

Pharmacy Policy Updates Effective 12/01/2026

- **ACL Inhibitors:** The 2026 American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines were updated to move ACL Inhibitors like Nexlizet and Nexletol as co-equal options to PCSK9 Inhibitors and ezetimibe. The policy has been updated to reflect the change and streamline the criteria. Major changes include: Removed the prescribing specialty requirement, updated that lipid panel and liver function tests must be obtained within one year of the request (rather than 30 days), updated statin intolerance and contraindication into a provider attestation, simplified the diagnosis requirement, increased initial approval duration to 12 months, extension criteria was updated to request chart notes documenting clinical benefit, provider attestation that the member is adherent to lifestyle modifications and demonstration of compliance with statin therapy for members not using ACL Inhibitors as monotherapy due to statin intolerance or contraindication.
- **Guselkumab (Tremfya):** For psoriatic arthritis, removed the requirement for chart notes documenting a failure of at least one NSAID at maximum tolerated dose unless the member has contraindications to NSAID therapy. For psoriatic arthritis, added a documented failure to an adequate trial of at least one tumor necrosis factor inhibitor (TNFi) OR a failure to an adequate trial of one of the following nonbiologic disease modifying anti-rheumatic drugs (DMARDs): leflunomide, sulfasalazine, or methotrexate. For psoriatic arthritis, removed the following: 1. Members with pure axial manifestations do not have to have a trial of DMARDs (since criteria now allows a trial of a TNFi OR a DMARD). 2. 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. For Ulcerative Colitis, removed requirement for chart notes identifying inadequate response, intolerance, or contraindication to conventional therapy for maintenance of remission. For Crohn's Disease, added requirement for "documentation includes baseline disease severity". Removed requirement for documented specifics of disease symptoms.

- **Hemophilia Factor:** Removed the exclusion “Child Health Plus: blood factors prior to 04/01/2014 are not covered”.
- **Immunoglobulin Therapy:** Added Gamastan, Qivigy and Yimmugo. Under Acute ITP, removed “to increase platelet counts prior to splenectomy”. Under Chronic refractory ITP, updated to “prior treatment with corticosteroids or splenectomy”.
- **Medicare Part B: Immunoglobulin Therapy:** Added Gamastan, Qivigy and Yimmugo.
- **Medicare Part B: Monoclonal Antibodies for Alzheimer's Disease:** Removed Aduhelm from the policy following its discontinuation by manufacturer in 2024.
- **Monoclonal Antibodies for Alzheimer's Disease:** Removed Aduhelm from the policy following its discontinuation by the manufacturer in 2024. Added a requirement for documentation confirming that a baseline brain MRI was completed within 12 months before treatment initiation. Removed the requirement for Leqembi IV members who have completed 18 months of infusion therapy to provide justification and documentation explaining why the member or caregiver cannot administer Leqembi SQ. Removed the requirement that members must complete at least 18 months of Leqembi IV infusion before initiating Leqembi IQLIK. Added a provider attestation requirement confirming that follow-up MRIs have been performed to monitor for amyloid-related imaging abnormalities (ARIA) before continuation of therapy is approved.
- **Risankizumab (Skyrizi):** Added gastroenterologist to the list of appropriate specialists. For Ulcerative Colitis, removed the required for “inadequate response, intolerance or contraindication to conventional therapy for maintenance of remission”. Current guidelines suggest early use of advanced therapies rather than a gradual step up. For Crohn’s disease, truncated documentation of disease assessment to “documentation includes assessment of baseline disease severity”.
- **Risankizumab (Skyrizi) Part B:** For Crohn’s Disease, removed the requirement that member must be intolerant to two different drug classes. Current guidelines suggest early use of advanced therapies rather than a gradual step up. For Ulcerative Colitis, removed the required for “inadequate response, intolerance or contraindication to conventional therapy for maintenance of remission”. Current guidelines suggest early use of advanced therapies rather than a gradual step up.
- **Secukinumab:** For ankylosing spondylitis and non-radiographic axial spondylarthritis, removed “members with pure axial manifestations do not have

to have a trial of nonbiologic disease modifying anti-rheumatic drugs (DMARDs)". For psoriatic arthritis, removed the requirement for chart notes documenting a failure of at least one NSAID at maximum tolerated dose unless the member has contraindications to NSAID therapy. For psoriatic arthritis, added a documented failure to an adequate trial of at least one tumor necrosis factor inhibitor (TNFi) OR a failure to an adequate trial of one of the following nonbiologic disease modifying anti-rheumatic drugs (DMARDs): leflunomide, sulfasalazine, or methotrexate. For psoriatic arthritis, removed the following: 1. Members with pure axial manifestations do not have to have a trial of DMARDs (since criteria now allows a trial of a TNFi OR a DMARD). 2. 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.

- **Secukinumab Part B:** For ankylosing spondylitis and non-radiographic axial spondylarthritis, removed "members with pure axial manifestations do not have to have a trial of nonbiologic disease modifying anti-rheumatic drugs (DMARDs)". For psoriatic arthritis, removed the requirement for chart notes documenting a failure of at least one NSAID at maximum tolerated dose unless the member has contraindications to NSAID therapy. For psoriatic arthritis, added a documented failure to an adequate trial of at least one tumor necrosis factor inhibitor (TNFi) OR a failure to an adequate trial of one of the following nonbiologic disease modifying anti-rheumatic drugs (DMARDs): leflunomide, sulfasalazine, or methotrexate. For psoriatic arthritis, removed the following: 1. Members with pure axial manifestations do not have to have a trial of DMARDs (since criteria now allows for a trial of a TNFi OR a DMARD). 2. 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.

- **Upadacitinib:** For Ulcerative Colitis and Crohn's Disease, removed the required for "inadequate response, intolerance or contraindication to conventional therapy for maintenance of remission". Current guidelines suggest early use of advanced therapies rather than a gradual step up. For polyarticular juvenile idiopathic arthritis, removed the bullet indicating "case by case" review. Rinvoq has FDA approval for the indication and current guidelines support use. For Crohn's disease, truncated documentation of disease assessment to "documentation includes assessment of baseline disease severity".
- **Vedolizumab (formerly Entyvio):** Renamed policy from "Entyvio" to "Vedolizumab". For Crohn's Disease and Ulcerative Colitis, the initial approval length was increased to 12 months. For Entyvio IV, added a requirement for chart notes documenting why a member or caregiver cannot use the self-administered pen. Per guidelines, subcutaneous formulations of vedolizumab have shown comparable efficacy to the intravenous maintenance doses. For Ulcerative Colitis: a. Removed the step through "conventional therapy". Current guidelines suggest early use of advanced therapies rather than a gradual step up. For Crohn's Disease: a. Removed the step through other therapies such as TNF blockers and conventional therapy (e.g. corticosteroids, methotrexate, etc). Current guidelines support early use of advanced therapies rather than a gradual step up. b. Truncated documentation of disease assessment to "documentation includes assessment of baseline disease severity".
- **Vedolizumab Part B (formerly Entyvio Part B):** For Crohn's Disease and Ulcerative Colitis, simplified extension criteria to "continuation of therapy will require documentation of continued benefit to therapy". For Crohn's Disease and Ulcerative Colitis, simplified initial criteria to "Documentation of moderately to severely active disease".
- **Zyncubo:** New policy for Zyncubo (copper histidinate) which is indicated for the treatment of Menkes disease in pediatric patients. Menkes disease is a rare, fatal X-linked genetic disorder caused by mutation in the ATP 7A gene which leads to severe copper deficiency throughout the body.



MVP Health Care Medical Policy

ACL Inhibitors

Type of Policy: Drug Therapy

Prior Approval Date: 11/01/2025

Approval Date: 10/01/2026

Effective Date: 12/01/2026

Related Policies: Inclisiran

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 major adverse cardiovascular events (cardiovascular death, myocardial infarction, stroke, or coronary revascularization) in adults at increased risk for these events who are unable to take recommended statin therapy (including those not taking a statin). It is also indicated as an adjunct to diet and exercise, 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 hypercholesterolemia, including heterozygous familial hypercholesterolemia (HeFH).

