelings and reactions typical of another gender.[2] Hormone therapy is necessary if it is appropriate to the enrollee's gender goals, recommended by the enrollee's treating provider, clinically appropriate for the type of surgery requested, not medically contraindicated, and the enrollee is otherwise able to take hormones.

Indications/Criteria

MVP Health Care recognizes that gender dysphoria affects people of all genders, and is not limited to people with binary gender identities. Coverage of medically necessary services is allowed for binary and non-binary gender identities.

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

Gonadotropin-releasing hormone agents (pubertal suppressants) are subject to retro-review and will be approved if all of the following criteria are met:

- Patient has a diagnosis of gender dysphoria;
- Patient has experienced puberty to at least Tanner stage 2, and pubertal changes have resulted in an increase in gender dysphoria;
- Patient does not suffer from psychiatric comorbidity that interferes with a diagnostic work-up or treatment
- Patient has adequate psychological and social support during treatment;
- Patient demonstrates knowledge and understanding of the expected outcomes of treatment with pubertal suppressants and cross-sex hormones, as well as the medical and social risks and benefits of sex reassignment.

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.

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 Retrospective Review
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 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.
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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	Refer to Transgender Hormone Policy (Commercial/Exchange/Child Health Plus)
MVP Premier	Refer to Transgender Hormone Policy (Commercial/Exchange/Child Health Plus)
MVP Premier Plus	Refer to Transgender Hormone Policy (Commercial/Exchange/Child Health Plus)
MVP Premier Plus HDHP	Refer to Transgender Hormone Policy (Commercial/Exchange/Child Health Plus)
MVP Secure	Refer to Transgender Hormone Policy (Commercial/Exchange/Child Health Plus)
MVP EPO	Refer to Transgender Hormone Policy (Commercial/Exchange/Child Health Plus)

MVP EPO HDHP	Refer to Transgender Hormone Policy (Commercial/Exchange/Child Health Plus)
MVP PPO	Refer to Transgender Hormone Policy (Commercial/Exchange/Child Health Plus)
MVP PPO HDHP	Refer to Transgender Hormone Policy (Commercial/Exchange/Child Health Plus)
Student Health Plans	Refer to Transgender Hormone Policy (Commercial/Exchange/Child Health Plus)
ASO	See SPD
Vermont Products	
POS in Plan	Refer to Transgender Hormone Policy (Commercial/Exchange/Child Health Plus)
POS OOP	Refer to Transgender Hormone Policy (Commercial/Exchange/Child Health Plus)
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D
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	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).	

***Medical Management Requirements**

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

MVP Health Care Medical Policy

Transthyretin-Mediated Amyloidosis Therapy

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

Drug(s) Requiring Prior Authorization (covered under the medical benefit)
J0222- Onpattro™ (patisiran), injection 0.1 mg
J0225- Amvuttra (vutrisiran), 25mg/0.5mL prefilled syringe for injection

Drug(s) Requiring Prior Authorization (covered under the pharmacy benefit)
Tegsedi™ (inotersen), 284mg/1.5mL prefilled syringe for injection
Vyndamax (tafamidis), 61mg oral capsule
Vyndaqel (tafamidis meglumine), 20mg oral capsule

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

Overview
Hereditary transthyretin amyloidosis (hATTR) is an inherited disease that often affects the liver, nerves, heart and kidneys. It is characterized by the deposit of an abnormal protein called amyloid in multiple organs of the body where it should not be, which causes disruption of organ tissue structure and function. The amyloid buildup most frequently occurs in the peripheral nervous system, which can result in a loss of sensation, pain, or immobility in the arms, legs, hands and feet.

Indications
Onpattro™ is indicated for the treatment of the polyneuropathy in hereditary transthyretin-mediated amyloidosis in adults. The active substance in Onpattro is a 'small interfering RNA' (siRNA), a very short piece of synthetic genetic material that has been designed to attach to and block the genetic material of the cell responsible for

producing transthyretin. This reduces production of defective transthyretin, thereby reducing the formation of amyloids and relieving the symptoms of hATTR amyloidosis.

Amvuttra is indicated for the treatment of the polyneuropathy in hereditary transthyretin-mediated amyloidosis in adults. The active substance in Amvuttra is a 'small interfering RNA' (siRNA), a very short piece of synthetic genetic material that has been designed to attach to and block the genetic material of the cell responsible for producing transthyretin. This reduces production of defective transthyretin, thereby reducing the formation of amyloids and relieving the symptoms of hATTR amyloidosis.

Tegsedi™ is indicated for treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults. Tegsedi™ is an 'antisense oligonucleotide', a very short piece of synthetic genetic material that has been designed to attach to and block the genetic material of the cell responsible for producing transthyretin. This reduces production of transthyretin, and the formation of amyloids, relieving the symptoms of hATTR amyloidosis.

Vyndaqel and Vyndamax are indicated for the treatment of wild type or hereditary transthyretin amyloid cardiomyopathy in adults to reduce cardiovascular mortality and cardiovascular-related hospitalization. Wild type amyloidosis does not involve genetic mutation- wild type occurs usually in older population when the normal TTR protein becomes unstable and begins to form amyloid fibrils. Hereditary amyloidosis is an inherited mutation in the DNA making the TTR protein unstable and form amyloid fibrils. It works as a selective transthyretin (TTR) stabilizer. Transthyretin amyloid cardiomyopathy is caused by the accumulations of transthyretin amyloid fibrils, which consist of TTR monomers. Tafamidis works by binding to sites on TTR and slowing monomer dissociation. Please note that Vyndaqel and Vyndamax are not equivalents on a mg-per-mg basis.

Policy Criteria

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

A. Onpattro will be considered medically necessary for the treatment of the polyneuropathy of hATTR amyloidosis in adults who meet the following criteria:

- Member has documented transthyretin (TTR) mutation as confirmed through genetic testing AND symptomatic polyneuropathy (i.e. weakness, sensory loss, decreased motor strength, decreased gait speed) characterized by ONE of the following:
    - Baseline polyneuropathy disability (PND) score < IIIb (see reference table)
    - Baseline FAP (familial amyloid polyneuropathy) Stage 1 or 2 (see reference table)
- Biopsy is positive for amyloid deposits or medical justification is provided as to why treatment should be initiated despite a negative biopsy or no biopsy
- Prescribed by a neurologist, immunologist, or physician who specializes in the treatment of amyloidosis

Initial approval will be for 6 months, continuation requests up to 6 months.

Continuation of therapy will be considered medically necessary with documentation of disease stability or improvement in symptoms (e.g., decrease in neuropathic pain, improved motor function, quality of life assessment, and/or serum TTR levels)

B. Amvuttra will be considered medically necessary for the treatment of the polyneuropathy of hATTR amyloidosis in adults who have **previously failed or have a contraindication to Onpattro**, AND who meet the following criteria:

- Member has documented transthyretin (TTR) mutation as confirmed through genetic testing AND symptomatic polyneuropathy (i.e. weakness, sensory loss, decreased motor strength, decreased gait speed) characterized by ONE of the following:
    - Baseline polyneuropathy disability (PND) score < IIIb (see reference table)
    - Baseline FAP (familial amyloid polyneuropathy) Stage 1 or 2 (see reference table)
- Biopsy is positive for amyloid deposits or medical justification is provided as to why treatment should be initiated despite a negative biopsy or no biopsy
- Baseline documentation of disease status must be submitted if applicable such as 10-meter walk test, quality of life assessment, nutritional health assessment or modified body mass index (mBMI), and ability to perform activities of daily living
- Prescribed by a neurologist, immunologist, or physician who specializes in the treatment of amyloidosis

Initial approval will be for 6 months, continuation requests up to 6 months.

Continuation of therapy will be considered medically necessary with documentation of disease stability or improvement in symptoms (e.g., decrease in neuropathic pain, improved motor function, improved gait speed, improved quality of life assessment, improved ability to perform activities of daily living, increased mBMI, and/or serum TTR levels)

C. Tegsedi will be considered medically necessary for the treatment of the polyneuropathy of hATTR amyloidosis in adults who meet the following criteria:

- Member has documented transthyretin (TTR) mutation as confirmed through genetic testing AND symptomatic polyneuropathy ((i.e. weakness, sensory loss, decreased motor strength, decreased gait speed) characterized by ONE of the following:
  - Baseline polyneuropathy disability (PND) score < IIIb (see reference table)
  - Baseline FAP (familial amyloid polyneuropathy) Stage 1 or 2 (see reference table)
- Biopsy is positive for amyloid deposits or medical justification is provided as to why treatment should be initiated despite a negative biopsy or no biopsy
- Member has a platelet count > 100 x 10^9/L
- Prescribed by a neurologist, immunologist, or physician who specializes in the treatment of amyloidosis
- If member has a history of liver transplant, a provider attestation is required that indicates ALT, AST and total bilirubin will be monitored monthly

Initial approval will be for 6 months, continuation requests up to 6 months.

Continuation of therapy will be considered medically necessary with documentation of disease stability or improvement in symptoms (e.g., decrease in neuropathic pain, improved motor function, quality of life assessment, and/or serum TTR levels).