Nexlizet (a combination of bempedoic acid, an adenosine triphosphate citrate lyase (ACL) inhibitor, and ezetimibe, a dietary cholesterol absorption inhibitor) is indicated as an adjunct to diet and exercise to reduce low-density lipoprotein cholesterol (LDL-C) in adults with hypercholesterolemia, including heterozygous familial hypercholesterolemia (HeFH). The Bempedoic acid, a component of NEXLIZET, is also indicated to reduce the risk of major adverse cardiovascular events (cardiovascular death, myocardial infarction,

stroke, or coronary revascularization) in adults at increased risk for these events who are unable to take recommended statin therapy (including those not taking a statin)

Indications/Criteria

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

- Chart notes document that the member has one of the following diagnoses:
 - Primary hypercholesterolemia, including heterozygous familial hypercholesterolemia **OR**
 - Established atherosclerotic cardiovascular disease (ASCVD) **OR**
 - Examples include 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
 - Increased risk for cardiovascular disease
- Chart notes document current lipid panel and liver function tests obtained within one year of request
- Provider attestation that the member has been adhering to lifestyle modifications (i.e heart healthy diet, regular exercise)
- The member meets one of the following:
 - Documentation that the member has received maximally tolerated statin with ezetimibe **OR**
 - Documentation of statin intolerance or contraindication
- Provider attestation that, if statins are **not** contraindicated or the member is **not** statin intolerant, that the statin at the maximally tolerated dose will continue as concurrent therapy.

Initial approval will be for 12 months.

Extension requests will be approved for 12 months if the member meets all of the criteria below:

- Current chart notes document that the member continues to have a clinical benefit to therapy. Benefit to therapy includes documentation demonstrating that the member has had a reduction or maintained a reduction in LDL-C from baseline
 - Extension requests where Nexletol or Nexlizet did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.
- Provider attestation that the member continues to be adherent to lifestyle modifications
- For members without a statin intolerance or contraindication, the member continues to demonstrate adherence to statin therapy. Claims history will be used to verify compliance.

Exclusions

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

References

1. Nexletol (bempedoic acid) [prescribing information]. Ann Arbor, MI: Esperion Therapeutics, Inc; Approved 2020. Revised 01/2026.
2. Nexlizet (bempedoic acid and ezetimibe) [prescribing information]. Ann Arbor, MI: Esperion Therapeutics, Inc; Approved 2020. Revised 01/2026.
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.
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7. Guidelines for the Management of High Blood Cholesterol - Endotext - NCBI Bookshelf (nih.gov)
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doi:10.1016/j.jacc.2025.11.016. [2026](#)
[ACC/AHA/AACVPR/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Dyslipidemia: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines](#)

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

MVP Health Care Medical Policy

MVP Harmonious Health Care Plan	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Medicare Complete Wellness	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare WellSelect PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess Complete D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
USA Care PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	
POS in Plan	Prior Auth
POS OOP	Prior Auth
MVP VT HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth

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

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



MVP Health Care Medical Policy

Guselkumab

Type of Policy: Drug Therapy
Prior Approval Date: 06/01/2025
Approval Date: 10/01/2026
Effective Date: 12/01/2026

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 medical benefit

J1628 Tremfya 100MG/ML Solution J1628 Injection, guselkumab

Drugs Requiring Prior Authorization under the pharmacy benefit

Tremfya (guselkumab) One Press Patient-Controlled Injector
Tremfya (guselkumab) Prefilled Syringe

Overview

Guselkumab is an interleukin 23 (IL-23) blocker approved for the treatment of the following:

- Adult and pediatric patients 6 years of age and older who also weigh at least 40 kg with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy
- Adult and pediatric patients 6 years of age and older who also weigh at least 40 kg with active psoriatic arthritis (PsA)
- Adults with moderately to severely active ulcerative colitis
- Adults with moderately to severely active Crohn's disease

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

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

Indications/Criteria

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

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

B. Plaque Psoriasis

Guselkumab may be considered for coverage for Plaque Psoriasis when the following criteria is met:

- The medication is ordered by or in consultation with a dermatologist

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

Initial approval duration will be 12 months

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

C. Psoriatic Arthritis (PsA)

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

- Member has a diagnosis of moderate to severe psoriatic arthritis **AND**
-
- Chart notes documenting a failure to an adequate trial of at least one tumor necrosis factor inhibitor (TNFi) OR a failure to an adequate trial of one of the following nonbiologic disease modifying anti-rheumatic drugs (DMARDs): leflunomide, sulfasalazine, or methotrexate.

Initial approval duration will be 12 months

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

D. Ulcerative Colitis

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

- A diagnosis of moderate to severe Ulcerative Colitis

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

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

E. Crohn's Disease

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

- A diagnosis of moderate to severe Crohn's disease
- Documentation includes baseline disease severity Induction therapy is indicated for either the subcutaneous or intravenous.

Initial approval will be for 6 months.

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

Exclusions

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

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

References

1. Tremfya [package insert]. Horsham, PA: Janssen Biotech, Inc.; Revised May2026.
2. Reich K, Armstrong, AW, Foley P, et al. Efficacy and safety of guselkumab, an anti-interleukin-23 monoclonal antibody, compared with adalimumab for the

treatment of patients with moderate to severe psoriasis with randomized withdrawal and retreatment: Results from the phase III, double-blind, placebo- and active comparator-controlled VOYAGE 2 trial. *Am J Clin Dermatol*. 2017;76(3):418-431.

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5. Gossec L, Baraliakos X, Kerschbaumer A, et al. European League Against Rheumatism (EULAR) recommendations for the management of psoriatic arthritis with pharmacological therapies: 2019 update. *Ann Rheum Dis*. 2020;79(6):700-712
6. Guselkumab. In: In Depth Answers [database on the Internet]. Greenwood Village (CO): IBM Corporation; 2017 [cited 2023 Jul 19]. Available from: www.micromedexsolutions.com. Subscription required to view.
7. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. *Journal of Psoriasis and Psoriatic Arthritis*. 2019;4(1):31-58. doi:[10.1177/2475530318812244](https://doi.org/10.1177/2475530318812244)
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9. Lichtenstein GR, Loftus EV Jr, Isaacs KL, et al. ACG Clinical Guideline: Management of Crohn's Disease in Adults. *Am J Gastroenterol*. 2025; 120(6):1225-1264.

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MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
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ASO	See SPD
Vermont Products	
POS in Plan	Prior Auth
POS OOP	Prior Auth
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MVP Secure	Prior Auth
ASO	See SPD
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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: 04/01/2025
Approval Date: 10/01/2026
Effective Date: 12/01/2026
Related Policies: Hemophilia Gene Therapy

Codes Requiring Retrospective Review

Must be obtained from Accredo Specialty Pharmacy, covered under the medical benefit. Please see Medicaid and Medicare Variations.

J7210	Injection, Factor VIII (antihemophilic factor, recombinant), Afstyla, per IU
J7179	Injection, von Willebrand factor (recombinant), Vonvendi, per IU
J7202	Injection, Factor IX albumin fusion protein (recombinant), Idelvion, per IU
J7207	Injection, Factor VIII (antihemophilic factor, recombinant), pegylated, per IU
J7209	Injection, Factor VIII (antihemophilic factor, recombinant), Nuwiq, per IU
J7182	Injection, Factor VIII (antihemophilic factor, recombinant), Novoeight, per IU
J7188	Injection, factor VIII (antihemophilic factor, recombinant), Obizur, per IU
J7175	Injection, Factor X (human), Coagadex, per IU
J7181	Factor XIII (antihemophilic factor, recombinant), Tretten, per 10 IU

J7201	Factor IX (antihemophilic factor, recombinant), Alprolix, per 1IU
J7200	Factor IX (antihemophilic factor, recombinant), Rixubis, per IU
J7180	Injection, factor XIII (antihemophilic factor, human), 1 IU
J7183	Injection, von Willebrand factor complex (human), Wilate, 1 IU VWF:RCO
J7185	Injection, factor VIII (antihemophilic factor, recombinant) (Xyntha), per IU
J7186	Injection, antihemophilic factor VIII/Von Willebrand factor complex (human), per factor VIII I.U.
J7187	Injection, Von Willebrand factor complex (Humate-P), per IU, VWF:RCO
J7189	Factor VIIa (antihemophilic Factor, recombinant), per 1mcg
J7190	Factor VIII (antihemophilic factor [human]) per IU
J7192	Factor VIII (antihemophilic factor, recombinant) per IU, not otherwise specified (Kogenate)
J7193	Factor IX (antihemophilic factor, purified, non-recombinant) per IU
J7194	Factor IX, complex, per IU
J7195	Factor IX (antihemophilic factor, recombinant) per IU (Benefix)
J7198	Anti-inhibitor, per IU
J7199/J7203	Hemophilia clotting factor, not otherwise classified (Adynovate, Rebinyn)
J7205	Factor VIII, Fc fusion protein (recombinant), (Eloctate)
J7207	Factor VIII, (antihemophilic factor, recombinant), pegylated, 1 IU
J7211	Factor VIII, (antihemophilic factor, recombinant), (Kovaltry), 1 IU
J7208	Factor VIII (antihemophilic factor, recombinant) pegylated-aucI (Jivi), 1 IU
J7170	Emicizumab injection (Hemlibra)
J7204	Factor VIII (antihemophilic factor, recombinant), Esperoct (glycopegylated-exei, per IU
J7214	Factor viii/von willebrand factor complex, recombinant (Altuviiiio), per factor viii i.u.

Overview

FDA approved indications for Factor VII

- Von Willebrand disease
- Classic Hemophilia

FDA Approved indications for Factor IX

- Factor IX deficiency (hemophilia B, Christmas disease)
- Bleeding in Patients with Antihemophilic Factor Inhibitors

Indications/Criteria

Factor products listed above will be covered when medically necessary for FDA approved indications.

Factor products must be obtained through Accredo Specialty Pharmacy.

- Utilization is subject to retrospective review in accordance with FDA approved indication(s).
- Prior authorization and medical justification is required for factor products obtained or administered in other outpatient settings.
- Please see Medicaid and Medicare Variations.

MVP Medicaid Variation

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

Medicare Variation

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

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

References

1. Clinical Pharmacology: Accessed 02/07/2025

2. New York State Department of Health. Clotting Factor Guidelines. Transition of Clotting Factor Products and Services from Medicaid Fee-For-Service to Medicaid Managed Care. [Clotting Factor Guidelines \(ny.gov\)](#)

Member Product	Medical Management Requirements*
New York Products	
HMO	Prior Auth
PPO in Plan	Prior Auth
PPO OOP	Prior Auth
POS in Plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Child Health Plus	Prior Auth
MVP Harmonious Health Care Plan	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Medicare Complete Wellness	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare WellSelect PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess Complete D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
USA Care PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	
POS in Plan	Prior Auth
POS OOP	Prior Auth
MVP VT HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD
♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).	
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***Medical Management Requirements**

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



MVP Health Care Medical Policy

Immunoglobulin Therapy

Type of Policy: Medical Therapy

Prior Approval Date: 08/01/2025

Approval Date: 10/01/2026

Effective Date: 12/01/2026

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

Refer to the MVP website for the Medicare Part D formulary for drugs that may be 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
J1460	Injection, gamma globulin, intramuscular ; Gamastan
J1552	Injection, immune globulin (Alyglo), 500 mg
J1553	Injection, immune globulin (Yimmugo), 100 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, intravenous, non-lyophilized (e.g. liquid), not otherwise specified, 500mg (Panzyga)
J1551	Immune globulin (SCIg) (Cutaquig), subcutaneous, 100mg
J1558	immune globulin (Xembify), subcutaneous, 100mg
J1577	Injection, immune globulin (Qivigy), 100 mg

Common Procedure Codes

CPT Codes: 96365, 96366, 96367, 96368, 96374, 96375, 90284

Overview

Intravenous Immunoglobulin 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 are used for pre or post exposure prophylaxis for specific infectious diseases, such as tetanus, rabies, hepatitis B, or cytomegalovirus.

Indications/Criteria

A. Intravenous Immunoglobulin

- **For all indications, the following criteria must be met in addition to the specific diagnosis criteria below for intravenous immunoglobulin.**
 - Intravenous Immunoglobulin is to be administered in the home setting, with the exception of the first dose, which may be given in a supervised outpatient setting.
 - Documentation must be provided indicating medical necessity for administering intravenous immunoglobulin in places of service other than the home.
 - IVIG and SCIG must be obtained from a preferred contracted IVIG vendor.
 - Please see Medicaid, Child Health Plus and Vermont Variation regarding place of service and where to obtain.

1. Primary humoral immunodeficiency

Intravenous Immunoglobulin may be considered for coverage for a primary humoral immunodeficiency when the following criteria is met:

- Member has a documented diagnosis of one of the following disorders:
 - Congenital agammaglobulinemia
 - Common variable immunodeficiency (CVID)
 - Wiskott-Aldrich Syndrome
 - X-linked agammaglobulinemia
 - Severe combined immunodeficiency (SCID)
 - X-linked hyper-IgM syndrome

- Documentation of current gamma globulin levels prior to the initial treatment and identifies deficiency in levels (i.e. <500mg/dL).
- Requests to maintain level above a trough range of 500-800mg/dL or more infusions more frequently than every 4 weeks must be submitted with appropriate supporting documentation.
- Documentation that the member demonstrates one of the following:
 - Recurrent severe infection and documented severe deficiency or absence of IgG subclass **OR**
 - Functional deficiency of humoral immunity as evidenced by documented failure to produce antibodies to specific antigens and a history of recurrent infections

2. Immune thrombocytopenia purpura (ITP) criteria

Intravenous Immunoglobulin may be considered for coverage for ITP (acute or chronic) when the following criteria is met:

- Acute ITP (treatment $\leq$ 5 consecutive days) for the treatment of:
 - Management of acute bleeding due to severe thrombocytopenia (platelet counts less than 30,000/ μ L; **or**
 - Severe thrombocytopenia (platelets less than 20,000/microliters) in members considered at risk for intracerebral hemorrhage.
- Chronic refractory ITP:
 - Prior treatment with corticosteroids or splenectomy; **and**
 - Duration of illness $\geq$ 3 months; **and**
 - Age of 10 years or older; **and**
 - No concurrent illness/disease explaining thrombocytopenia **and**
 - Platelet count < 30,000/mcL **or**
 - Platelet count <50,000/mcL and significant bleeding symptoms or rapid increase in platelets is required

3. Chronic lymphocytic leukemia with associated hypogammaglobulinemia criteria:

Intravenous Immunoglobulin may be considered for coverage for Chronic lymphocytic leukemia with associated hypogammaglobulinemia when the following criteria is met

- IVIG is being prescribed for prophylaxis of bacterial infection **AND**
- IgG level is less than 500mg/dL **or**
- Documentation of specific antibody deficiency **AND** the presence or repeated bacterial infections within the past 12 months.

4. Symptomatic human immunodeficiency virus (HIV)

Intravenous Immunoglobulin may be considered for coverage for HIV when the following criteria is met:

- Chart notes identifying a HIV diagnosis
- Documentation of recurrent infections
- Documentation of IgG level <500mg/dl

5. Bone marrow transplant

Intravenous Immunoglobulin may be considered for coverage for bone marrow transplant when the following criteria is met:

- Member is seropositive for cytomegalovirus (CMV) before transplantation, or the patient and donor were seronegative and were undergoing allogeneic transplantation for hematologic neoplasms.
- Documentation that member has a current IgG level <500mg/dL
- May be covered up to 90 days only.

6. Solid organ transplantation

Intravenous Immunoglobulin may be considered for coverage for solid organ transplant when the following criteria is met:

- Chart notes identifying of a solid organ transplantation

7. Kawasaki Disease (mucocutaneous lymph node syndrome)

Intravenous Immunoglobulin may be considered for coverage for Kawasaki Disease the following criteria is met:

- Chart notes identifying a diagnosis of Kawasaki Disease

8. Immune thrombocytopenic purpura in pregnancy.

For Immune thrombocytopenic purpura in pregnancy, Intravenous immunoglobulin is covered for any of the following:

- Pregnant members who have previously delivered infants with autoimmune thrombocytopenia
- Pregnant members who have platelet counts less than 50,000/mm³ during the current pregnancy
- Pregnant members with past history of splenectomy.

9. Autoimmune mucocutaneous blistering diseases

Intravenous Immunoglobulin may be considered for coverage for autoimmune mucocutaneous blistering diseases when the following criteria is met:

- Chart notes identifying that diagnosis has been confirmed by biopsy and pathology report
- Documentation that the condition is rapidly progressing, extensive and/or debilitating
- Documentation of a failure of standard therapy (i.e. corticosteroids, immunosuppressant agents)
- Approval will cover short-term use. Maintenance therapy is not a covered benefit.

10. Scleromyxedema

Intravenous Immunoglobulin may be considered for coverage for Scleromyxedema when the following criteria is met:

- Documentation of a diagnosis of scleromyxedema

11. Humoral or vascular allograft rejection

Intravenous Immunoglobulin may be considered for coverage for Humoral or vascular allograft rejection when the following criteria is met:

- Documentation of Humoral or vascular allograft rejection

12. Hemolytic anemia

Intravenous Immunoglobulin may be considered for coverage for Hemolytic anemia when the following criteria is met:

- Member is 18 years of age or younger
- Chart notes identifying a diagnosis of hemolytic anemia
- Members with hepatomegaly or hepatosplenomegaly will be considered for coverage on a case-by-case basis

13. Polymyositis and dermatomyositis

Intravenous Immunoglobulin may be considered for coverage for Polymyositis and dermatomyositis when the following criteria is met:

- Chart notes identifying that diagnosis is confirmed by objective test results such as electromyogram (EMG), muscle biopsy, and blood analysis
- Documentation of a failure, contraindication, adverse effects or ineffective response to steroids or immunosuppressants
- Documentation that IVIG will be used to decrease the doses of other drugs that are needed for treatment.