- If member has a history of liver transplant, a provider attestation is required that indicates ALT, AST and total bilirubin are being monitored monthly

Polyneuropathy Disability Score (PND) Reference Table

- **Stage 0: No impairment**
- **Stage I: Sensory disturbances but preserved walking capability**
- **Stage II: Impaired walking capability but ability to walk without a stick or crutches**
- **Stage IIIa: Walking only with the help of one stick or crutch**
- **Stage IIIb: Walking with the help of two sticks or crutches**
- **Stage IV: Confined to a wheelchair or bedridden**

Familial Amyloid Polyneuropathy (FAP) Stage Reference Table

- **Stage 0: No symptoms of sensory or motor neuropathy**
- **Stage 1: Unimpaired ambulation; mostly mild sensory, autonomic, or motor neuropathy in lower limbs**
- **Stage 2: Requires assistance with ambulation; mostly moderate impairment progression in lower limbs, upper limbs, and trunk**
- **Stage 3: Confined to wheelchair or bedridden; severe sensory, autonomic, and motor involvement of all limbs**

D. Vyndaqel and **Vyndamax** will be considered medically necessary for the treatment of the cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) in adults who meet all of the following criteria:

- Chart notes documenting a diagnosis of wild type or hereditary transthyretin-mediated amyloidosis cardiomyopathy AND baseline disease severity
- Chart notes documenting member has New York Heart Association (NYHA) functional class I to III heart failure
- Documentation of the presence of TTR genotype confirmed by genetic testing for hereditary transthyretin-mediated amyloidosis
- Biopsy is positive for amyloid deposits or medical justification is provided as to why treatment should be initiated despite a negative biopsy or no biopsy

Initial approval will be for 6 months, continuation requests up to 6 months.

Continuation of therapy will be considered medically necessary with documentation of disease stability or improvement in symptoms (e.g., quality of life assessment, decrease cardiac related hospitalizations)

Exclusions

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling Tafamidis therapy in members with NYHA class IV heart failure or severely impaired renal function (eGFR < 25 mL/min/1.73 m^2 BSA)
- Treatment with Onpattro or Tegsedi for members without the presence of a polyneuropathy symptoms associated with hATTR amyloidosis
- Treatment with Onpattro or Tegsedi when member has form of amyloidosis that is not due to a genetic mutation in the TTR gene
- Tegsedi therapy in members with a history of acute glomerulonephritis caused by Tegsedi
- Concurrent use of Tegsedi with Amvuttra, Onpattro, or tafamidis
- Concurrent use of Vyndaqel and Vyndamax

References

1. ONPATTRO (patisiran) [package insert]. Cambridge, MA: Alnylam Pharmaceuticals, Inc; 2018.
2. Coutinho P, Martins da Silva A, Lopes Lima J, Resende Barbosa A. (1980) Forty years of experience with type I amyloid neuropathy. Review of 483 cases. In: Glenner G., Costa P., de Freitas A., editors. (eds), Amyloid and Amyloidosis. Amsterdam: Execerpta Medica, pp. 88–98
3. Yamamoto S, Wilczek H, Nowak G, et al. Liver transplantation for familial amyloidotic polyneuropathy (FAP): a single-center experience over 16 years. Am J Transplant. 2007 Nov;7(11):2597-604.
4. Adams D, Suhr OB, Dyck PJ, et al. Trial design and rationale for APOLLO, a Phase 3, placebo-controlled study of patisiran in patients with hereditary ATTR amyloidosis with polyneuropathy. BMC Neurol. 2017 Sep 11;17(1):181.
5. Adams D, Gonzalez-Duarte A, O'Riordan WD, et al. Patisiran, an RNAi Therapeutic, for Hereditary Transthyretin Amyloidosis. N Engl J Med. 2018 Jul 5;379(1):11-21
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13. ONPATTRO (patisiran) [handout/package insert]. Cambridge, MA: Alnylam Pharmaceuticals, Inc; 1/2023.
14. Amvuttra Prescribing Information. Cambridge, MA: Alnylam Pharmaceuticals, Inc; 2/2023
15. Tegsedi Prescribing Information. Watham, MA: Akcea Therapeutics, Inc.; 5/2021.
16. Vyndaqel and Vyndamax Prescribing Information. New York, NY: Division of Pfizer, Inc.; 10/2023

Member Product	Medical Management Requirements*
New York Products	
HMO	Prior Auth
PPO in Plan	Prior Auth
PPO OOP	Prior Auth
POS in Plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Child Health Plus	Prior Auth
MVP Harmonious Health Care Plan	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Medicare Gold Giveback	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Secure HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare WellSelect PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare WellSelect Plus PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Patriot Plan PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess Complete D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.

MVP DualAccess Plus D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Select PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Secure PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	
POS in Plan	Prior Auth
POS OOP	Prior Auth
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D
MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part D
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UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D
MVP VT HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	See SPD
ASO	
♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).	

***Medical Management Requirements**

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

MVP Health Care Medical Policy

Medicare Part B:
Transthyretin-Mediated Amyloidosis Therapy

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

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

Drug(s) Requiring Prior Authorization (covered under the medical benefit)

J0222- Onpattro™ (patisiran), injection 0.1 mg

J0225 Amvuttra (vutrisiran), 25mg/0.5mL prefilled syringe for injection

Overview/Summary of Evidence

Hereditary transthyretin amyloidosis (hATTR) is an inherited disease that often affects the liver, nerves, heart and kidneys. It is characterized by the deposit of an abnormal protein called amyloid in multiple organs of the body where it should not be, which causes disruption of organ tissue structure and function. The amyloid buildup most frequently occurs in the peripheral nervous system, which can result in a loss of sensation, pain, or immobility in the arms, legs, hands and feet.

Indications

Onpattro™ is indicated for the treatment of the polyneuropathy in hereditary transthyretin-mediated amyloidosis in adults. The active substance in Onpattro is a 'small interfering RNA' (siRNA), a very short piece of synthetic genetic material that has been designed to attach to and block the genetic material of the cell responsible for producing transthyretin. This reduces production of defective transthyretin, thereby reducing the formation of amyloids and relieving the symptoms of hATTR amyloidosis.

Amvuttra is indicated for the treatment of the polyneuropathy in hereditary transthyretin-mediated amyloidosis in adults. The active substance in Amvuttra is a 'small interfering RNA' (siRNA), a very short piece of synthetic genetic material that has been designed to attach to and block the genetic material of the cell responsible for producing transthyretin. This reduces production of defective transthyretin, thereby reducing the formation of amyloids and relieving the symptoms of hATTR amyloidosis.

Tegsedi™ is indicated for treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults. Tegsedi™ is an 'antisense oligonucleotide', a very short piece of synthetic genetic material that has been designed to attach to and block the genetic material of the cell responsible for producing transthyretin. This reduces production of transthyretin, and the formation of amyloids, relieving the symptoms of hATTR amyloidosis.

Vyndaqel and Vyndamax are indicated for the treatment of wild type or hereditary transthyretin amyloid cardiomyopathy in adults to reduce cardiovascular mortality and cardiovascular-related hospitalization. Wild type amyloidosis does not involve genetic mutation- wild type occurs usually in older population when the normal TTR protein becomes unstable and begins to form amyloid fibrils. Hereditary amyloidosis is an inherited mutation in the DNA making the TTR protein unstable and form amyloid fibrils. It works as a selective transthyretin (TTR) stabilizer. Transthyretin amyloid cardiomyopathy is caused by the accumulations of transthyretin amyloid fibrils, which consist of TTR monomers. Tafamidis works by binding to sites on TTR and slowing monomer dissociation. Please note that Vyndaqel and Vyndamax are not equivalents on a mg-per-mg basis.

Policy Criteria

A. Onpattro will be considered medically necessary for the treatment of the polyneuropathy of hATTR amyloidosis in adults who meet the following criteria:

- Member has documented transthyretin (TTR) mutation as confirmed through genetic testing AND symptomatic polyneuropathy (i.e. weakness, sensory loss, decreased motor strength, decreased gait speed) characterized by ONE of the following:
    - Baseline polyneuropathy disability (PND) score < IIIb (see reference table)
    - Baseline FAP (familial amyloid polyneuropathy) Stage 1 or 2 (see reference table)
- Biopsy is positive for amyloid deposits or medical justification is provided as to why treatment should be initiated despite a negative biopsy or no biopsy

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

Initial approval will be for 6 months, continuation requests up to 6 months.

Continuation of therapy will be considered medically necessary with documentation of disease stability or improvement in symptoms (e.g., decrease in neuropathic pain, improved motor function, quality of life assessment, and/or serum TTR levels)

B. Amvuttra will be considered medically necessary for the treatment of the polyneuropathy of hATTR amyloidosis in adults who have **previously failed or have a contraindication to Onpattro**, AND who meet the following criteria:

- Member has documented transthyretin (TTR) mutation as confirmed through genetic testing AND symptomatic polyneuropathy (i.e. weakness, sensory loss, decreased motor strength, decreased gait speed) characterized by ONE of the following:
    - Baseline polyneuropathy disability (PND) score < IIIb (see reference table)
    - Baseline FAP (familial amyloid polyneuropathy) Stage 1 or 2 (see reference table)
- Biopsy is positive for amyloid deposits or medical justification is provided as to why treatment should be initiated despite a negative biopsy or no biopsy
- Baseline documentation of disease status must be submitted if applicable such as 10-meter walk test, quality of life assessment, nutritional health assessment or modified body mass index (mBMI), and ability to perform activities of daily living
- Prescribed by a neurologist, immunologist, or physician who specializes in the treatment of amyloidosis

Initial approval will be for 6 months, continuation requests up to 6 months.