14.Sensitized renal cell transplant

Intravenous Immunoglobulin may be considered for coverage for Sensitized renal cell transplant when the following criteria is met:

- Chart notes identifying renal cell transplant

15.Stiff-person syndrome

Intravenous Immunoglobulin may be considered for coverage for Stiff-person syndrome when the following criteria is met:

- Chart notes identifying diagnosis of stiff-person syndrome
- Documentation of inadequate response to first-line treatment (benzodiazepines/baclofen)

16.Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

Intravenous Immunoglobulin may be considered for coverage for CIDP when the following criteria is met:

- Chart notes identifying a diagnosis of CIDP confirmed by electrodiagnostic studies
- Documentation of progressive or relapsing/remitting disease
- Documentation of moderate to severe functional disability

17.Other supported diagnoses (such as acute inflammatory demyelinating polyradiculoneuropathy, 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. Subcutaneous Immune Globulin (SCIG): Gammaked, Gammagard, Gamunex-C, Hizentra, HyQvia, Cutaquig, and Xembify

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

- Member meets the diagnosis criteria above AND subcutaneous IG is indicated for their diagnosis
- Current documentation indicating that intravenous IVIG is inappropriate
- Documentation that the member has a serum IgA level > 0.05g/L
- Documentation of no known antibodies to IgA
 - a. Subcutaneous Immunoglobulin is contraindicated for IgA deficient patients with antibodies against IgA
- Attestation that the member does not have a history of severe systemic response to immune globulin preparations and
- Subcutaneous immunoglobulin is to be administered in the home setting, with the exception of the first dose, which may be given in a supervised outpatient setting.
 - a. Chart notes must be provided documentation medical necessity for administering intravenous immunoglobulin in places of service other than the home.
 - b. IVIG and SCIG must be obtained from a preferred contracted IVIG vendor.
- Please see Medicaid, Child Health Plus and Vermont Variation regarding place of service and where to obtain.

Initial approval will be up to one treatment every 28-30 days up to 3 months unless otherwise noted for the diagnosis

Extension requests will be approved up to 6 months if the member has documentation of ALL the following:

- Current documentation that the member has continued benefit to therapy
- Current documentation demonstrating objective improvement
- Current documentation of appropriate laboratory reports

Medicaid Variation:

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

Child Health Plus Variation: Members are not required to receive IVIG in the home setting.

Vermont Variation: Members are not required to receive IVIG in the home setting

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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17. Centers for Medicare & Medicaid Services. Local Coverage Determination (LCD) for Intravenous Immune Globulin (L33610) Original Effective Date 10/01/2015. Revision Effective Date 01/01/2023.
18. Centers for Medicare & Medicaid Services. Intravenous Immune Globulin – Policy Article (A52509) Original Effective Date 10/01/2015. Revision Effective Date: 01/01/2023.
19. Centers for Medicare & Medicaid Services. Local Coverage Determination (LCD) for External Infusion Pumps (L33794) Original Effective Date 10/01/2015. Revision Effective Date 04/01/2023.
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Member Product	Medical Management Requirements*
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HMO	Prior Auth
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POS OOP	Prior Auth
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MVP Child Health Plus	Prior Auth
MVP Harmonious Health Care Plan	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Medicare Complete Wellness	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.

MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare WellSelect PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
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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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MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	
POS in Plan	Prior Auth
POS OOP	Prior Auth
MVP VT HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
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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

Potential for Retrospective Review

Retro Review

Not Covered

See SPD

Prior Authorization Required

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

Retrospective Review Required

Service is not a covered benefit.

See Specific Plan Design



MVP Health Care Medical Policy

Medicare Part B: Immunoglobulin Therapy

Type of Policy: Medical Therapy

Prior Approval Date: 08/01/2025

Approval Date: 10/01/2026

Effective Date: 12/01/2026

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

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

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

Drugs Requiring Prior Authorization under the medical benefit

Billing Code(s)	Medication
J1459	Injection, immune globulin (Privigen), intravenous, non-lyophilized (e.g. liquid), 500 mg
J1460	Injection, gamma globulin, intramuscular ; Gamastan
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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
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J1577	Injection, immune globulin (Qivigy), 100 mg

(Common Procedure Codes)

CPT Codes: 96365, 96366, 96367, 96368, 96374, 96375, 90284

Overview/Summary of Evidence

Intravenous Immunoglobulin Therapy (IVIG)

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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 are used for pre or post exposure prophylaxis for specific infectious diseases, such as tetanus, rabies, hepatitis B, or cytomegalovirus.

Indications/Criteria

Intravenous Immunoglobulin

- **This policy is a supplement to Medicare National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs). Refer to the applicable NCD or LCD at www.cms.gov for the most up to date coverage guidance.**
- IVIG and SCIG must be obtained from a preferred contracted IVIG vendor.

Medicare Coverage:

- Please refer to the current coverage guidelines at www.cms.gov.
- IVIG is covered under the Part B benefit in all treatment settings for Primary Immunodeficiency. Refer to LCD L33610 for Intravenous Immune Globulin and the accompanying Policy Article A52509 for coverage guidance.
 - Conditions not addressed in this policy will be reviewed on a case-by-case basis and must meet criteria for Experimental & Investigational therapies for coverage under Part B.
- Part B coverage of subcutaneous immune globulin administered in the home setting follows Medicare guidance under LCD L33794 for External Infusion Pumps. Please refer to LCD L33794 and the accompanying Policy Article A52507 for coverage guidance.
- Refer to the Medicare Part D formulary for drugs that may be covered under the Part D benefit.
- Medicare members are not required to receive IVIG in the home setting.

Initial Coverage

Initial coverage period will be for up to 3 months

Extension of Therapy

Continuation of therapy requests must be submitted along with documentation of all pertinent laboratory reports and objective evidence of improvement. Extensions of therapies will be for up to 6 months.

Exclusions

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

References

1. National Government Services. Article for Intravenous Immune Globulin (IVIG) (A52446) – Related to LCD L33394. Original Article Effective Date 10/1/2005. Article Revision Effective Date 7/18/2021
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MVP Health Care Medical Policy

Monoclonal Antibodies for Alzheimer's Disease

Type of Policy: Drug Therapy
Prior Approval Date: 12/01/2025
Approval Date: 10/01/2026
Effective Date: 12/01/2026

Related Policies: N/A

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

Drugs Requiring Prior Authorization under the medical benefit

J0174 Leqembi (lecanemab-irmb)

J0175 Kisunla (donanemab-azbt)

Drugs Requiring Prior Authorization under the pharmacy benefit

Leqembi IQLIK

Overview

Kisunla and Leqembi are amyloid beta-directed antibody indicated for the treatment of Alzheimer's disease.

Kisunla and Leqembi can cause amyloid related imaging abnormalities-edema (ARIA-E), which can be observed on MRI as brain edema or sulcal effusions, and amyloid related imaging abnormalities hemosiderin deposition (ARIA-H), which includes microhemorrhage and superficial siderosis.

Clinical Criteria

Indications/Criteria

Kisunla, Leqembi IV and Leqembi IQLIK may be considered for coverage when ALL the following criteria is met:

1. Documented clinical diagnosis of mild cognitive impairment (MCI) due to Alzheimer's Disease (AD) or mild AD dementia consistent with Stage 3 and Stage 4 Alzheimer's disease
2. Confirmed presence of amyloid beta pathology
3. Documentation of one of the following scores:
 - a. Clinical Dementia Rating (CDR)-Global Score of 0.5 to 1
 - b. Mini-Mental Status Exam (MMSE) score between 19 to 30
 - c. Montreal Cognitive Assessment (MoCA) score of at least 18
4. Documentation of the following pre-treatment testing:
 - a. Genetic testing to assess apolipoprotein E ε4 carrier status, **AND**
 - b. Positron emission tomography (PET) scan or cerebrospinal fluid (CSF) analysis to confirm the presence of amyloid beta deposits.
5. Documentation that a baseline brain magnetic resonance imaging (MRI) has been completed within 12 months prior to initiation of treatment
6. Leqembi IQLIK
 - a.
 - b. Provider attestation that the member or caregiver can administer Leqembi IQLIK and that self-administration is reassessed with extension requests.

Initial authorization for 6 months

Extension requests may be approved up to 6 months when accompanied by a provider attestation that the member's score remained stable or improved, utilizing the same baseline assessment tool as outlined for initiation of therapy and follow up MRIs have been completed to monitor for amyloid related imaging abnormalities (ARIA)

Exclusions

- Diagnosis, dosing, age, and/or frequency outside of the FDA approved package labeling
- Combination therapy of Kisunla and Leqembi

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11. Leqembi [package insert]. Nutley, NJ: Eisai Inc. and Biogen; Revised July 2026.
12. Kisunla [package insert]. Indianapolis, IN: Eli Lilly; Revised July 2025.

Member Product	Medical Management Requirements*
New York Products	
HMO	Prior Auth
PPO in Plan	Prior Auth
PPO OOP	Prior Auth
POS in Plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization

MVP Child Health Plus	Prior Auth
MVP Harmonious Health Care Plan	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Complete Wellness	Refer to the MVP website for the Medicare Part B and Part D
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D
MVP Medicare Secure HMO POS	Refer to the MVP website for the Medicare Part B and Part D
MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part D
MVP Medicare WellSelect PPO	Refer to the MVP website for the Medicare Part B and Part D
MVP Medicare WellSelect Plus PPO	Refer to the MVP website for the Medicare Part B and Part D
MVP Medicare Patriot Plan PPO	Refer to the MVP website for the Medicare Part B and Part D
MVP DualAccess D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D
MVP DualAccess Complete D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D
MVP DualAccess Plus D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D
UVM Health Advantage Select PPO	Refer to the MVP website for the Medicare Part B and Part D
USA Care PPO	Prior Auth
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	
POS in Plan	Prior Auth
POS OOP	Prior Auth
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D
MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part D
MVP VT HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD
♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).	
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***Medical Management Requirements**

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



MVP Health Care Medical Policy

Medicare Part B: Monoclonal Antibodies for Alzheimer's Disease

Type of Policy: Drug Therapy

Prior Approval Date: 08/01/2025

Approval Date: 10/01/2026

Effective Date: 12/01/2026

Related Policies: N/A

Drugs Requiring Prior Authorization (covered under the medical benefit)

J0174 Leqembi (lecanemab-irmb)

J0175 Kisunla (donanemab-azbt)

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

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

Overview

Kisunla and Leqembi are amyloid beta-directed antibody therapies indicated for the treatment of Alzheimer's disease.

Kisunla and Leqembi can cause amyloid related imaging abnormalities-edema (ARIA-E), which can be observed on MRI as brain edema or sulcal effusions, and amyloid related imaging abnormalities hemosiderin deposition (ARIA-H), which includes microhemorrhage and superficial siderosis.

This policy may not list all available therapies for the treatment of Alzheimer's Disease (AD). If the Food and Drug Administration (FDA) grants traditional approval for a drug used to slow the progression of Alzheimer's disease, Medicare will cover the drug in accordance with the National Coverage Determination (NCD) for Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease (NCD 200.3).

Clinical Criteria

Effective April 7, 2022, CMS covers FDA-approved monoclonal antibodies directed against amyloid for the treatment of Alzheimer's Disease (AD) under coverage with evidence development (CED) for members with a clinical diagnosis of mild cognitive impairment due to AD or mild AD dementia, both with confirmed presence of amyloid beta pathology consistent with AD, according to the coverage criteria outlined in the National Coverage Determination (NCD) for Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease (NCD 200.3). Please refer to this NCD for coverage guidance.

Before initiating treatment for monoclonal antibodies directed against amyloid for the treatment of Alzheimer's Disease (AD), the following criteria must be met (consistent with NCD 200.3):

- Clinical diagnosis of mild cognitive impairment (MCI) due to AD or mild AD dementia, both with confirmed presence of amyloid beta pathology consistent with AD
- The member must have a physician participating in a registry with an appropriate clinical team and follow-up care. Registries are listed at www.cms.gov. If the Food and Drug Administration (FDA) grants traditional approval for a drug used to slow the progression of Alzheimer's disease, Medicare will cover the drug in appropriate settings that also support the collection of real-world information to study the usefulness of these drugs for people with Medicare. Clinicians must participate in the Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease Registry available nationwide at www.cms.gov.

Approval Duration: (unless otherwise indicated in applicable NCD/LCD or CMS guidance if available)*

Initial authorization for 6 months

For continuation of therapy, providers must provide documentation necessary for approval based on current NCD/CMS guidance and will be for up to 6 months

Exclusions

- Indication, diagnosis, dosing, age, and/or frequency outside of the FDA approved package labeling
- Monoclonal antibodies directed against amyloid for the treatment of AD provided outside of an FDA-approved randomized controlled trial, CMS-approved studies, or studies supported by the NIH are nationally non-covered.

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10. [Clinical Dementia Rating - an overview | ScienceDirect Topics](#)
11. Leqembi [package insert]. Nutley, NJ: Eisai Inc. and Biogen; Revised January 2026.
12. Kisunla [package insert]. Indianapolis, IN: Eli Lilly; Revised July 2025.



MVP Health Care Medical Policy

Risankizumab

Type of Policy: Drug/Medical Therapy

Prior Approval Date: 10/01/2025

Approval Date: 10/01/2026

Effective Date: 12/01/2026

Related Policies: Adalimumab

Apremilast

Etanercept

Infliximab

Secukinumab

Tofacitinib

Upadacitinib

Ustekinumab

Zeposia

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

Drugs Requiring Prior Authorization under the pharmacy benefit

Skyrizi (risankizumab) Prefilled Pen

Skyrizi (risankizumab) Prefilled Syringe

Skyrizi (Risankizumab) Prefilled Cartridge Kit

Drugs Requiring Prior Authorization under the medical benefit

Skyrizi (risankizumab) 60mg/mL solution –J2327

Overview

Skyrizi (Risankizumab), an interleukin-23 antagonist, is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy, the treatment of active psoriatic arthritis in adults as monotherapy or in combination with non-biologic disease-modifying antirheumatic drugs (DMARDs) and for the treatment of adults with moderate to severely active Crohn's disease (CD) for induction and remission maintenance.

Providers should perform screening for tuberculosis (TB) according to the local practice.

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

Initial approval duration will be for 6 months and **continuation approval** duration will be for 12 months for applicable medical benefit drugs.

Indications/Criteria

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

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

B. Crohn's Disease

Risankizumab may be considered for coverage for Crohn's Disease when the following criteria are met:

- Diagnosis of moderate to severe active Crohn's disease confirmed by endoscopy (or capsule endoscopy when appropriate) **AND** Documentation includes an assessment of baseline disease severity

Initial approval duration will be 12 months

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

Medicaid Variation: Initial approval duration will be for 6 months and continuation approval duration will be for 12 months for applicable medical benefit drugs.

C. Plaque Psoriasis

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

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

Initial approval duration will be 12 months

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

Medicaid Variation: Initial approval duration will be for 6 months and continuation approval duration will be for 12 months for applicable medical benefit drugs.

D. Psoriatic Arthritis (PsA):

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

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

Initial approval duration will be 12 months

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

Medicaid Variation: Initial approval duration will be for 6 months and continuation approval duration will be for 12 months for applicable medical benefit drugs.

E. Ulcerative Colitis

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

- A diagnosis of moderate to severe Ulcerative Colitis

Initial approval duration will be 12 months

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

Medicaid Variation: Initial approval duration will be for 6 months and continuation approval duration will be for 12 months for applicable medical benefit drugs.

Exclusions

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

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

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9. [American Gastroenterological Association](#). *Pharmacological management of moderate-to-severe Crohn's disease*. Published November 20, 2025. Accessed July 29, 2026. [View guideline](#)

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

MVP Medicaid Managed Care	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Child Health Plus	Prior Auth
MVP Harmonious Health Care Plan	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Medicare Complete Wellness	Refer to the MVP website for the Medicare Part B and Part
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part
MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part
MVP Medicare WellSelect PPO	Refer to the MVP website for the Medicare Part B and Part
MVP DualAccess D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part
MVP DualAccess Complete D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part
USA Care PPO	Refer to the MVP website for the Medicare Part B and Part
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	
POS in Plan	Prior Auth
POS OOP	Prior Auth
MVP VT HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD
♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).	
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***Medical Management Requirements**

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



MVP Health Care Medical Policy

Medicare Part B: Risankizumab

Type of Policy: Drug/Medical Therapy

Prior Approval Date: 10/01/2025

Approval Date: 10/01/2026

Effective Date: 12/01/2026

Related Policies: Abatacept, Certolizumab, Golimumab, Infliximab, Tocilizumab, Ustekinumab

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

Drugs Requiring Prior Authorization under the medical benefit

Skyrizi (risankizumab) 60mg/mL solution –J2327

Overview/Summary of Evidence

Skyrizi (Risankizumab), an interleukin-23 antagonist, is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy, the treatment of active psoriatic arthritis in adults as monotherapy or in combination with non-biologic disease-modifying antirheumatic drugs (DMARDs) and for the treatment of adults with moderate to severely active Crohn's disease (CD) for induction and remission maintenance.