Continuation of therapy will be considered medically necessary with documentation of disease stability or improvement in symptoms (e.g., decrease in neuropathic pain, improved motor function, improved gait speed, improved quality of life assessment, improved ability to perform activities of daily living, increased mBMI, and/or serum TTR levels

Polyneuropathy Disability Score (PND) Reference Table

- **Stage 0: No impairment**
- **Stage I: Sensory disturbances but preserved walking capability**
- **Stage II: Impaired walking capability but ability to walk without a stick or crutches**
- **Stage IIIa: Walking only with the help of one stick or crutch**
- **Stage IIIb: Walking with the help of two sticks or crutches**
- **Stage IV: Confined to a wheelchair or bedridden**

Familial Amyloid Polyneuropathy (FAP) Stage Reference Table

- **Stage 0: No symptoms of sensory or motor neuropathy**
- **Stage 1: Unimpaired ambulation; mostly mild sensory, autonomic, or motor neuropathy in lower limbs**
- **Stage 2: Requires assistance with ambulation; mostly moderate impairment progression in lower limbs, upper limbs, and trunk**
- **Stage 3: Confined to wheelchair or bedridden; severe sensory, autonomic, and motor involvement of all limbs**

Exclusions

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling Concurrent use with Tegsedi
- Treatment with Onpattro for members without the presence of a polyneuropathy symptoms associated with hATTR amyloidosis
- Treatment with Onpattro when member has form of amyloidosis that is not due to a genetic mutation in the TTR gene

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MVP Health Care Medical Policy

Ultomiris (rivulizumab-cwvz)

Type of Policy:	**Drug/Medical Therapy**
Prior Approval Date:	**NA**
Approval Date:	**10/01/2023**
Effective Date:	**12/01/2023**
Related Policies:	Orphan Drug(s) and Biologicals

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

Drugs Requiring Prior Authorization under the medical benefit

J1303 IV Injection, rivulizumab 300 mg/3 mL solution in a single-dose vial (Ultomiris)

J1303 IV Injection, rivulizumab 1,100 mg/11 mL solution in a single-dose vial (Ultomiris)

Overview

Rivulizumab 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), and paroxysmal nocturnal hemoglobinuria.

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 patients 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. Must be prescribed for an FDA approved indication.
b. Prescriber is enrolled in Ultomiris REMS program.
c. 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 administer in accordance with ACIP guidelines.
    i. If ravulizumab must be initiated immediately and the meningococcal vaccination is administered less than 2 weeks before ravulizumab initiation, documentation of a 2-week course of antibacterial drug prophylaxis is required.

A. Paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis
a. Flow cytometric confirmation of large population (>50%) of glycosylphosphatidylinositol-anchored proteins (GPI-AP) deficient polymorphonuclear cells (PMNs)
b. Documentation demonstrating clinical or biochemical evidence of intravascular hemolysis (serum concentration of lactate hydrogenase [LDH], bilirubin [fractionated], and haptoglobin)

B. Atypical hemolytic uremic syndrome (aHUS) to prevent complement-mediated thrombotic microangiopathy.
a. Documentation of the absence of Shiga toxin
b. ADAMTS 13 activity level above 5%
c. Documentation of baseline platelet count and LDH

C. Anti-acetylcholine receptor antibody positive generalized myasthenia gravis (gMG) in adult patients 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 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
rituximab

Initial approval will be for 6 months

Extension requests will be approved for up to 12 months if the members meeting the following criteria per applicable indication:

PNH: No evidence of disease progression while on current regimen and documentation of positive response to therapy (reduction in blood transfusions, stabilization in hemoglobin concentrations, reduction of exacerbation rate, improved quality of life scores/fatigue, and/or normalization of LDH levels).

aHUS: No evidence of disease progression while on the current regimen and documentation of a positive response to therapy (e.g., normalization of lactate dehydrogenase (LDH) levels, platelet counts).

gMG: No evidence of disease progression while on the current regimen and documentation of a positive response to therapy (e.g., improvement in MG-ADL score, changes compared to baseline in Quantitative Myasthenia Gravis (QMG) total score).

Exclusions

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

- For the treatment of patients with Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS).
- Indication, dosage, frequency, duration of therapy, and age outside of FDA approved labeling.
- Patients with unresolved Neisseria meningitidis infection
- Patients 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	
HMO	Prior Auth
PPO in 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	Prior Auth
MVP Medicare Secure HMO POS	Prior Auth
MVP Medicare Secure Plus HMO POS	Prior Auth
MVP Medicare WellSelect PPO	Prior Auth
MVP Medicare WellSelect Plus PPO	Prior Auth
MVP Medicare Patriot Plan PPO	Prior Auth
MVP DualAccess D-SNP HMO	Prior Auth
MVP DualAccess Complete D-SNP HMO	Prior Auth
MVP DualAccess Plus D-SNP HMO	Prior Auth
UVM Health Advantage Select PPO	Prior Auth
UVM Health Advantage Secure PPO	Prior Auth
UVM Health Advantage Preferred 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
UVM Health Advantage Select PPO	Prior Auth
UVM Health Advantage Secure PPO	Prior Auth
UVM Health Advantage Preferred PPO	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

Upadacitinib

Type of Policy: Drug Therapy
Prior Approval Date: 03/01/2023
Approval Date: 10/01/2023
Effective Date: 12/01/2023
Related Policies: Adalimumab
Apremilast
Etanercept
Infliximab
Risankizumab
Secukinumab
Tofacitinib
Upadacitinib
Ustekinumab
Ozanimod

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

Drugs Requiring Prior Authorization under the pharmacy benefit

Rinvoq (upadacitinib)

Overview

Upadacitinib is an oral Janus kinase (JAK) inhibitor and is considered a targeted synthetic disease-modifying antirheumatic drug (tsDMARD).

Upadacitinib is indicated for adults with moderately to severely active rheumatoid arthritis (RA), active psoriatic arthritis, active ankylosing spondylitis (AS), moderately to severely active ulcerative colitis (UC) who have had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) inhibitors, Crohn's disease and non-radiographic axial spondyloarthritis. It is also indicated for the treatment of adults and pediatric members 12 years and older with refractory, moderate to severe atopic dermatitis whose disease is not adequately controlled with other systemic medications (including biologics) or when use of those therapies is not advisable.

Caution may be necessary when co-administered with certain drugs that inhibit or induce certain CYP isoenzymes. Use with potent CYP3A4 inducers may result in loss of or reduced clinical response to upadacitinib. Providers should perform screening for tuberculosis (TB) according to the local practice.

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, or colorectal surgeon

B. Ankylosing Spondylitis (AS):

Upadacitinib may be considered for coverage for Ankylosing Spondylitis when the following criteria is met:

- 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**
- 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 **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)

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 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 **OR**
    - Topical calcineurin inhibitors (i.e. tacrolimus ointment, pimecrolimus cream) **OR**

- **OR**
- 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 4 months

Extension requests will be approved for **up to 12 months** 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 3 months

Extension requests will be approved for **up to 12 months** 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 4 months

Extension requests will be approved **up to 12 months** 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 moderately to severely 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 6 months

Extension requests will be approved **up to 12 months** 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 6 months

Extension requests will be approved **up to 12 months** 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)

  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 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:

- Dosing, age, and/or frequency outside of the FDA approved package labeling
- Combination therapy that is not supported by current guidelines
- Should not be used for members at high risk for infections or who have active infections including chronic or localized infections
- Avoid using upadacitinib in members that may be at increased risk of thrombosis and thromboembolism; use with caution in those with thromboembolic disease

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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	Prior Auth
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).	

***Medical Management Requirements**

Prior Auth	Prior Authorization Required
Potential for Retrospective Review	No Prior Authorization Required. May be subject to Retrospective Review.
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:	**10/01/2023**
Approval Date:	**12/01/2023**
Effective Date:	**02/01/2024**
Related Policies:	**Adalimumab**
	Apremilast
	Etanercept
	Infliximab
	Risankizumab
	Secukinumab
	Tofacitinib
	Upadacitinib
	Zeposia

Drugs Requiring Prior Authorization under the pharmacy benefit

Stelara prefilled syringe (ustekinumab)

Drugs Requiring Prior Authorization under the medical benefit

J3358, J3357 Stelara (ustekinumab intravenous injection, 1mg)

Overview

Ustekinumab (Stelara®) is a human IgG1 monoclonal antibody that binds to the p40 protein used by both IL-12 and IL-23 cytokines.

Ustekinumab is indicated for moderate to severe plaque psoriasis in members 6 years or older who are candidates for phototherapy or systemic therapy, active psoriatic arthritis

(PsA) alone or in combination with methotrexate (MTX), moderately to severely active Crohn's disease (CD), and moderately to severely active ulcerative colitis (UC).

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

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 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. 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

Medicare Part B Variation: 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:

- 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.

Medicare Part B Variation: 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:

- 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%.