Providers should perform screening for tuberculosis (TB) according to the local practice.

Indications/Criteria

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

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

B. Crohn's Disease

Risankizumab may be considered for coverage for Crohn's Disease when the following criteria are met:

- Documentation of moderate to severely active Crohn' disease

Initial approval duration will be 6 months

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

C. Plaque Psoriasis

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

- Documentation of moderate to severe chronic plaque psoriasis OR involvement of the palms, soles of feet and scalp.
- An appropriate trial was not effective or contraindicated with one of the following: methotrexate, oral retinoids, cyclosporine.

Initial approval duration will be 6 months

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

D. Psoriatic Arthritis (PsA):

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

- Documentation of active psoriatic arthritis with an inadequate response or intolerance to methotrexate or other disease-modifying antirheumatic drugs (DMARDs) and one (1) NSAID trial.

Initial approval duration will be 6 months

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

E. Ulcerative Colitis

Risankizumab may be considered for coverage for ulcerative colitis when the following criteria are met:

- A diagnosis of moderate to severe Ulcerative Colitis

Initial approval duration will be 6 months

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

Exclusions

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

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

References

1. Skyrizi (risankizumab) injection package insert. North Chicago, IL: AbbVie Inc.; June 2024
2. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. *Journal of Psoriasis and Psoriatic Arthritis*. 2019;4(1):31-58. doi:[10.1177/2475530318812244](https://doi.org/10.1177/2475530318812244)
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4. Menter, A., Strober, B., Kaplan, D., et al. (2019). Journal of the American Academy of Dermatology. Volume 80, Issue 4, P1029-1072. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics - Journal of the American Academy of Dermatology (jaad.org)
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6. D'Haens G, Panaccione R, Baert F, et al. Risankizumab as induction therapy for Crohn's disease: results from the phase 3 ADVANCE and MOTIVATE induction trials. *Lancet*. 2022;399(10340):2015-2030.
7. Long, M. D., Isaacs, K. L., Barnes, E. L., Loftus, E. V., Lichtenstein, G. R., Ha, C. Y., & Afzali, A. (2025). ACG Clinical Guideline: Management of Crohn's Disease in Adults. *American Journal of Gastroenterology*, 120(6), 1225–1264. <https://doi.org/10.14309/ajg.0000000000003465>
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9. [American Gastroenterological Association](#). *Living guideline for pharmacological management of moderate-to-severe ulcerative colitis*. Published November 19, 2024. Accessed July 29, 2026. [View guideline](#)
10. [American Gastroenterological Association](#). *Pharmacological management of moderate-to-severe Crohn's disease*. Published November 20, 2025. Accessed July 29, 2026. [View guideline](#)



MVP Health Care Medical Policy

Secukinumab

Type of Policy: Drug/Medical Therapy

Prior Approval Date: 10/01/2025

Approval Date: 10/01/2026

Effective Date: 12/01/2026

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

J3247Cosentyx intravenous solution (secukinumab)

Overview

Secukinumab is a human IgG1 monoclonal antibody that selectively binds to the interleukin-17A (IL-17A) cytokine, inhibiting its interaction with the IL-17A receptor. It is FDA approved for several indications including ankylosing spondylitis, psoriasis, psoriatic arthritis, enthesitis-related arthritis (ERA), and hidradenitis suppurativa (HS). Secukinumab carries an increased risk of infection; members should be screened for immunologic and infectious disease prior to initiating therapy.

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

Indications/Criteria

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

- Prescription drugs covered under the pharmacy benefit must be self-administered. If office administration is 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 the following criteria are met:

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

- Insufficient response to at least one local corticosteroid injection in patients with symptomatic peripheral arthritis **AND**

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 following criteria are met::

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

Initial approval 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 the following criteria are met:

- Member has a diagnosis of moderate to severe psoriatic arthritis
- **AND**
- Chart notes documenting a failure to respond to an adequate trial of at least one tumor necrosis factor inhibitor (TNFi) OR at least one of the following nonbiologic disease modifying anti-rheumatic drugs (DMARDs): leflunomide, sulfasalazine, or methotrexate.

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 the following criteria are met:

- 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 the following criteria are met::

- Member has a documented diagnosis of moderate to severe disease (Hurley State II or III) **AND**
- Failure or contraindication to clinically appropriate antibiotic **OR**
- Failure or contraindication to clinically appropriate TNF inhibitor

Initial approval will be for 6 months.

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

Exclusions

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

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling.
 - Secukinumab in combination with other biologics is excluded from coverage
 - Combination therapy that is not supported by guidelines
-

References

1. Clinical Pharmacology
2. Cosentyx (secukinumab) injection. Prescribing Information. East Hanover, NJ. Novartis Pharmaceuticals Corporation. Approved 2015. Revised 04/2026.
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, Sacroiliitis 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, Christopher 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 Auth
PPO in Plan	Prior Auth
PPO OOP	Prior Auth
POS in Plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Child Health Plus	Prior Auth
MVP Harmonious Health Care Plan	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Medicare Complete Wellness	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare WellSelect PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess Complete D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
USA Care PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
Healthy NY	Prior Auth
MVP Premier	Prior Auth
MVP Premier Plus	Prior Auth
MVP Premier Plus HDHP	Prior Auth
MVP Secure	Prior Auth
MVP EPO	Prior Auth
MVP EPO HDHP	Prior Auth
MVP PPO	Prior Auth
MVP PPO HDHP	Prior Auth
Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	
POS in Plan	Prior Auth
POS OOP	Prior Auth
MVP VT HMO	Prior Auth
MVP VT Plus HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
MVP Secure	Prior Auth
ASO	See SPD
♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).	
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***Medical Management Requirements**

Prior Auth

Potential for Retrospective Review

Retro Review

Not Covered

See SPD

Prior Authorization Required

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

Retrospective Review Required

Service is not a covered benefit.

See Specific Plan Design



MVP Health Care Medical Policy

Medicare Part B: Secukinumab

Type of Policy: Drug/Medical Therapy

Prior Approval Date: 10/01/2025

Approval Date: 10/01/2026

Effective Date: 12/01/2026

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

J3247 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 the following criteria are met:

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

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 the following criteria are met:

- Member has a diagnosis of moderate to severe psoriatic arthritis
- **AND**
- Chart notes documenting a failure to respond to an adequate trial of at least one TNF inhibitor OR at least one of the following nonbiologic disease modifying anti-rheumatic drugs (DMARDs): leflunomide, sulfasalazine, or methotrexate.

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 08/14/2026. Accessed 08/19/2026.
2. Cosentyx (secukinumab) injection. Prescribing Information. East Hanover, NJ. Novartis Pharmaceuticals Corporation. Approved 2015. Revised 04/2026.
3. Ward Michael, Atul Deodhar et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. Arthritis and Rheumatology. Vol 71 (No. 10). October 2019, pp 1599-1613. Available at: <https://www.rheumatology.org/Portals/0/Files/AxialSpA-Guideline-2019.pdf>
4. Ringold, Sarah; Angeles-Han Sheila et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Treatment Approaches for Non-Systemic Polyarthritis, Sacroilitis and Enthesitis. American College of Rheumatology. Vol 71 (No 6). June 2019, pp 717-734.
5. Ward MM, Deodhar A, Gensler LS, et al. 2019 update of the American college of rheumatology/spondylitis association of America/spondyloarthritis research and treatment network recommendations for the treatment of ankylosing spondylitis and nonradiographic axial spondyloarthritis. Arthritis Rheumatol. 2019;71(10):1599-1613. doi:10.1002/art.41042



MVP Health Care Medical Policy

Upadacitinib

Type of Policy: Drug Therapy
Prior Approval Date: 10/01/2025
Approval Date: 10/01/2026
Effective Date: 12/01/2026

Related Policies: Adalimumab
Apremilast
Etanercept
Infliximab
Risankizumab
Secukinumab
Tofacitinib

Ustekinumab
Ozanimod

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

Drugs Requiring Prior Authorization under the pharmacy benefit

Rinvoq (upadacitinib)

Overview

Upadacitinib is an oral Janus kinase (JAK) inhibitor and is considered a targeted synthetic disease-modifying antirheumatic drug (tsDMARD).

Upadacitinib is indicated for the following indications:

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

Caution may be necessary when co-administered with certain drugs that inhibit or induce certain CYP isoenzymes. Use with potent CYP3A4 inducers may result in loss of or reduced clinical response to upadacitinib.

Providers should perform screening for tuberculosis (TB) according to the local practice.

Indications/Criteria

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

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

- a. Must be prescribed for an FDA approved indication
- b. Must be ordered by or with consult from an appropriate specialist: rheumatologist, immunologist, dermatologist, gastroenterologist or colorectal surgeon

B. Ankylosing Spondylitis (AS):

Upadacitinib may be considered for coverage for Ankylosing Spondylitis when the following criteria is met:

- Member has a diagnosis of moderate to severe AS
- Chart notes are provided documenting failure of at least one non-steroidal anti-inflammatory drug (NSAID) at maximum tolerated dose unless the member has contraindications to NSAID therapy such as cardiovascular disease, peptic ulcer disease or renal disease **AND**
- Chart notes are provided documenting significant clinical symptoms such as fatigue, spinal pain, arthralgia, inflammation of joints and tendons, and/or morning stiffness **AND**

- Chart notes are provided documenting an insufficient response to at least one local corticosteroid injection in members with symptomatic peripheral arthritis **AND**
- Chart notes are provided documenting an inadequate response or intolerance to one tumor necrosis factor (TNF) inhibitor
 - Documentation must be provided if TNF inhibitor therapy is not considered medically appropriate

Initial approval will be for 12 months

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

C. Atopic Dermatitis:

Upadacitinib may be considered for coverage for Atopic Dermatitis when the following criteria is met:

- Member is diagnosed with refractory moderate-to-severe atopic dermatitis (widespread areas of dry skin, severe limitation of everyday activities, nightly loss of sleep) **AND**
- Must have at least 10% BSA involvement at baseline **AND**
- Chart notes provided confirm symptom control has not been achieved with **one** of the following after an adequate trial:
 - Medium high or very-high potency topical corticosteroids
 - Topical calcineurin inhibitors (i.e. tacrolimus ointment, pimecrolimus cream)
 - Topical PDE-4 inhibitor (e.g. Eucrisa)
 - Documentation that disease is not adequately controlled with other systemic medications, including biologics, or when use of those therapies is not advisable.

Initial approval will be for 12 months

Extension requests will be approved for up to 3 years if the member has a continued benefit to therapy. Extension requests where the upadacitinib did

not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

D. Psoriatic Arthritis (PsA):

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

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

AND

- Chart notes are provided documenting an inadequate response or intolerance to one tumor necrosis factor (TNF) inhibitor
 - Documentation must be provided if TNF inhibitor therapy is not considered medically appropriate

Initial approval will be for 12 months

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

E. Rheumatoid Arthritis (RA):

Upadacitinib may be considered for coverage for Rheumatoid Arthritis when the following criteria is met:

- Member is diagnosed with moderate to severe active adult rheumatoid arthritis as defined by persistent or recurrent symptoms with documented synovitis and morning stiffness of significant duration to inhibit activities of daily living **AND**
- Chart notes are provided documenting a failure to respond to a three-month trial of methotrexate at a maximally tolerated dose.
 - Failure is demonstrated by documentation of provider assessment without improvement in joint counts and/or physical symptoms and inflammatory markers while on therapy.
 - If the member has a contraindication or significant intolerance to methotrexate
 - Chart notes documenting a failure to respond to at least one other nonbiologic DMARDs at a maximally tolerated dose for at least 3 months AND documentation confirming why methotrexate cannot be used is required. If a trial of methotrexate is not appropriate due to alcohol use, chart notes must be provided indicating that the patient has been counseled on the need to abstain from alcohol use while taking methotrexate and is unwilling to abstain from alcohol use.
 - Upadacitinib may be used without prior DMARD trial if the member has an acute, aggressive, very rapidly progressive intense inflammatory symmetrical arthritis disease as defined by their rheumatologist
- Chart notes are provided documenting an inadequate response or intolerance to one tumor necrosis factor (TNF) inhibitor
 - Documentation must be provided if TNF inhibitor therapy is not considered medically appropriate

Initial approval will be for 12 months

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

F. Ulcerative Colitis:

Upadacitinib may be considered for coverage for Ulcerative Colitis (UC) when the following criteria is met:

- Member is diagnosed with moderate to severe active ulcerative colitis
- Chart notes documenting an inadequate response or intolerance to one tumor necrosis factor (TNF) inhibitor
 - Documentation must be provided if TNF inhibitor therapy is not considered medically appropriate

Initial approval will be for 12 months

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

G. Non-Radiographic Axial Spondylarthritis (nr-axSpA)

Upadacitinib may be considered for coverage for Non-Radiographic Axial Spondylarthritis (nr-axSpA) when the following criteria is met:

- Member is diagnosed with Non-Radiographic Axial Spondylarthritis (nr-axSpA)
- Chart notes are provided documenting failure of at least one non-steroidal anti-inflammatory drug (NSAID) at maximum tolerated dose unless the member has contraindications to NSAID therapy such as cardiovascular disease, peptic ulcer disease or renal disease **AND**
- Failure of sulfasalazine or methotrexate at maximum tolerated dose
- Chart notes are provided documenting an inadequate response or intolerance to one tumor necrosis factor (TNF) inhibitor

- Documentation must be provided if TNF inhibitor therapy is not considered medically appropriate

Initial approval will be for 12 months

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

H. Crohn's Disease

Upadacitinib 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 includes an assessment of baseline disease severity Chart notes are provided documenting an inadequate response or intolerance to one tumor necrosis factor (TNF) inhibitor
 - Documentation must be provided if TNF inhibitor therapy is not considered medically appropriate

Initial approval will be for 12 months.

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

I. Polyarticular juvenile idiopathic arthritis

- Upadacitinib is indicated for members who have had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) inhibitor.
- The request must include chart notes documenting an inadequate response or intolerance to one tumor necrosis factor (TNF) inhibitor OR documentation must be provided if TNF inhibitor therapy is not considered medically appropriate

Initial approval will be for 12 months.

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

J. Giant Cell Arteritis

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

- Treatment must be directed by or in consultation with a Rheumatologist or Immunologist
- Member has received high-dose glucocorticoids (prednisone 40mg to 60mg) but is unable to taper without disease flare **OR**
- The member has a contraindication to the use of glucocorticoids

Initial approval will be for 12 months.

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

Exclusions

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

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling
 - The dosing Rinvoq 45mg once daily is indicated for short term induction for Crohn's Disease and Ulcerative Colitis
- Combination therapy that is not supported by current guidelines
- Should not be used for members at high risk for infections or who have active infections including chronic or localized infections
- Avoid using upadacitinib in members that may be at increased risk of thrombosis and thromboembolism; use with caution in those with thromboembolic disease

References

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10. [American Gastroenterological Association](#). *Pharmacological management of moderate-to-severe Crohn's disease*. Published November 20, 2025. Accessed July 29, 2026. [View guideline](#)
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Member Product	Medical Management Requirements*
New York Products	
HMO	Prior Auth
PPO in Plan	Prior Auth
PPO OOP	Prior Auth
POS in Plan	Prior Auth
POS OOP	Prior Auth
Essential Plan	Prior Auth
MVP Medicaid Managed Care	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
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Student Health Plans	Prior Auth
ASO	See SPD
Vermont Products	
POS in Plan	Prior Auth
POS OOP	Prior Auth
MVP VT HMO	Prior Auth

MVP VT Plus HMO	Prior Auth
MVP VT HDHP HMO	Prior Auth
MVP VT Plus HDHP HMO	Prior Auth
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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

Potential for Retrospective Review

Retro Review

Not Covered

See SPD

Prior Authorization Required

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

Retrospective Review Required

Service is not a covered benefit.