Medicare Part B Variation: 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:

- 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

Medicare Part B Variation: 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

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

***Medical Management Requirements**

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

MVP Health Care Medical Policy

Valchlor

Type of Policy:	**Drug Therapy**
Prior Approval Date:	**04/01/2023**
Approval Date:	**04/01/2024**
Effective Date:	**06/01/2024**
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[2]:
    - 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

Initialapproval 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

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2. Valchlor (mechlorethamine) gel. Prescribing Information. South San Francisco, CA. Actelion Pharmaceuticals, Inc. January 2020.
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4. NCCN Guidelines for Patients. Mycosis Fungoides/Sezary Syndrome. 2021. NCCN Guidelines for Patients Mycosis Fungoides/Sézary Syndrome

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

POS in Plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
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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
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UVM Health Advantage Select PPO	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Secure PPO	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D
MVP VT HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD

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

***Medical Management Requirements**

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

MVP Health Care Medical Policy

Vascular Endothelial Growth Factor (VEGF) Inhibitors

Type of Policy: **Drug/Medical Therapy**
Prior Approval Date: 02/01/2024
Approval Date: **06/01/2024**
Effective Date: **08/01/2024**
Related Policies: **NA**

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

Drugs subject to retrospective review under the medical benefit

J9035 bevacizumab (Avastin)

Q5107 bevacizumab-awwb (Mvasi)

Q5118 bevacizumab-bvzr (Zirabev)

Drugs requiring prior authorization under the medical benefit for new starts only

J0178 aflibercept (Eylea)

J0177aflibercept (Eylea HD)

J0179 brolucizumab-dbll (Beovu)

J2777 faricimab-svoa (Vabysmo)

J2778 ranibizumab (Lucentis)

Q5124 ranibizumab-nuna (Byooviz)

Q5128 ranibizumab-eqrn (Cimerli)

Overview

VEGF inhibitors slow the abnormal growth of blood vessels associated with certain cancers and degenerative eye conditions. VEGF binds to and activates both VEGFR-1 and VEGFR-2, promoting angiogenesis, vascular permeability, cell migration, and gene expression. VEGF inhibitors are indicated for neovascular age-related macular degeneration, diabetic macular edema, diabetic retinopathy, macular edema following retinal vein occlusion, or myopic choroidal neovascularization.
VEGF inhibitors are administered via intravitreal injection.

Brand	Generic	Indication
Avastin	bevacizumab	Supported in compendia: Neovascular (Wet) age-related macular degeneration (AMD), Diabetic Macular Edema (DME), Diabetic Retinopathy (DR) Macular Edema following Retinal Vein Occlusion (RVO), Myopic Choroidal Neovascularization (mCNV)
Mvasi	Bevacizumab-AWWB	Supported in compendia: Neovascular (Wet) age-related macular degeneration (AMD), Diabetic Macular Edema (DME), Diabetic Retinopathy (DR) Macular Edema following Retinal Vein Occlusion (RVO), Myopic Choroidal Neovascularization (mCNV)
Zirabev	Bevacizumab-BVZR	Supported in compendia: Neovascular (Wet) age-related macular degeneration (AMD), Diabetic Macular Edema (DME), Diabetic Retinopathy (DR) Macular Edema following Retinal Vein Occlusion (RVO), Myopic Choroidal Neovascularization (mCNV)
Eylea	Aflibercept	Neovascular (Wet) age-related macular degeneration (AMD), Diabetic Macular Edema (DME), Diabetic Retinopathy (DR) Macular Edema following Retinal Vein Occlusion (RVO), Myopic Choroidal Neovascularization (mCNV), Retinopathy of prematurity(ROP)
Beovu	Brolucizumab-DBLL	Neovascular (Wet) age-related macular degeneration (AMD), Diabetic Macular Edema (DME)
Vabysmo	Faricimab-SVOA	Neovascular (Wet) age-related macular degeneration (AMD), Diabetic Macular Edema (DME)
Lucentis	Ranibizumab	Neovascular (Wet) age-related macular degeneration (AMD), Diabetic Macular Edema (DME), Diabetic Retinopathy (DR) Macular Edema following Retinal Vein Occlusion (RVO), Myopic Choroidal Neovascularization (mCNV)
Byooviz	Ranibizumab-NUNA	Neovascular (Wet) age-related macular degeneration (AMD), Macular Edema following Retinal Vein Occlusion (RVO), Myopic Choroidal Neovascularization (mCNV)

Cimerli	Ranibizumab-EQRN	Neovascular (Wet) age-related macular degeneration (AMD), Diabetic Macular Edema (DME), Diabetic Retinopathy (DR) Macular Edema following Retinal Vein Occlusion (RVO), Myopic Choroidal Neovascularization (mCNV)

Indications/Criteria

A. For the following indications, the criteria below must be met for new starts only:
Neovascular (Wet) age-related macular degeneration (AMD), OR Diabetic Macular Edema (DME), OR Diabetic Retinopathy (DR) OR Macular Edema following Retinal Vein Occlusion (RVO), OR Myopic Choroidal Neovascularization (mCNV):

For Retrospective review of Bevacizumab, the following criteria must be met:

- Member has one of the listed diagnoses above
- AND Member is at least 18 years of age;
- AND Member is free of ocular and/or peri-ocular infection;
- AND Therapy will not be used concomitantly with other ophthalmic VEGF inhibitors (i.e., aflibercept, ranibizumab, pegaptanib, brolucizumab, faricimab-svoa, etc.);
- AND Member's best corrected visual acuity (BCVA) is measured at baseline and periodically during treatment;
    - For members with diabetic macular edema with a baseline visual acuity worse than 20/40, Eylea is the preferred product and a trial of bevacizumab is not required.
- AND Member has a diagnosis of Neovascular (Wet) age-related macular degeneration (AMD), OR Diabetic Macular Edema (DME), OR Diabetic Retinopathy (DR) OR Macular Edema following Retinal Vein Occlusion (RVO), OR Myopic Choroidal Neovascularization (mCNV).

All other products in this policy may be considered for coverage for the indications listed when the following criteria is met:

- member meets the **criteria above** prior to initiating therapy.
- AND chart notes documenting a contraindication, intolerance, or failure of bevacizumab
- For members **currently** receiving therapy with any of the products in this policy, the products do not require prior authorization for on label use. This policy only applies to new starts only.

Initial approval will be for 12 months.

Extension requests will be considered when:

- Member continues to meet coverage criteria above;
- AND there is no toxicity from the drug. Examples of unacceptable toxicity include: severe injection site reactions, bleeding, or serious eye infections and vision loss due to endophthalmitis, etc.;
- AND Member has had a beneficial response to therapy (e.g., improvement in the baseline best corrected visual acuity (BCVA), etc.) and continued administration is necessary for the maintenance treatment of the condition;
- OR for treatment of Myopic choroidal neovascularization ONLY: Continued administration is necessary due to disease activity (i.e., drop in vision, visual symptoms (e.g., metamorphopsia), or the presence of intra-/sub- retinal fluid or active leakage).

B. Retinopathy of Prematurity (ROP):

Eylea (aflibercept) will be covered when:

- Member has a diagnosis of retinopathy of prematurity.
- AND Member is a premature infant with a maximum gestational age at birth of 32 weeks OR a birth weight of >800 to 1500 g
- AND Member is free of ocular and/or peri-ocular infection;

- AND Therapy will not be used concomitantly with other ophthalmic VEGF inhibitors.

Initial approval will be for 12 months.

Extension requests will be considered when:

- Member continues to meet coverage criteria above;
- AND there is no toxicity from the drug. Examples of unacceptable toxicity include: severe injection site reactions, bleeding, or serious eye infections and vision loss due to endophthalmitis, etc.;
- AND documentation indicating that retreatment is required.

Exclusions

- Age, dose, duration of therapy and frequency should be in accordance with the FDA label or recognized compendia (for off-label uses). Services performed in excess of established parameters will be considered experimental/investigational and excluded from 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 Gold Giveback	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Secure HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare WellSelect PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare WellSelect Plus PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Patriot Plan PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess Complete D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess Plus D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Select PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Secure PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth

Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	
POS in Plan	Prior Auth
POS OOP	Prior Auth
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D
MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Select PPO	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Secure PPO	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D
MVP VT HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD
♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).	

***Medical Management Requirements**

Prior Auth	Prior Authorization Required
Potential for Retrospective Review	No Prior Authorization Required. May be subject to Retrospective Review.
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:
Vascular Endothelial Growth Factor (VEGF) Inhibitors

Type of Policy: **Drug/Medical Therapy**
Prior Approval Date: **02/01/2024**
Approval Date: **06/01/2024**
Effective Date: **08/01/2024**
Related Policies: **Medicare Part B Step Therapy**

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

Drugs subject to retrospective review under the medical benefit

J9035 bevacizumab (Avastin)

Q5107 bevacizumab-awwb (Mvasi)

Q5118 bevacizumab-bvzr (Zirabev)

Drugs requiring prior authorization under the medical benefit for new starts only

J0178 aflibercept (Eylea)

J0177 aflibercept (Eylea HD)

J0179 brolucizumab-dbll (Beovu)

J2777 faricimab-svoa (Vabysmo)

J2778 ranibizumab (Lucentis)

Q5124 ranibizumab-nuna (Byooviz)

Q5128 ranibizumab-eqrn (Cimerli)

Overview/Summary of Evidence

VEGF inhibitors slow the abnormal growth of blood vessels associated with certain cancers and degenerative eye conditions. VEGF binds to and activates both VEGFR-1 and VEGFR-2, promoting angiogenesis, vascular permeability, cell migration, and gene expression. VEGF inhibitors are indicated for neovascular age-related macular degeneration, diabetic macular edema, diabetic retinopathy, macular edema following retinal vein occlusion, or myopic choroidal neovascularization.
VEGF inhibitors are administered via intravitreal injection.