See Specific Plan Design



MVP Health Care Medical Policy

Vedolizumab

Type of Policy: Drug/Medical Therapy

Prior Approval Date: 10/01/2025

Approval Date: 10/01/2026

Effective Date: 12/01/2026

Related Policies:

Experimental or Investigational Procedures

Infliximab,

Certolizumab

Risankizumab

Upadacitinib

Ustekinumab

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

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

Drugs Requiring Prior Authorization (covered under the medical benefit)

J3380 Entyvio (vedolizumab, injection 1mg)

Drugs Requiring Prior Authorization (covered under the pharmacy benefit)

Entyvio subcutaneous prefilled pen

Overview

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

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

Indications/Criteria

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

- Must be prescribed for an FDA approved indication
- Must be ordered by or with consult from an appropriate specialist: immunologist, gastroenterologist or colorectal surgeon

B. Crohn's Disease

Entyvio may be considered for coverage for moderately to severely **active Crohn's Disease** when the following criteria are met:

- Diagnosis of moderate to severe active Crohn's disease confirmed by endoscopy (or capsule endoscopy when appropriate)
- Documentation includes an assessment of baseline disease severity

Entyvio IV may be considered for coverage for moderately to severely **Crohn's Disease** when the following criteria are met:

- Member is diagnosed with moderate to severe active Crohn's Disease
- Chart notes document why the member or caregiver cannot use the self administered pen.
- Site of Care
 - i. Per the MVP Health Care Pharmacy Management Programs policy, Entyvio IV is subject to Site of Care requirements and must be obtained through a preferred home infusion vendor or contracted provider office. Prior Authorization and medical justification are required for Entyvio IV obtained and administered in a non-preferred site of care (i.e. outpatient hospital setting).
 - A. MVP will allow 60 days after prior authorization approval for members to transfer to a preferred infusion site.
 - B. This requirement does not apply to MVP Medicare and Medicaid, CHP members

Initial approval for 12 months

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

C. Ulcerative Colitis

Entyvio may be considered for coverage for moderately to severely **ulcerative colitis** when the following criteria are met:

- Member is diagnosed with moderate to severe active ulcerative colitis
- Entyvio IV may be considered for coverage for moderate to severe **ulcerative colitis** when the following criteria are met:
- Member is diagnosed with moderate to severe active ulcerative colitis
 - Chart notes document why member or caregiver cannot use the self administered pen.
 - Site of Care

- ii. Per the MVP Health Care Pharmacy Management Programs policy, Entyvio IV is subject to Site of Care requirements and must be obtained through a preferred home infusion vendor or contracted provider office. Prior Authorization and medical justification are required for Entyvio IV obtained and administered in a non-preferred site of care (i.e. outpatient hospital setting).
 - C. MVP will allow 60 days after prior authorization approval for members to transfer to a preferred infusion site.
 - D. This requirement does not apply to MVP Medicare and Medicaid, CHP members

Initial approval for 12 months

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

D. Immune Checkpoint Inhibitor-Related Diarrhea/Colitis/Pneumonitis

Entyvio IV may be considered for coverage for the management of Immune Checkpoint Inhibitor-Related Diarrhea/Colitis/Pneumonitis when the following criteria is met:

- Member has been receiving therapy with an immune checkpoint inhibitor (e.g., nivolumab, pembrolizumab, atezolizumab, avelumab, durvalumab, cemiplimab, etc.); AND
- Member has moderate (grade 2) to severe (grade 3-4) diarrhea, colitis, or pneumonitis related to their immunotherapy; AND
- Documented failure, contraindication, or ineffective response to systemic corticosteroids or infliximab.

Entyvio IV for Immune Checkpoint Inhibitor Related Diarrhea/Colitis/Pneumonitis may not be renewed

Exclusions

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

References

1. Entyvio [package insert]. Lexington, MA 02421; Takeda Pharmaceuticals America, Inc; Approved 2014. Revised 02/2026.
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New York Products	
HMO	Prior Auth
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***Medical Management Requirements**

Prior Auth

Potential for Retrospective Review

Retro Review

Not Covered

See SPD

Prior Authorization Required

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

Retrospective Review Required

Service is not a covered benefit.

See Specific Plan Design



MVP Health Care Medical Policy

Medicare Part B: Vedolizumab

Type of Policy: Drug/Medical Therapy

Prior Approval Date: 10/01/2025

Approval Date: 10/01/2026

Effective Date: 12/01/2026

Related Policies:

Experimental or Investigational Procedures

Infliximab

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

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

Drugs Requiring Prior Authorization (covered under the medical benefit)

J3380 Entyvio (vedolizumab, injection 1mg)

Overview/Summary of Evidence

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

Indications/Criteria

Coverage is provided in the following conditions:

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

- Member is at least 18 years of age; AND
- Must be prescribed by, or in consultation with, a specialist in gastroenterology; AND
- Member is not on concurrent treatment with another TNF-inhibitor, biologic response modifier, natalizumab products or other non-biologic agent (i.e., apremilast, tofacitinib, baricitinib, upadacitinib, etc.);
- Coverage duration (unless otherwise specified for applicable indication)
 - **Initial coverage up to 6 months**
 - **Continuation of coverage 12 months**

B. Crohn's disease:

Entyvio may be considered for coverage for moderately to severely **active Crohn's Disease** when the following criteria are met:

- Documentation of moderately to severely active disease
Documentation includes an assessment of baseline disease severity
Continuation of therapy will require documentation of continued benefit to therapy.

C. Ulcerative Colitis:

Entyvio may be considered for coverage for moderately to severely **ulcerative colitis** when the following criteria are met:

- Documentation of moderately to severely active disease

Continuation of therapy will require documentation of a continued benefit to therapy.

D. Management of Immune Checkpoint Inhibitor-Related Diarrhea/Colitis/Pneumonitis:

- Member has been receiving therapy with an immune checkpoint inhibitor (e.g., nivolumab, pembrolizumab, atezolizumab, avelumab, durvalumab, cemiplimab, etc.); AND
- Member has moderate (grade 2) to severe (grade 3-4) diarrhea, colitis, or pneumonitis related to their immunotherapy; AND
- Documented failure, contraindication, or ineffective response to systemic corticosteroids or infliximab.

Entyvio IV for Immune Checkpoint Inhibitor Related Diarrhea/Colitis/ Pneumonitis may not be renewed

Exclusions

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

References

1. Entyvio [package insert]. Lexington, MA 02421; Takeda Pharmaceuticals America, Inc; Approved 2014. Revised 02/2026.
2. 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

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MVP Health Care Medical Policy

Zycubo (copper histidinate)

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

Prior Approval Date: NA

Approval Date: 10/01/2026

Effective Date: 12/01/2026

Related Policies: Orphan Drugs and Biologicals

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

Drugs Requiring Prior Authorization under the pharmacy benefit

Zycubo

Overview

Copper histidinate is a copper replacement therapy indicated for the treatment of Menkes disease. It is the first treatment approved for Menkes disease in pediatric patients. Menkes disease is a rare X-linked recessive genetic disorder caused by pathogenic variants in the ATP7A gene, which encodes a copper-transporting ATPase required for the absorption and systemic distribution of dietary copper. The disorder primarily affects male infants, although females are typically carriers and may be affected in rare cases. Impaired intestinal copper absorption and defective copper transport to the brain and other tissues result in a profound deficiency of copper-dependent enzymes, leading to clinical manifestations that include seizures, hypoglycemia, prolonged jaundice, failure to thrive, growth retardation, thermoregulatory instability, developmental delays, and intellectual disability.

In clinical studies, individuals who initiated copper histidinate treatment within 4 weeks of birth demonstrated a significant improvement in overall survival compared with untreated historical controls, corresponding to a 78% reduction in the risk of death; median survival was substantially longer in early-treated individuals (177.1 months) than in untreated controls (17.6 months), and nearly half of early-treated individuals survived beyond 6 years, whereas no untreated individuals survived past 6 years of age. Individuals who initiated treatment after 4 weeks of birth also experienced a significant survival benefit, with a 73% reduction in the risk of death; approximately 31% survived beyond 6 years, while no untreated individuals survived beyond this age.

Indications/Criteria

A. Menkes Disease

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

- Chart notes document a diagnosis of Menkes disease and confirmed by genetic testing.
 - Genetic testing must be included and indicate a pathogenic or pathogenic variant in the ATP7A gene.
- The member is less than 17 years old
- Zycubo is prescribed by or in consultation with a geneticist, pediatric neurologist, or specialist with expertise in the treatment of Menke's Disease.

Initial approval will be for 12 months

Quantity Limits

- For children less than 12 months old- 1.45mg twice daily
- For children and adolescents 1 to 16 years old- 1.45mg once daily

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

Quantity Limits

- For children less than 12 months old- 1.45mg twice daily
- For children and adolescents 1 to 16 years old- 1.45mg once daily

Exclusions

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

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

References

1. National Library of Medicine (US). *Copper Histidine Therapy for Menkes Diseases* (ClinicalTrials.gov Identifier: NCT00001262). ClinicalTrials.gov. Updated October 30, 2015. Accessed August 24, 2026. [Study Details | NCT00001262 | Copper Histidine Therapy for Menkes Diseases | ClinicalTrials.gov](#)
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***Medical Management Requirements**

Prior Auth
Potential for Retrospective Review
Retro Review
Not Covered
See SPD

Prior Authorization Required
No Prior Authorization Required. May be subject to Retrospective Review.
Retrospective Review Required
Service is not a covered benefit.
See Specific Plan Design