Brand	Generic	Indication
Avastin	bevacizumab	Supported in compendia: Neovascular (Wet) age-related macular degeneration (AMD), Diabetic Macular Edema (DME), Diabetic Retinopathy (DR) Macular Edema following Retinal Vein Occlusion (RVO), Myopic Choroidal Neovascularization (mCNV)
Mvasi	Bevacizumab-AWWB	Supported in compendia: Neovascular (Wet) age-related macular degeneration (AMD), Diabetic Macular Edema (DME), Diabetic Retinopathy (DR) Macular Edema following Retinal Vein Occlusion (RVO), Myopic Choroidal Neovascularization (mCNV)
Zirabev	Bevacizumab-BVZR	Supported in compendia: Neovascular (Wet) age-related macular degeneration (AMD), Diabetic Macular Edema (DME), Diabetic Retinopathy (DR) Macular Edema following Retinal Vein Occlusion (RVO), Myopic Choroidal Neovascularization (mCNV)
Eylea	Aflibercept	Neovascular (Wet) age-related macular degeneration (AMD), Diabetic Macular Edema (DME), Diabetic Retinopathy (DR) Macular Edema following Retinal Vein Occlusion (RVO), Myopic Choroidal Neovascularization (mCNV), Retinopathy of prematurity(ROP)
Beovu	Brolucizumab-DBLL	Neovascular (Wet) age-related macular degeneration (AMD), Diabetic Macular Edema (DME)
Vabysmo	Faricimab-SVOA	Neovascular (Wet) age-related macular degeneration (AMD), Diabetic Macular Edema (DME)
Lucentis	Ranibizumab	Neovascular (Wet) age-related macular degeneration (AMD), Diabetic Macular Edema (DME), Diabetic Retinopathy (DR) Macular Edema following Retinal Vein Occlusion (RVO), Myopic Choroidal Neovascularization (mCNV)
Byooviz	Ranibizumab-NUNA	Neovascular (Wet) age-related macular degeneration (AMD), Macular Edema following Retinal Vein Occlusion (RVO), Myopic Choroidal Neovascularization (mCNV)

Cimerli	Ranibizumab-EQRN	Neovascular (Wet) age-related macular degeneration (AMD), Diabetic Macular Edema (DME), Diabetic Retinopathy (DR) Macular Edema following Retinal Vein Occlusion (RVO), Myopic Choroidal Neovascularization (mCNV)

Indications/Criteria

A. For the following indications, the criteria below must be met for new starts only:
Neovascular (Wet) age-related macular degeneration (AMD), OR Diabetic Macular Edema (DME), OR Diabetic Retinopathy (DR) OR Macular Edema following Retinal Vein Occlusion (RVO), OR Myopic Choroidal Neovascularization (mCNV):

For Retrospective review of Bevacizumab, the following criteria must be met:

- Member has one of the listed diagnoses above
- AND Member is at least 18 years of age;
- AND Member is free of ocular and/or peri-ocular infection;
- AND Therapy will not be used concomitantly with other ophthalmic VEGF inhibitors (i.e., aflibercept, ranibizumab, pegaptanib, brolucizumab, faricimab-svoa, etc.);
- AND Member's best corrected visual acuity (BCVA) is measured at baseline and periodically during treatment;
    - For members with diabetic macular edema with a baseline visual acuity worse than 20/40, Eylea is the preferred product and a trial of bevacizumab is not required.
- AND Member has a diagnosis of Neovascular (Wet) age-related macular degeneration (AMD), OR Diabetic Macular Edema (DME), OR Diabetic Retinopathy (DR) OR Macular Edema following Retinal Vein Occlusion (RVO), OR Myopic Choroidal Neovascularization (mCNV).

All other products in this policy may be considered for coverage for the indications listed when the following criteria is met:

- member meets the **criteria above** prior to initiating therapy.
- AND chart notes documenting a contraindication, intolerance, or failure of bevacizumab
- For members **currently** receiving therapy with any of the products in this policy, the products do not require prior authorization for on label use. This policy only applies to new starts only.

Initial approval will be for 12 months.

Extension requests will be considered when:

- Member continues to meet coverage criteria above;
- AND there is no toxicity from the drug. Examples of unacceptable toxicity include: severe injection site reactions, bleeding, or serious eye infections and vision loss due to endophthalmitis, etc.;
- AND Member has had a beneficial response to therapy (e.g., improvement in the baseline best corrected visual acuity (BCVA), etc.) and continued administration is necessary for the maintenance treatment of the condition;
- OR for treatment of Myopic choroidal neovascularization ONLY: Continued administration is necessary due to disease activity (i.e., drop in vision, visual symptoms (e.g., metamorphopsia), or the presence of intra-/sub- retinal fluid or active leakage).

B. Retinopathy of Prematurity (ROP):

Eylea (aflibercept) will be covered when:

- Member has a diagnosis of retinopathy of prematurity.
- AND Member is a premature infant with a maximum gestational age at birth of 32 weeks OR a birth weight of >800 to 1500 g
- AND Member is free of ocular and/or peri-ocular infection;

- AND Therapy will not be used concomitantly with other ophthalmic VEGF inhibitors.

Initial approval will be for 12 months.

Extension requests will be considered when:

- Member continues to meet coverage criteria above;
- AND there is no toxicity from the drug. Examples of unacceptable toxicity include: severe injection site reactions, bleeding, or serious eye infections and vision loss due to endophthalmitis, etc.;
- AND documentation indicating that retreatment is required.

Exclusions

- Age, dose, duration of therapy and frequency should be in accordance with the FDA label or recognized compendia (for off-label uses). Services performed in excess of established parameters will be considered experimental/investigational and excluded from coverage.

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27. Wells JA, Glassman AR, Jampol LM, et al., for the Diabetic Retinopathy Clinical Research Network. Association of Baseline Visual Acuity and Retinal Thickness with 1-year Efficacy of Aflibercept, Bevacizumab, and Ranibizumab for Diabetic Macular Edema. JAMA Ophthalmol. 2016 Feb;134(2):127-34.

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MVP Health Care Medical Policy

Weight Loss Medications

Type of Policy: Drug/Medical Therapy
Prior Approval Date: 10/01/2023
Approval Date: 07/01/2024
Effective Date: 07/01/2024
Related Policies: NA

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

Drugs Requiring Prior Authorization under the pharmacy benefit

Saxenda (liraglutide)

Wegovy (semaglutide)

Zepbound (tirzepatide)

Overview

Glucagon-like peptide-1 receptor agonists (GLP-1 RA) are part of a class of anti-diabetic medications known as incretin mimetics that exert their main effect once released into circulation through the gut by stimulating glucose-dependent insulin release from the pancreatic islets. Primarily used for treatment of type 2 diabetes, some GLP-1 RAs also provide benefit in reducing the risk of both nonfatal cardiovascular disease and cardiovascular mortality in patients with Type 2 diabetes and facilitate weight loss. Saxenda, Zepbound and Wegovy carry indications for FDA-approved, on-label use as weight loss agents to treat obesity.

Indications/Criteria

A. Weight loss for adult members

Saxenda, Zepbound and Wegovy may be considered for coverage for weight loss **for adults** when all the following criteria is met:

- Chart notes documenting all the of following:
  - Member's current body mass index (BMI)
    - 30 kg/m^2 or greater (obesity), or
    - 27 kg/m^2 or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia)
  - Member's current body weight and height
- Provider attestation of a failure of lifestyle modifications for at least 6 months. This must include an exercise program AND calorie deficit meal plan to the maximum extent clinically possible.
- Chart notes documenting proof of consult with an appropriate healthcare professional regarding the benefits of dietary changes and exercise for weight loss. The following specialties are not considered an appropriate consult: anesthesiology, dentistry, emergency medicine, nuclear medicine, ophthalmology, pathology, and radiology.

Initial approval will be for 6 months

Extension requests will be approved up to 6 months when

- Current chart notes documenting ALL of the following:
  - Clinical benefit to the medication which can include:
    - Continues to meet the criteria above
    - A decrease in baseline Body Mass Index (BMI)
    - A decrease in baseline body weight (at least 5 percent of baseline)
- Member's prescription history must show compliance with medication.
- Provider attestation indicating compliance with an appropriate exercise and calorie deficit meal plan to the maximum extent clinically possible

B. Cardiovascular disease risk reduction

Wegovy may be considered for coverage to reduce the risk of heart attack and stroke in obese or overweight adults with cardiovascular disease when the following criteria is met:

- Member meets the above criteria in Section A **AND**
- Member does not have type 2 diabetes
- Chart notes documenting a cardiovascular diagnosis

- Chart notes documenting that the member is concurrently taking guidelines-directed management and therapy for cardiovascular disease (i.e. lipid lowering agents, antiplatelets, beta-blockers, etc). Claims history will be reviewed.

Initial approval will be for 6 months

Extension requests will be approved up to 6 months when
- Current chart notes documenting ALL of the following:
  - Clinical benefit to the medication which can include: Continues to meet the criteria above
  - A decrease in baseline Body Mass Index (BMI)
  - A decrease in baseline body weight (at least 5 percent of baseline)
- Member's prescription history must show compliance with medication.
- Provider attestation indicating compliance with an appropriate exercise and calorie deficit meal plan to the maximum extent clinically possible

C. Weight loss for pediatric members

Saxenda and Wegovy may be considered for coverage for weight loss **for pediatric members** when all the following criteria is met:

- Member is 12 years of age of older
- For Wegovy requests
  - Member has an initial BMI at the 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

Medicare Variation

Weight loss products are not covered for Medicare members. Some Employer group plans do allow for coverage of weight loss products. Those plans will follow this policy, including the lifetime limit of 12 months of therapy per lifetime.

Exclusions

The use of the medications listed in this policy will not be covered for the following situations:

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling.
- Combination therapy with other products for weight loss
- Over-the-counter products are not a covered benefit
- Saxenda, Zepbound and Wegovy used for the treatment of type 2 diabetes or in combination with another GLP-1 Receptor agonist.

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Member Product	Medical Management Requirements*
New York Products	
HMO	Prior Authorization
PPO in Plan	Prior Authorization
PPO OOP	Prior Authorization
POS in Plan	Prior Authorization
POS OOP	Prior Authorization
Essential Plan	Prior Authorization
MVP Medicaid Managed Care	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Child Health Plus	Prior Authorization
MVP Harmonious Health Care Plan	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Medicare Gold Giveback	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Secure HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
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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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UVM Health Advantage Secure PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
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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.
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UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP VT HMO	Prior Authorization
MVP VT Plus HMO	Prior Authorization
MVP VT HDHP HMO	Prior Authorization
MVP VT Plus HDHP HMO	Prior Authorization
MVP Secure	Prior Authorization
ASO	See SPD
♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).	

***Medical Management Requirements**

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

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MVP Health Care Medical Policy

Xolair® (omalizumab)

Type of Policy: **Medical Therapy *(administered by the pharmacy department)***
Prior Approval Date: **07/01/2023**
Approval Date: **04/01/2024**
Effective Date: **04/01/2024**
Related Policies: **Dupixent, Select Injectables for Asthma**

Drugs Requiring Prior Authorization (covered under the medical benefit)
J2357 Xolair® (omalizumab)

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.

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:

- The NHLBI Expert Panel recommends that omalizumab may be considered as adjunctive therapy in step 5 or 6 care for patients who have allergies and severe

persistent asthma that is inadequately controlled with the combination of high-dose ICS and LABA.

- Documentation by the prescriber must meet the following criteria:
    - Requests must be submitted by a participating plan allergist, immunologist, or pulmonologist who has managed the patient for at least six months
        - NIH-NHLBI classification of severe persistent asthma, for > 1 year, with claims history and/or medical chart documentation of all the following:
            - 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
- 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
        - 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)
    - 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.

Initial approval will be for 3 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
- The following must also be considered when renewing Xolair for asthma
  - Doses would be adjusted if there are significant changes in body weight.
  - Re-testing of IgE levels should not be used as a guide for dose adjustment unless Xolair therapy has been interrupted for a minimum of one year.

C. Chronic idiopathic urticaria:

Xolair may be considered for coverage for chronic idiopathic urticaria when the following criteria is met:

- Requests must be submitted by an allergist, immunologist, or pulmonologist who has managed the member for at least six months
- 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 for a 3-months

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.

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 immunologistAttestation 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 6 months.

Continued authorization up to 12 monthsmust be accompanied by current chart notes identifying a continued benefit and compliance with combination therapy. Claims history must show compliance with combination therapy

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 an 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 6 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:
Extensions of therapy will be up to 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

Medicare Variation:
Self-administration of Xolair is a Medicare Part D benefit and follows the Medicare Part D Prior Authorization criteria requirements.

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 alternatives such as
    1. High dose inhaled corticosteroids (ICS)
    2. Leukotriene modifiers or theophylline if preferred therapies (ICS, LABA/LAMA) are not appropriate.
    3. Long-acting beta agonists
    4. Allergy injections (immunotherapy)
    5. Member compliance
    6. Inhaler technique
    7. Environmental controls
-

For chronic idiopathic urticaria:

- A diagnosis other than chronic idiopathic urticaria
    - Xolair is not indicated for acute urticaria, urticarial vasculitis, or urticaria with a known cause

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Member Product	Medical Management Requirements*
New York Products	
HMO	Prior Authorization
PPO in Plan	Prior Authorization
PPO OOP	Prior Authorization
POS in Plan	Prior Authorization
POS OOP	Prior Authorization
Essential Plan	Prior Authorization
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MVP Child Health Plus	Prior Authorization
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MVP Premier Plus HDHP	Prior Authorization
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MVP VT HDHP HMO	Prior Authorization
MVP VT Plus HDHP HMO	Prior Authorization
MVP Secure	Prior Authorization
ASO	See SPD
♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).	
© 2024 MVP Health Plan, Inc. All rights reserved. Descriptions contained within MVP's Medical Policies are not a guarantee of coverage. Each MVP Group or Subscriber Contract contains specific limitations, exclusions and requirements that may affect a Policy. If there is any discrepancy between your Group or Subscriber Contract and a Policy, your Group or Subscriber Contract shall in all cases govern.	

***Medical Management Requirements**

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

MVP Health Care Medical Policy

Medicare Part B: Xolair® (omalizumab)

Type of Policy:	**Medical Therapy *(administered by the pharmacy department)***
Prior Approval Date:	**11/01/2023**
Approval Date:	**04/01/2024**
Effective Date:	**06/01/2024**
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

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. Treatment for Xolair will be considered for the following indications:

1. For moderate to severe persistent asthma:

a. The NHLBI Expert Panel recommends that omalizumab may be considered as adjunctive therapy in step 5 or 6 care for patients who have allergies and severe persistent asthma that is inadequately controlled with the combination of high-dose ICS and LABA.

b. Documentation by the prescriber must meet the following criteria:

- Requests must be submitted by a participating plan allergist, immunologist, or pulmonologist who has managed the patient for at least six months
- NIH-NHLBI classification of severe persistent asthma, for > 1 year, with claims history and/or medical chart documentation of all the following:

1. Continual or daily symptoms (daytime or nighttime)

2. Limited physical activity or exacerbations affecting activities of daily living (ADL's)
3. Frequent exacerbations or exacerbations at least 2 times a week which may last days
4. FEV_1 or PEF ≤80% predicted
5. PEF variability >30%
6. Increasing use of short acting beta2 agonist or use >2 days/week for symptom relief

c. 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

d. Specific relevant allergic sensitivities to perennial aeroallergens (dust mites, mold, animal dander, cockroaches, etc.) determined by:
- Skin tests or
- *In vitro* testing

e. 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)

f. Be a non-smoker by history or have a successful smoking cessation for at least 6 weeks.

g. Documentation that other medical and environmental conditions known to exacerbate asthma have been evaluated and treated.

Initial authorization for 3 months

Extension of therapy up to 12 months. Clinical documentation showing a positive clinical response must be provided.

2. For chronic idiopathic urticaria:

a. Documentation by the prescriber must meet the following criteria:
   - Requests must be submitted by an allergist, immunologist, or pulmonologist who has managed the member for at least six months
   - 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 3 months

Extension of therapy 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.

3. For chronic rhinosinusitis with nasal polyps

a. The use of Xolair may be considered medically necessary if all the following criteria 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
   - 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 3 months.

Requests for continuation of therapy 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.

4. **IgE-mediated Food Allergies**
    - **a.** 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 3 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
- current treatment has not been optimized using applicable alternatives such as
    1. high dose inhaled corticosteroids (ICS)
    2. leukotriene modifiers or theophylline if preferred therapies (ICS, LABA/LAMA) are not appropriate.
    3. long-acting beta agonists
    4. allergy injections (immunotherapy)
    5. member compliance
    6. inhaler technique
    7. environmental controls

When used for chronic idiopathic urticaria:

- a diagnosis other than chronic idiopathic urticaria
- omalizumab (Xolair) is not indicated for acute urticaria, urticarial vasculitis, or urticaria with a known cause

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References

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2. U.S. Department of Health and Human Services (2002). Expert panel report: guidelines for the diagnosis and management of asthma: update on selected topics 2002. National Asthma Education and Prevention Program.
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5. US Food and Drug Administration Alert (February 2007) online at www.fda.gov
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7. National Government Services, Inc. Article for omalizumab (e.g., Xolair) – Related to LCD L25820 (A46088). Original Article Effective Date 12/01/2007. Article Revision Effective Date 6/5/2009. Available: http://www.ngsmedicare.com

8. Joint Task Force on Practice Parameters. The diagnosis and management of acute and chronic urticaria: a 2014 update. J Allergy Clin Immunol 2014; 133 (5): 1270-77.
9. Schaefer P. Urticaria: Evaluation and Treatment. Am Fam Physician. 2011;83(9):1078-84.
10. 2020 Focused Updates to the Asthma Management Guidelines: A Report from the National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group | NHLBI, NIH
11. Acute and Chronic Urticaria: Evaluation and Treatment - American Family Physician (aafp.org)
12. A Comparison of the United States and International Perspective on Chronic Urticaria Guidelines (jaci-inpractice.org)

MVP Health Care Medical Policy

Zinplava (bezlotoxumab)

Type of Policy:	**Drug Therapy**
Prior Approval Date:	**12/01/2022**
Approval Date:	**12/01/2023**
Effective Date:	**02/01/2024**
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 patients. About 1/3 of patients 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 patients 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
- Patient 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
- Patient should be receiving standard C. diff therapy (vancomycin, fidoxomicin, 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 patient has a history of congestive heart failure (CHF), the provider must acknowledge that the benefits outweigh the risk.
- Zinplava single dose of 10mg/kg IV infused over 60 minutes

Exclusions

- Any repeat dose is considered experimental or investigational
- Dose or duration outside of the FDA approved package label
- Zinplava monotherapy used to treat C-difficile infection (Zinplava should only 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)

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

UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	
POS in Plan	Prior Auth
POS OOP	Prior Auth
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D
MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Select PPO	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Secure PPO	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D
MVP VT HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD
♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).	

***Medical Management Requirements**

Prior Auth	Prior Authorization Required
Potential for Retrospective Review	No Prior Authorization Required. May be subject to Retrospective Review.
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:	**N/A**
Approval Date:	**1/01/2024**
Effective Date:	**01/01/2024**
Related Policies:	**C. Difficile Drug Therapy**

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

Codes Requiring Prior Authorization (covered under the medical benefit)

J0565 Zinplava (injection, bezlotoxumab 10mg)

Overview/Summary of Evidence

C. difficile is the most common cause of infectious diarrhea in hospitalized patients. About 1/3 of patients 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 patients 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
- Patient 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
- Patient should be receiving standard C. diff therapy (vancomycin, fidoxomicin, 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 patient has a history of congestive heart failure (CHF), the provider must acknowledge that the benefits outweigh the risk.
- Zinplava single dose of 10mg/kg IV infused over 60 minutes

Exclusions

- Any repeat dose is considered experimental or investigational
- Dose or duration outside of the FDA approved package label
- Zinplava monotherapy used to treat C-difficile infection (Zinplava should only 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
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MVP Health Care Medical Policy

Zoladex- Medicaid

Type of Policy: **Medical Therapy**
Prior Approval Date: **05/14/2022**
Approval Date: **11/01/2023**
Effective Date: **01/01/2024**

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 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
UVM Health Advantage Secure PPO	Potential for Retrospective Review
UVM Health Advantage Preferred 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
UVM Health Advantage Select PPO	Potential for Retrospective Review
UVM Health Advantage Secure PPO	Potential for Retrospective Review
UVM Health Advantage Preferred PPO	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).	
© 2023 MVP Health Plan, Inc. All rights reserved. Descriptions contained within MVP's Medical Policies are not a guarantee of coverage. Each MVP Group or Subscriber Contract contains specific limitations, exclusions and requirements that may affect a Policy. If there is any discrepancy between your Group or Subscriber Contract and a Policy, your Group or Subscriber Contract shall in all cases govern.	

***Medical Management Requirements**

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

MVP Health Care Medical Policy

Zulresso ™ (brexanolone)

Type of Policy: **Medical Therapy *(administered by the pharmacy department)***
Prior Approval Date: **11/01/2022**
Approval Date: **02/01/2023**
Effective Date: **04/01/2023**
Related Policies: **NA**

Codes Requiring Prior Authorization (covered under the medical benefit)

J1632 Zulresso ™ (brexanolone)

Overview

Peripartum Depression (formerly Postpartum depression (PPD))is a mood disorder that can occur during pregnancy or after childbirth which is accompanied by persistent, intense feelings of anxiety, despair or sadness and changes in energy, sleep, and appetite. The symptoms can interfere with a mother's daily tasks and taking care of their child(ren). PPD is different from "baby blues", which is a common occurrence that subsides within a few days to 1-2 weeks without treatment. An estimated one in seven women experience peripartum depression. Current treatment includes psychotherapy (counseling or "talk therapy"), antidepressants or both. Zulresso ™ (brexanolone) is the first available medication specifically indicated for the treatment of postpartum depression (PPD) in adults. It is a neuroactive steroid gamma-aminobutyric acid (GABA) A receptor positive modulator that is administered as a one-time continuous intravenous infusion given over 60 hours (2.5 days). Zulresso must be administered in an inpatient setting as it requires continuous monitoring by a healthcare provider for hypoxia, loss of consciousness and excessive sedation. Zulresso is only available through a REMS program.

Indications/Criteria

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

- Must be 15 years old or older
- Must be female
- Member is ≤ 12 months postpartum
- Must have a confirmed diagnosis of PPD
    - Documentation of baseline Hamilton Depression Rating Scale (HAM-D) score ≥ 20
    - Chart notes documenting a diagnosis of PPD
    - Symptom onset within third trimester of pregnancy or within 4 weeks of delivery
- Documentation of a failure, contraindication, or intolerance to at least a 4-week trial of first line antidepressant therapy (i.e. SSRI (sertraline, escitalopram), mirtazapine, venlafaxine, duloxetine) at the maximally tolerated FDA-approved dose **OR**
- If a 4-week trial with an oral antidepressant is inappropriate, clinical rationale must be documented in the medical record and will be considered on a case by case basis (such as cases of severe PPD) Limit one treatment course per postpartum period- one continuous 60-hour intravenous infusion with

a healthcare provider available on site to continuously monitor the patient at a healthcare setting that is certified in the REMS program.

Approval will be for one infusion per postpartum period

Exclusions

- End stage renal disease (ESRD)
- Home infusion
- Male
- Concurrent active psychosis, bipolar disorder and schizoaffective disorder
- Multiple infusions in the same postpartum period
- Pregnant

References

1. Zulresso TM (brexanolone) injection, for intravenous use. Prescribing Information. Cambridge, MA. Sage Therapeutics. June 2022.
2. American College of Obstetricians and Gynecologists. Frequently Asked Question Labor, Delivery, and Postpartum Care. December 2013. Available at: https://www.acog.org/Patients/FAQs/Postpartum-Depression
3. National Institute of Mental Health. Postpartum Depression Facts. Available at: https://www.nimh.nih.gov/health/publications/postpartum-depression-facts/index.shtml#pub2
4. Melzer-Brody S, Colquhoun H, Reisenberg R, et al. Brenaxolone injection in post-partum depression: two multicenter, double-blind, randomized, placebo-controlled, phase 3 trials. *Lancet*. 2018; 392(10152):1058-1070.
5. Frieder A, Fersh M, Hainline R, et al. Pharmacotherapy of Postpartum Depression: Current Approaches and Novel Drug Development. *CNS Drugs*. 2019 Feb; 33(1): 265-282.
6. Williams J, Ryan D, Thomas-Peter K, et al. Best Practice Guidelines for Mental Health Disorders in the Perinatal Period. BC Reproductive Mental Health Program & Perinatal Services. 2014 Mar; 13-89
7. Yonkers KA, Wisner KL, Stewart DE, et al. The management of depression during pregnancy: a report from the American Psychiatry Association and the American College of Obstetricians and Gynecologists. *Gen Hosp Psychiatry* 2009;31:403-13

   Davé S1, Petersen I, Sherr L, Nazareth I. Incidence of maternal and paternal depression in primary care: a cohort study using a primary care database. Arch Pediatr Adolesc Med. 2010 Nov;164(11):1038-44.

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

Essential Plan	Prior Authorization
MVP Medicaid Managed Care	Prior Authorization
MVP Child Health Plus	Prior Authorization
MVP Harmonious Health Care Plan	Prior Authorization
MVP Medicare Preferred Gold HMO POS	Prior Authorization
MVP Medicare Secure HMO POS	Prior Authorization
MVP Medicare Secure Plus HMO POS	Prior Authorization
MVP Medicare WellSelect PPO	Prior Authorization
MVP Medicare WellSelect Plus PPO	Prior Authorization
MVP Medicare Patriot Plan PPO	Prior Authorization
MVP DualAccess D-SNP HMO	Prior Authorization
MVP DualAccess Complete D-SNP HMO	Prior Authorization
MVP DualAccess Plus D-SNP HMO	Prior Authorization
UVM Health Advantage Select PPO	Prior Authorization
UVM Health Advantage Secure PPO	Prior Authorization
UVM Health Advantage Preferred PPO	Prior Authorization
Healthy NY	Prior Authorization
MVP Premier	Prior Authorization
MVP Premier Plus	Prior Authorization
MVP Premier Plus HDHP	Prior Authorization
MVP Secure	Prior Authorization
MVP EPO	Prior Authorization
MVP EPO HDHP	Prior Authorization
MVP PPO	Prior Authorization
MVP PPO HDHP	Prior Authorization
Student Health Plans	Prior Authorization
ASO	See SPD
Vermont Products	
POS in Plan	Prior Authorization
POS OOP	Prior Authorization
MVP Medicare Preferred Gold HMO POS	Prior Authorization
MVP Medicare Secure Plus HMO POS	Prior Authorization
UVM Health Advantage Select PPO	Prior Authorization
UVM Health Advantage Secure PPO	Prior Authorization
UVM Health Advantage Preferred PPO	Prior Authorization
MVP VT HMO	Prior Authorization
MVP VT Plus HMO	Prior Authorization
MVP VT HDHP HMO	Prior Authorization
MVP VT Plus HDHP HMO	Prior Authorization
MVP Secure	Prior Authorization
ASO	See SPD
♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).	

***Medical Management Requirements**

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

MVP Health Care Medical Policy

Medicare Part B: Zulresso ™ (brexanolone)

Type of Policy:	**Medical Therapy**
Prior Approval Date:	**N/A**
Approval Date:	**11/01/2023**
Effective Date:	**01/01/2023**

Related Policies: **NA**

Codes Requiring Prior Authorization (covered under the medical benefit)

J1632 Zulresso ™ (brexanolone)

Overview/Summary of Evidence

Peripartum Depression (formerly Postpartum depression (PPD))is a mood disorder that can occur during pregnancy or after childbirth which is accompanied by persistent, intense feelings of anxiety, despair or sadness and changes in energy, sleep, and appetite. The symptoms can interfere with a mother's daily tasks and taking care of their child(ren). PPD is different from "baby blues", which is a common occurrence that subsides within a few days to 1-2 weeks without treatment. An estimated one in seven women experience peripartum depression. Current treatment includes psychotherapy (counseling or "talk therapy"), antidepressants or both. Zulresso ™ (brexanolone) is the first available medication specifically indicated for the treatment of postpartum depression (PPD) in adults. It is a neuroactive steroid gamma-aminobutyric acid (GABA) A receptor positive modulator that is administered as a one-time continuous intravenous infusion given over 60 hours (2.5 days). Zulresso must be administered in an inpatient setting as it requires continuous monitoring by a healthcare provider for hypoxia, loss of consciousness and excessive sedation. Zulresso is only available through a REMS program.

Indications/Criteria

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

- Must be 15 years old or older
- Must be female
- Member is ≤ 12 months postpartum
- Must have a confirmed diagnosis of PPD
    - Documentation of baseline Hamilton Depression Rating Scale (HAM-D) score ≥ 20
    - Chart notes documenting a diagnosis of PPD

    - Symptom onset within third trimester of pregnancy or within 4 weeks of delivery
- Documentation of a failure, contraindication, or intolerance to at least a 4-week trial of first line antidepressant therapy (i.e. SSRI (sertraline, escitalopram), mirtazapine, venlafaxine, duloxetine) at the maximally tolerated FDA-approved dose **OR**
- If a 4-week trial with an oral antidepressant is inappropriate, clinical rationale must be documented in the medical record and will be considered on a case by case basis (such as cases of severe PPD) Limit one treatment course per postpartum period- one continuous 60-hour intravenous infusion with a healthcare provider available on site to continuously monitor the patient at a healthcare setting that is certified in the REMS program.

Approval will be for one infusion per postpartum period

Exclusions

- End stage renal disease (ESRD)
- Home infusion
- Male
- Concurrent active psychosis, bipolar disorder and schizoaffective disorder
- Multiple infusions in the same postpartum period
- Pregnant

References

1. Zulresso TM (brexanolone) injection, for intravenous use. Prescribing Information. Cambridge, MA. Sage Therapeutics. June 2022.
2. American College of Obstetricians and Gynecologists. Frequently Asked Question Labor, Delivery, and Postpartum Care. December 2013. Available at: https://www.acog.org/Patients/FAQs/Postpartum-Depression
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4. Melzer-Brody S, Colquhoun H, Reisenberg R, et al. Brenaxolone injection in post-partum depression: two multicenter, double-blind, randomized, placebo-controlled, phase 3 trials. *Lancet*. 2018; 392(10152):1058-1070.
5. Frieder A, Fersh M, Hainline R, et al. Pharmacotherapy of Postpartum Depression: Current Approaches and Novel Drug Development. *CNS Drugs*. 2019 Feb; 33(1): 265-282.

6. Williams J, Ryan D, Thomas-Peter K, et al. Best Practice Guidelines for Mental Health Disorders in the Perinatal Period. BC Reproductive Mental Health Program & Perinatal Services. 2014 Mar; 13-89
7. Yonkers KA, Wisner KL, Stewart DE, et al. The management of depression during pregnancy: a report from the American Psychiatry Association and the American College of Obstetricians and Gynecologists. *Gen Hosp Psychiatry* 2009;31:403-13

Davé S1, Petersen I, Sherr L, Nazareth I. Incidence of maternal and paternal depression in primary care: a cohort study using a primary care database. Arch Pediatr Adolesc Med. 2010 Nov;164(11):1038-44.

MVP Health Care Medical Policy

Zynteglo

Type of Policy:	**Drug/Medical Therapy**
Prior Approval Date:	**11/01/2022**
Approval Date:	**01/01/2024**
Effective Date:	**10/27/2023**
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

J3590 Zynteglo (betibeglogene autotemcel)

Overview

Zynteglo is a cell-based gene therapy that is indicated for the treatment of pediatric and adult patients with beta-thalassemia who require regular red blood cell (RBC) transfusion.

Indications/Criteria

Zynteglo may be considered for coverage when:

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

B. 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. Patient is at least 4 years of age; **AND**
        ii. Patient 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. Patient 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 patient 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. Patient will receive periodic life-long monitoring for hematological malignancies; **AND**
        viii. Patient is eligible to undergo hematopoietic stem cell transplant (HSCT) and has not had prior HSCT or other gene-therapy; **AND**
        ix. Patient has a documented diagnosis of beta thalassemia (excludes alpha-thalassemia and hemoglobin S/ß-thalassemia variants) as outlined by the following:
            1. Patient diagnosis is confirmed by HBB sequence gene analysis showing biallelic pathogenic variants; **OR**
            2. Patient 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**

3. Patient 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**
4. Patient does not have any of the following:
    a. Severely elevated iron in the heart (i.e., patients with cardiac T2* less than 10 msec by magnetic resonance imaging [MRI]); **OR** Advanced liver disease; **OR**
    b. Patients 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 patients 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 outside of the FDA approved package labeling

Appendix I: Dosing and Administration

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.

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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.

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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 Authorization
PPO in Plan	Prior Authorization
PPO OOP	Prior Authorization
POS in Plan	Prior Authorization
POS OOP	Prior Authorization
Essential Plan	Prior Authorization
MVP Medicaid Managed Care	Prior Authorization. *Zynteglo (the drug only) is reviewed by MVP Health Care and billed to NYRX via coordination with NYS Department of Health
MVP Child Health Plus	Prior Authorization
MVP Harmonious Health Care Plan	Prior Authorization. *Zynteglo (the drug only) is reviewed by MVP Health Care and billed to NYRX via coordination with NYS Department of Health
MVP Medicare Gold Giveback	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Secure HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare WellSelect PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare WellSelect Plus PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Patriot Plan PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess Complete D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess Plus D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Select PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Secure PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
Healthy NY	Prior Authorization
MVP Premier	Prior Authorization
MVP Premier Plus	Prior Authorization
MVP Premier Plus HDHP	Prior Authorization
MVP Secure	Prior Authorization
MVP EPO	Prior Authorization
MVP EPO HDHP	Prior Authorization
MVP PPO	Prior Authorization

MVP PPO HDHP	Prior Authorization
Student Health Plans	Prior Authorization
ASO	See SPD
Vermont Products	
POS in Plan	Prior Authorization
POS OOP	
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D
MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Select PPO	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Secure PPO	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D
MVP VT HMO	Prior Authorization
MVP VT Plus HMO	Prior Authorization
MVP VT HDHP HMO	Prior Authorization
MVP VT Plus HDHP HMO	Prior Authorization
MVP Secure	Prior Authorization
ASO	See SPD
♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).	

***Medical Management Requirements**

Prior Auth	Prior Authorization Required
Potential for Retrospective Review	No Prior Authorization Required. May be subject to Retrospective Review.
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:	**N/A**
Approval Date:	**01/01/2024**
Effective Date:	**01/01/2024**

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 Zynteglo (betibeglogene autotemcel)

Overview/Summary of Evidence

Zynteglo is a cell-based gene therapy that is indicated for the treatment of pediatric and adult patients with beta-thalassemia who require regular red blood cell (RBC) transfusion.

Indications/Criteria

Zynteglo may be considered for coverage when:

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

B. 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. Patient is at least 4 years of age; **AND**
    ii. Patient 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. Patient 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 patient 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. Patient will receive periodic life-long monitoring for hematological malignancies; **AND**
    viii. Patient is eligible to undergo hematopoietic stem cell transplant (HSCT) and has not had prior HSCT or other gene-therapy; **AND**
    ix. Patient has a documented diagnosis of beta thalassemia (excludes alpha-thalassemia and hemoglobin S/ß-thalassemia variants) as outlined by the following:
        1. Patient diagnosis is confirmed by HBB sequence gene analysis showing biallelic pathogenic variants; **OR**
        2. Patient 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**

3. Patient 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**
4. Patient does not have any of the following:
    a. Severely elevated iron in the heart (i.e., patients with cardiac T2* less than 10 msec by magnetic resonance imaging [MRI]); **OR** Advanced liver disease; **OR**
    b. Patients 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 outside of the FDA approved package labeling

Appendix I: Dosing and Administration

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.

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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